

Fall 2005

Regulating the Regulators: The Impact of FDA Regulation on Corporations' First Amendment Rights, 39 J. Marshall L. Rev. 95 (2005)

Lisa M. Fealk-Stickler

Follow this and additional works at: <https://repository.law.uic.edu/lawreview>



Part of the [Business Organizations Law Commons](#), [Constitutional Law Commons](#), [Consumer Protection Law Commons](#), [First Amendment Commons](#), [Food and Drug Law Commons](#), [Health Law and Policy Commons](#), [Intellectual Property Law Commons](#), [Jurisprudence Commons](#), [Legislation Commons](#), [Litigation Commons](#), and the [Marketing Law Commons](#)

Recommended Citation

Lisa M. Fealk-Stickler, Regulating the Regulators: The Impact of FDA Regulation on Corporations' First Amendment Rights, 39 J. Marshall L. Rev. 95 (2005)

<https://repository.law.uic.edu/lawreview/vol39/iss1/9>

This Comments is brought to you for free and open access by UIC Law Open Access Repository. It has been accepted for inclusion in UIC Law Review by an authorized administrator of UIC Law Open Access Repository. For more information, please contact repository@jmls.edu.

REGULATING THE REGULATORS: THE IMPACT OF FDA REGULATION ON CORPORATIONS' FIRST AMENDMENT RIGHTS

LISA M. FEALK-STICKLER*

INTRODUCTION

“Congress shall make no law . . . abridging the freedom of speech.”¹

Freedom of speech is our most fundamental right. Justice Benjamin Cardozo referred to freedom of expression as “the matrix, the indispensable condition, of nearly every other form of freedom.”²

Regulatory agencies, such as the Food and Drug Administration (FDA), are not given free reign when instituting their directives.³ The agencies' actions must pass constitutional scrutiny.⁴ It is especially important that the actions of these agencies not compromise our most fundamental constitutional right, our First Amendment right to free speech. Despite this requirement, the Nutrition Labeling and Education Act (NLEA),⁵ as well as certain FDA regulations, do infringe upon the constitutional freedoms of corporations and private citizens.⁶ While placing certain limitations on speech may be justified,⁷ overly restrictive and paternalistic approaches are not.⁸

* J.D. Candidate, May 2006. This Comment is dedicated to the memory of my editor, Patricia Gerdes.

1. U.S. CONST. amend. I.

2. *Palko v. Connecticut*, 302 U.S. 319, 327 (1937).

3. Courts have determined that all administrative regulations must comply with the Constitution and statutory authority. 2 AM. JUR. 2D *Administrative Law* § 225 (2004); see also Eric F. Greenberg, *Surprise! You Have the Right to Free Speech*, PACKAGING DIGEST, Sept. 2002, available at <http://www.packagingdigest.com/Legal/0902legal.php> (explaining that the actions of a government agency must be supported by “substantial evidence”).

4. See, e.g., Greenberg, *supra* note 3 (discussing how the Supreme Court has previously struck down FDA restrictions on advertising as unconstitutional).

5. Pub. L. No. 101-535, 104 Stat. 2353 (1990) (codified in scattered sections of 21 U.S.C.).

6. See *Wash. Legal Found. v. Friedman*, 13 F. Supp. 2d 51, 73 (D.D.C. 1998) (finding an FDA regulation affecting the promotion of off-label drugs an unconstitutional infringement on the First Amendment rights of drug manufacturers).

7. See Amber K. Spencer, Note, *The FDA Knows Best . . . Or Does It? First Amendment Protection of Health Claims on Dietary Supplements: Pearson v. Shalala*, 15 BYU J. PUB. L. 87, 88-89 (2000) (discussing how creation of and reliance on administrative agencies, such as the FDA, is borne out of a New Deal-era desire to protect individuals from the “dangers of modern society”).

8. John M. Blim, Comment, *Free Speech and Health Claims Under the Nutrition*

Put simply, the NLEA and the FDA's nutrition labeling regulations are overly paternalistic.⁹ The NLEA requires food and drug manufacturers to include specific information on their product labels.¹⁰ It also strictly regulates the use of health claims on product packaging.¹¹ Congress created the NLEA in an effort to improve the dietary practices of our nation's citizens.¹² The importance of pursuing this goal is not in dispute. Equally indisputable is the fact that the methods used to achieve this goal must be constitutional. Nevertheless, the NLEA, in its current form, infringes upon protected corporate speech. Product labels are a form of corporate expression and corporate advertising. As such, these labels constitute constitutionally protected commercial speech,¹³ which cannot be compromised.

As the food and drug industry continues to grow, so does the impact of this unconstitutional act. Freedom of speech¹⁴ is a right afforded to all U.S. citizens and corporations.¹⁵ This right must not be violated.

Part I of this Comment will discuss the three regulatory agencies that have jurisdiction over product claims made by food manufacturers. These agencies are the FDA, the Federal Trade Commission (FTC), and the United States Department of Agriculture (USDA).¹⁶ This Comment will focus on the NLEA and the applicable FDA regulations. The purpose of this Act and the regulations, as well as the manner in which they operate, will be explained in Part I. Part I will also include a brief, historical discussion of protected corporate speech.

Part II will begin by exploring the broad impact of FDA regulations, which stems from the significant deference other government agencies, such

Labeling and Education Act of 1990: Applying a Rehabilitated Central Hudson Test for Commercial Speech, 88 NW. U.L. REV. 733, 755 n.127 (1994); see also *Whitney v. California*, 274 U.S. 357, 375-76 (1927) (Brandeis, J., concurring) (stating that speech is preferable to silence and should be encouraged and protected by the federal government).

9. See Lars Noah & Barbara A. Noah, *Liberating Commercial Speech: Product Labeling Controls and the First Amendment*, 47 FLA. L. REV. 63, 69 (1995) (expressing doubts as to whether the intense regulatory scheme of the FDA can, in fact, encourage manufacturers to produce healthier food products).

10. *Id.* at 68.

11. *Id.*

12. See *Pub. Citizen, Inc. v. Shalala*, 932 F. Supp. 13, 14 (D.D.C. 1996) (stating that the overall purpose of the NLEA was the creation of a healthier society).

13. See, e.g., *Rubin v. Coors Brewing Co.*, 514 U.S. 476, 481 (1995) (finding information on beer labels to be commercial speech and as such deserving of constitutional protection).

14. See *Va. State Bd. of Pharmacy v. Va. Citizens Consumer Council, Inc.*, 425 U.S. 748, 763-70 (1976) (holding that commercial speech, like other forms of speech, is constitutionally protected under the First Amendment).

15. See *Wooley v. Maynard*, 430 U.S. 705, 714 (1977) (stating that companies and private citizens are afforded the same First Amendment protections). See also *First Nat'l Bank of Boston v. Bellotti*, 435 U.S. 765, 777 (1978) (explaining that the identity of the speaker, whether it be a private individual, an association, or a corporation, does not diminish or alter the level of protection afforded to speech under the First Amendment).

16. Enforcement Policy Statement on Food Advertising, 59 Fed. Reg. 28,388 (June 1, 1994).

as the FTC, afford the FDA. Part II will also explain how the NLEA and the regulations that the FDA promulgates affect constitutionally protected commercial speech. To demonstrate the unconstitutional nature of the Act, the four-part *Central Hudson* test¹⁷ will be applied. This test is used to evaluate the constitutionality of the manner in which the government regulates commercial speech.¹⁸ Through analysis of this test, the stifling impact that the NLEA has on food and drug manufacturers' constitutionally-protected rights of free speech and expression will be discussed.

Part III will propose a more effective, less restrictive, constitutional solution to our nation's dietary problems. This proposal will suggest a purely educational campaign that will help improve the dietary practices of our nation's citizens by teaching consumers the "right way to eat."

I. AGENCIES, REGULATIONS, AND FIRST AMENDMENT RIGHTS

A. Regulatory Agencies

1. The Food and Drug Administration (FDA)

The FDA is a regulatory agency that is housed in the federal government's executive branch¹⁹ as part of the Department of Health and Human Services.²⁰ The FDA has the power to regulate food, drugs, medical devices, and cosmetics.²¹ The primary goal of the FDA is to protect the public's health.²² In pursuing this goal, the FDA has adopted a regulatory approach.²³

In 1990, Congress enacted the NLEA.²⁴ Three years later, the FDA promulgated its final enabling regulations²⁵ and fully implemented the Act.²⁶

17. *Thompson v. W. States Med. Ctr.*, 535 U.S. 357, 360 (2002) (citing *Cent. Hudson Gas & Elec. Corp. v. Pub. Serv. Comm'n of N.Y.*, 447 U.S. 557 (1980)).

18. *Id.* at 360.

19. Thomas B. Leary, *The Ongoing Dialogue Between the Food and Drug Administration and the Federal Trade Commission*, 59 FOOD DRUG L.J. 209 (2004).

20. John P. Swann, *History of the FDA*, <http://www.fda.gov/oc/history/historyoffda/default.htm> (last visited Oct. 16, 2005). The Agency was created in 1862. *Id.* At that time, the FDA was part of the USDA and was staffed by one chemist. In 2001, 9,100 employees worked for the FDA. *Id.*

21. 21 U.S.C. §§ 301-395 (2000).

22. The FDA's Mission Statement is as follows: "The FDA is responsible for protecting the public health by assuring the safety, efficacy, and security of . . . our nation's food supply . . ." U.S. Food and Drug Administration, *FDA's Mission Statement*, <http://www.fda.gov/opacom/morechoices/mission.html> (last visited Oct. 16, 2005).

23. J. Howard Beales, *Regulatory Consistency and Common Sense: FTC Policy Toward Food Advertising Under Revised Labeling Regulations*, 14 J. PUB. POL'Y & MKTG 154, 155 (1995).

24. Federal Food, Drug, and Cosmetic Act, *Pub. L. No. 101-535*, 104 Stat. 2353 (Nov. 8, 1990) (codified in scattered sections of 21 U.S.C.).

25. 21 C.F.R. § 101.9 (2004).

26. The Act was implemented in 1993. *Id.* It became effective in May 1994. Rodolfo M. Nayga, Jr., *Looking for the Nutritional Label: Does it Make a Difference?*, CHOICES,

The implementation of the NLEA is the epitome of the regulatory approach that the FDA has adopted when instituting its directives.²⁷ The goal of the NLEA is to improve the dietary practices of our nation's citizens²⁸ through strict regulation of product labels.²⁹ One requirement of the NLEA is that manufacturers must disclose detailed nutrition information on their product labels.³⁰ Before implementation of the NLEA, food manufacturers were not obligated to disclose a complete listing of their products' nutrition information.³¹ Rather, the decision of whether or not to supply this

Winter 2001-2002, at 39, available at <http://www.choicesmagazine.org/2002-4/2002-4-07.pdf>.

27. Beales, *supra* note 23, at 155. For instance, the FDA regulations only allow food manufacturers to highlight certain health claims on their products. *Id.* This approach affords the FDA broad control over foods the Agency thinks consumers should select. *Id.*

28. Enforcement Policy Statement on Food Advertising, 59 Fed. Reg. 28,388. See also *Pub. Citizen*, 932 F. Supp. at 14 (delineating the three original purposes behind the enactment of the NLEA: (1) to provide nutrition information that will help consumers select healthier foods, (2) to prevent consumer confusion by requiring uniform nutritional claims, and (3) to encourage the creation of more nutritional foods).

29. Enforcement Policy Statement on Food Advertising, 59 Fed. Reg. at 28,388.

30. Leary, *supra* note 19, at 211; see also Noah & Noah, *supra* note 9, at 68-69 (discussing the key features of the Act). The nutrition labeling requirement was an amendment to the Federal Food, Drug and Cosmetic Act (FDCA), 21 U.S.C. § 301 (2000). *Pub. Citizen*, 932 F. Supp. at 14. This provision, which details the nutrition information required on product labels, was codified at 21 U.S.C. § 343(q)(2000). The information that must be disclosed includes serving size or number of units typically consumed, the number of servings available in the container, the total caloric count, the number of calories from fat, the amount of "total fat, saturated fat, cholesterol, sodium, total carbohydrates, complex carbohydrates, sugars, dietary fiber, and total protein contained in each serving size," and the vitamins and minerals contained in the product. 21 U.S.C. § 343(q)(1)(A)-(E). The NLEA authorizes the FDA to exclude nutrient information. Fred F. Degnan, *Biotechnology and the Food Label: A Legal Perspective*, 55 FOOD DRUG L.J. 301, 303 (2000). The FDA exercises this right when the Agency believes that the consumer will still be able to make an informed dietary decision in the absence of certain information. *Id.* With this decision making authority, the FDA can restrict the expression of any information that a manufacturer wants to place on a label. It is not up to the government to determine if value is derived from information provided by protected speech. *Edenfield v. Fane* 507 U.S. 761, 767 (1993). Determining the value of information is a joint decision that is made between the party that is providing the information and the party that is receiving the information. *Id.*

31. See Degnan, *supra* note 30, at 302 (explaining the historical changes that have been made to the FDA's rulemaking authority). The changes primarily hinge upon the addition of the word "require." *Id.* at 301-02. While food labels have been regulated for over 100 years, the manner in which the NLEA now regulates these labels is unique. *Id.* In 1938, long before the enactment of the NLEA, Congress did not "require" that manufacturers place a complete listing of product ingredients on their product labels. *Id.* Rather than focusing on labeling requirements, Congress was primarily concerned with ensuring that the information food manufacturers placed on their products was not false or misleading. *Id.* Years later, Congress realized that, while the prohibition of false or misleading advertising was a noble goal, it did not sufficiently allow the FDA to regulate food labels in a manner that would ensure that consumers had ample information about the foods they were purchasing. *Id.* To remedy this concern, Congress gave the FDA the authority to require that "crucial" information be listed on food labels. *Id.* Such mandatory information included naming the ingredients used to produce the food, listing the net weight of the food's contents, listing the name and address of the food

information was solely within the manufacturers' discretion.³²

The Act also regulates the placement of health messages on product labels and packaging.³³ The impetus behind the NLEA's regulation of health claims was a 1984 advertisement campaign launched by the Kellogg Company.³⁴ The cereal company placed an "advertisement" on its boxes of All-Bran cereal informing consumers that adopting a high-fiber diet might reduce their risk of acquiring certain types of cancer.³⁵ Upon the enactment of the NLEA, the FDA regulated health claims such as this one by stipulating that these claims can only be made if they are supported by "significant scientific agreement."³⁶ Even broad, generalized health claims must adhere to this strict standard.³⁷

Clearly, the implementation of the NLEA has had a dramatic impact on food manufacturers. It has changed the way nutrition information is communicated and the circumstances under which health claims can be made.³⁸

2. *The Federal Trade Commission (FTC)*

Unlike the FDA, the FTC³⁹ is an independent agency associated with the executive, legislative, and judicial branches of government.⁴⁰ Such

manufacturer or party responsible for its marketing, and setting forth the name of the food. *Id.* Only this limited information was required. See Enforcement Policy Statement on Food Advertising, 59 Fed. Reg. at 28,388 (stating that the FDA's purpose is broader than simply working to prevent misleading or untruthful advertising); see also Nayga, *supra* note 26, at 39 (stating that prior to the enactment of the NLEA, the government did not strictly regulate nutrition content and health claims).

32. Nayga, *supra* note 26, at 39.

33. Pub. L. No. 101-535, 104 Stat. 2353 (codified at 21 U.S.C. § 343(r) (2000)). The regulation of health claims was also an amendment to the FDCA, 21 U.S.C. § 301(403)(i) (2000). *Pub. Citizen*, 932 F. Supp. at 15. A statement on a label constitutes a health claim when it implies the existence of a relationship between a nutrient found in the food product and a "disease or a health-related condition." 21 U.S.C. § 343(r)(1)(B) (2000).

34. Matt Hellman, *Commercial Drug Claims, the FDA, and the First Amendment*, June 8, 2001, <http://leda.law.harvard.edu/leda/data/583/Hellman01.html>.

35. Although the National Cancer Institute supported this claim, Congress was concerned that the FDA had not personally tested this claim. *Id.*

36. 21 U.S.C. § 343(r)(3)(B)(i); see also Noah & Noah, *supra* note 9, at 67 & n.21 (explaining the FDA's use of the "significant scientific agreement" test in order to determine the validity of health claims made by manufacturers). Significant scientific agreement exists when a substantial number of scientific experts agree that the health claim is supported by all available scientific evidence. 21 U.S.C. § 343(r)(3)(B)(i).

37. Noah & Noah, *supra*, note 9, at 69. For example, in order to lawfully place a claim on a product label such as "a low fat diet may reduce the risk of cancer," the product must be "low fat" and it can contain only a specified level of sodium or cholesterol. *Id.* Other examples of nutrition-content claims and health claims are set forth in *Pub. Citizen*, 932 F. Supp. at 15. "Low sodium" and "lite" are both examples of regulated nutrition content claims. *Id.* An example of a regulated health-claim is "fiber helps to prevent cancer." *Id.*

38. U.S. Food and Drug Administration, History of the FDA: Trends on the Last Quarter Century, <http://www.fda.gov/oc/history/historyoffda/section5.html> (last visited Oct. 16, 2005).

39. 15 U.S.C. § 41 (2000).

40. The FTC is staffed by five Commissioners. 1-4 ADMIN. LAW § 4.04(2)(e). These

independent agencies are not heavily regulated by the executive branch,⁴¹ but are authorized to administer certain laws.⁴²

The FTC's primary goal is to prevent deceptive advertising practices or acts.⁴³ The mandates set forth by the FTC are as follows: (1) advertisements cannot be deceptive,⁴⁴ (2) advertisers must be able to support their claims, and (3) advertisements must be fair.⁴⁵ Unlike the FDA, the FTC does not look specifically at the words that are used in advertisements.⁴⁶ Rather, the Agency is primarily concerned with the reliability and truthfulness of the advertisement's overall message.⁴⁷

A very fine line exists between the authority of the FTC and the authority of the FDA.⁴⁸ Over fifty years ago, the two agencies created a Memorandum of Understanding to clarify their responsibilities.⁴⁹ Pursuant to this memorandum, the FDA regulates labels while the FTC regulates "the advertising, of 'food, drugs, devices and cosmetics.'"⁵⁰ Over the years, this understanding has not changed.⁵¹

Commissioners are appointed by the President, who acts in accordance with the advice and consent of the Senate. *Id.* The Commissioners are appointed for a term of seven years and are subject to removal by the President if they do not work efficiently, neglect their duties, or commit acts of malfeasance related to their position with the FTC. *Id.*

41. While these agencies are relatively independent from the executive branch, the President does have the ability to remove their members. *Id.* at § 4.04 (1).

42. Both legislative and judicial powers have been delegated to these independent agencies. *Id.* at § 4.04 (2).

43. Enforcement Policy Statement on Food Advertising, 59 Fed. Reg. at 28,388.

44. *Id.* Advertising is deemed deceptive by the FTC if there is a likelihood consumers will be misled due to the substance of the advertisement or by a material omission of fact contained therein. *Id.* See, e.g., *United States v. 116 Boxes, etc. Arden Assorted Candy Drops*, 80 F. Supp. 911, 913 (D. Mass. 1948) (explaining that the proper standard for determining if a label is deceptive is whether the ultimate consumer, as opposed to an expert, would be misled).

45. Federal Trade Commission, Frequently Asked Questions: A Guide for Small Business 3, <http://www.ftc.gov/bcp/online/pubs/buspubs/ad-faqs.htm> (last visited Oct. 16, 2005).

46. Leary, *supra* note 19, at 209.

47. *Id.* Another key difference between the FDA and FTC is that the FTC reviews the legality of the ads it oversees on a case-by-case basis, whereas the FDA has adopted a more general approach. Noah & Noah, *supra* note 9, at 70.

48. Typically, product advertising is regulated by the FTC while product labeling is regulated by the FDA. Federal Trade Commission, *supra* note 45. See Noah & Noah, *supra* note 9, at 69-70 (stating that in situations involving product labeling, the FDA's control is extensive). The general rule is that the FTC has authority over product advertising, with the exception of ads pertaining to prescription drugs and restricted medical devices. *Id.* As explained in *Kordel v. United States*, 335 U.S. 345, 348 (1948), any expressive material that accompanies an item can be classified as a label. Indeed, the FDA's control over product labels also extends to "written, printed or graphic matter" that accompanies a product. *Id.* Thus, such marketing materials are governed by the FDA, not the FTC. *Id.*

49. Leary, *supra* note 19, at 209.

50. *Id.* at 209-10 (quoting Working Agreement Between the FTC and the Food and Drug Administration, 4 TRADE REG. REP. 9850.1 (1971)).

51. "The FTC handles most matters regarding claims in food advertisements. The FDA handles most matters regarding food labels." Federal Trade Commission, *supra* note

3. *The United States Department of Agriculture (USDA)*

The USDA is an executive branch agency.⁵² Its authority to regulate product claims made by food manufacturers is derived from the Federal Meat Inspection Act⁵³ and the Poultry Products Inspection Act.⁵⁴ When Congress enacted the NLEA, the Food Safety and Inspection Service (FSIS) of the USDA also set forth nutrition labeling requirements regarding meat and poultry products.⁵⁵ The NLEA did not require the FSIS to issue such regulations.⁵⁶

B. First Amendment Rights: Protected Commercial Speech

The First Amendment of the Bill of Rights states:

Congress shall make no law respecting an establishment of religion, or prohibiting the free exercise thereof; or abridging the freedom of speech, or of the press; or the right of the people peaceably to assemble, and to petition the Government for a redress of grievances.⁵⁷

The First Amendment neither specifically explains the meaning of the terms that it contains,⁵⁸ nor does it distinguish between “‘pure’ speech and the lesser degree of protection used for subcategories such as commercial speech”⁵⁹ This distinction has been created by the court system.⁶⁰ At its core, commercial speech is speech that simply offers a commercial transaction.⁶¹

The first case in which the Supreme Court granted First Amendment protection to commercial speech was *Va. State Bd. of Pharmacy v. Va. Citizens*.⁶² In this case, a state statute prohibited pharmacists from

45, at 21.

52. *Wyoming v. USDA*, 277 F. Supp. 2d 1197, 1203 (D. Wyo. 2003).

53. 21 U.S.C. § 601(n)(1) (2000).

54. 21 U.S.C. § 453(h)(1) (2000).

55. Enforcement Policy Statement on Food Advertising, 59 Fed. Reg. at 28,388.

56. *Id.*

57. U.S. CONST. amend. I.

58. In order to convince the states to ratify the Constitution, The Bill of Rights was added as an addendum. Spencer, *supra* note 7, at 89. (citing Robert Bork, *Neutral Principles and Some Fundamental First Amendment Problems*, 47 MD. L.J. 1, 22 (1971)). Prior to the addition of The Bill of Rights, the states were concerned that the Constitution afforded the federal government too much power. *Id.* This “quick addendum” failed to specifically define the terms of each amendment’s text. *Id.* Consequently, the Supreme Court is free to construe the meaning of the term “speech.” *Id.*

59. *Id.* See also 44 *Liquormart, Inc. v. Rhode Island*, 517 U.S. 484, 522 (1996) (Thomas, J., dissenting) (proposing the notion that commercial speech may in fact warrant more protection than its noncommercial counterpart). In his dissenting opinion, Justice Thomas reiterates the fact that there is no historical support for the notion that commercial speech should be afforded less constitutional protection than noncommercial speech. *Id.* at 522.

60. *Id.*

61. *Va. St. Bd. of Pharmacy*, 425 U.S. at 762 (quoting *Pittsburgh Press Co. v. Pittsburgh Comm’n on Human Relations*, 413 U.S. 376, 385 (1973)).

62. *Id.* at 770. Before 1975, commercial speech was not afforded constitutional protection. Ann K. Wooster, *Protection of Commercial Speech Under First Amendment—*

advertising prescription drug prices.⁶³ The Court held that even though these pharmacists were neither advancing political messages nor editorializing in any way, their advertisements were still protected by the First Amendment.⁶⁴ The Court deemed “the free flow of commercial information” to be of paramount importance.⁶⁵ The Court, however, was not implying that all commercial speech deserves First Amendment protection.⁶⁶ A four-part test created by the Court in *Central Hudson Gas & Electricity Corp. v. Public Service Commission of N.Y.* is used to determine the constitutionality of a restriction that has been placed upon commercial speech.⁶⁷

The primary example of protected commercial speech is advertising.⁶⁸ In *Rubin v. Coors*, the Supreme Court held that information contained on beer labels constitutes a form of constitutionally protected commercial speech.⁶⁹

Supreme Court Cases, 164 A.L.R. FED. 1, 2 (2004).

63. *Va. St. Bd. of Pharmacy*, 425 U.S. at 749-50.

64. Hellman, *supra* note 34 (citing *Va. State Bd. of Pharmacy*, 425 U.S. at 761). The mere fact that a party is using speech to sell a product, does not take this speech out of the realm of constitutional protection. *Va. State Bd. of Pharmacy*, 425 U.S. at 761. Moreover, the fact that money is spent to promote speech, does not place it outside the realm of First Amendment protection. *Id.* Additionally, the same is true even if the interest of the party promoting the speech is purely economic in nature. *Id.* at 762.

65. *Va. St. Bd. of Pharmacy*, 425 U.S. at 763.

66. *See* Wooster, *supra* note 62, at 2 (warning that not all commercial speech is automatically afforded First Amendment protection). Generally, the government cannot regulate a message’s content. *Id.* Commercial speech is viewed differently than ordinary speech, however, and in order for it to be constitutionally protected it must pertain to a lawful activity and cannot be misleading. *Id.* Additionally, speech that “proposes an illegal transaction” is afforded no constitutional protection. *Id.* To a certain extent, the government’s authority to regulate commercial speech is premised on the idea that an advertiser is able to review its commercial messages in order to determine if any misstatements were made. *Id.*

67. *Greater New Orleans Broad. Ass’n v. United States*, 527 U.S. 173, 183 (1999). A regulation of commercial speech is deemed constitutional if the government has a substantial interest in promoting the regulation, the regulation directly advances this government interest, and the regulation is not too extensive. *Cent. Hudson Gas & Elec. Corp.*, 447 U.S. at 566. Consequently, a regulation that does not effectively support the government’s interest is unconstitutional. Wooster, *supra* note 62, at 2. When a regulation of commercial speech only remotely supports the government’s interest the regulation may not be upheld. *Id.*; *see also* Spencer, *supra* note 7, at 91 (labeling the *Central Hudson* test a test of intermediate scrutiny). When the constitutionality of a regulation that has been placed on commercial speech is questioned, the government bears the burden to prove that the regulation is constitutional and thus adheres to First Amendment guidelines. Edward Dunkelberger & Sarah E. Taylor, *The NLEA, Health Claims, and the First Amendment*, 48 FOOD DRUG L.J. 631, 634 (1993).

68. *Nike, Inc. v. Kasky*, 539 U.S. 654, 678 (2003). *See* Richard A. Posner, *Free Speech in an Economic Perspective*, 20 SUFFOLK U. L. REV. 1, 6 (1986) (providing examples of free speech such as “art, entertainment, defamation of private persons, [and] commercial advertising . . .”).

69. *Rubin*, 514 U.S. at 481; *see also Kordel*, 335 U.S. at 349-50 (providing a very broad definition for what constitutes a label). The broader the definition of what is a label, the greater the reach of the NLEA. Despite the fact that the NLEA’s regulations have restricted the First Amendment rights of corporations, the preamble of the originally proposed regulations did not mention the relevant First Amendment issues. Dunkelberger

The protections that the First Amendment affords private citizens are also afforded to corporations.⁷⁰ Both individuals and corporations contribute to the distribution of information.⁷¹ Determining whether speech is constitutionally protected has nothing to do with the identity of the speaker, rather it is the type of information that is being communicated that warrants evaluation.⁷²

Recently, in cases in which the constitutionality of certain FDA regulations has been challenged, the court system has been deferential to the First Amendment protections owed to food and drug manufacturers.⁷³ This deference reinforces the importance of protecting a corporation's right to free speech.

II. THE BROAD IMPACT AND UNCONSTITUTIONAL NATURE OF THE NLEA AND THE FDA REGULATIONS

The enactment of the NLEA and the FDA's regulations altered the authority and operations of both the FDA and FTC. Part A will explain the manner in which these regulations have impacted the FTC. This section will also discuss the effect of this paternalistic approach on corporate commercial speech. Part B will define the test that is used to evaluate the constitutionality of a restriction placed on commercial speech.⁷⁴ Through application of this test, the unconstitutional nature of the NLEA and the FDA regulations becomes evident. Additionally, application of this test will demonstrate how this excessive regulation stifles the promotional efforts of corporate entities.

A. *The Wide Impact of the NLEA and the FDA Regulations*

As noted earlier, the boundary between the authority of the FDA and the authority of the FTC is very narrow.⁷⁵ Part I described the Memorandum

& Taylor, *supra* note 67, at 633. The preamble to the final NLEA regulations does contain a blanket disclaimer stating that neither the Act nor the regulations themselves violate constitutional First Amendment protections. *Id.*

70. Pacific Gas and Elec. Co. v. Pub. Utilities Comm'n of Cal., 475 U.S. 1, 8 (1986) (citing *First Nat'l Bank of Boston*, 435 U.S. at 776).

71. *Id.* See also *First Nat'l Bank of Boston*, 435 U.S. at 783 (finding a state prohibition that targeted corporate speech unconstitutional and thus concluding that the prohibition at issue was inappropriate and invalid).

72. *Id.*

73. Hellman, *supra* note 34. See *Wash. Legal Found.*, 13 F. Supp 2d. at 51 (discussing a case in which an FDA regulation that did not directly advance the government's interest and was too extensive was therefore unconstitutional); *W. States Med. Ctr.*, 535 U.S. at 376 (holding that an FDA instituted regulation on compounded drug advertising unconstitutionally restricted commercial speech). The court applied the *Central Hudson* test to evaluate the constitutionality of this regulation. *W. States Med. Ctr.*, 535 U.S. at 360. During the completion of this evaluation two "prongs" of the *Central Hudson* were called into question, first, the court did not find that this regulation directly advanced the governmental interest at issue, and second, the regulation was more extensive than necessary. *Id.* at 371.

74. The test that is used to evaluate such restrictions was set forth in *Cent. Hudson Gas & Elec. Corp.*, 447 U.S. at 557.

75. Noah & Noah, *supra* note 9; see *Fed. Trade Comm'n v. Texaco, Inc.*, 555 F.2d

on Understanding⁷⁶ which the FDA and FTC created in order to clarify their respective responsibilities.⁷⁷ Both the FDA and the FTC have the statutory authority to regulate food advertising.⁷⁸ While the Memorandum on Understanding states that the FDA is primarily responsible for the regulation of product labeling, and the FTC primarily reviews the advertising of such products, the responsibilities of the two agencies still overlap significantly. In *Rubin v. Coors*, the Court determined that labels constitute commercial speech.⁷⁹ The distinction between the commercial speech in product advertising, an area regulated by the FTC, and the commercial speech in a product label, an area regulated by the FDA, is negligible. Both mediums are used to communicate promotional information.⁸⁰ Thus, the FDA's labeling regulations also constitute a restriction on product advertising, demonstrating the significant overlap in the responsibilities of these two agencies.⁸¹

When the NLEA was enacted and the FDA regulations were finalized, the FTC recognized the need to clarify the impact of these actions.⁸² In order to do this, the FTC issued the Enforcement Policy Statement on Food Advertising (Policy Statement).⁸³ This Policy Statement notes how deferential the FTC is to the FDA. In the Policy Statement, the FTC Commission expressed the Agency's desire to conform to the NLEA guidelines when evaluating advertising under its control.⁸⁴ This significant deference demonstrates the broad impact of the NLEA and the FDA regulations and highlights the importance of ensuring the constitutionality of these actions.

862, 881 (1977) (noting the overlap between regulatory agencies). In *Thompson Med. Co. v. FTC*, 791 F.2d 189 (D.C. Cir. 1986), the FTC informed Thompson Medical that its advertising of Aspercreme was deceptive. The FTC required that in marketing and packaging its product, the company acknowledge the fact that its cream does not contain aspirin. *Id.* at 191. Thompson contested the FTC regulation, arguing that only the FDA should be allowed to regulate the labeling and advertising of a drug. *Id.* at 192. The court stated that the FTC did have the authority to make this determination. *Id.* at 192-93.

76. Leary, *supra* note 19, at 209.

77. Federal Trade Commission, *supra* note 45.

78. Enforcement Policy Statement on Food Advertising, 59 Fed. Reg. at 28,388. The FTC's authority is found in 15 U.S.C. §§ 45-52 (2000).

79. *Rubin*, 514 U.S. at 481.

80. See *Hanson v. United States* 417 F. Supp. 30, 35 (D. Minn. 1976) (explaining the many ways to communicate a product's "intended use").

81. See *supra* notes 47-50 and accompanying text (delineating the responsibilities of the FDA and the FTC).

82. Enforcement Policy Statement on Food Advertising, 59 Fed. Reg. at 28,388.

83. *Id.*

84. *Id.* The Commission stated that when a claim can be regulated by both the FDA and the FTC, deference will be given to the FDA. *Id.* at 28,390. This concept applies to the FDA regulations at issue. *Id.* The FDA has strictly defined words such as "high" and "low" in terms of a food product's nutrient content. *Id.* The FTC has agreed to use the FDA's definitions of these words when they are used in product advertising. *Id.* The functional rationale behind this approach is the Agency's desire to promote uniformity, thus preventing confusion among consumers when these "FDA-defined terms" are found in advertising. *Id.* at 28,391.

B. *The Central Hudson Test*

Central Hudson was a case brought by a utility company to contest an advertising ban inflicted on the company by the Public Service Commission of the State of New York.⁸⁵ The Commission initially enacted the ban to reduce consumer demand for fuel during a time of inadequate supply.⁸⁶ Once the fuel shortage ended, however, the Commission decided to extend the advertising ban.⁸⁷ The Central Hudson Gas and Electric Company opposed this extension claiming that it constituted an unlawful restraint on commercial speech in violation of its First Amendment rights.⁸⁸ In determining the constitutionality of the advertising ban, the Court created a four-part test.⁸⁹ This test is still used today to evaluate the constitutionality of restrictions on commercial speech.

In the *Central Hudson* test, courts evaluate whether: (1) the commercial speech at issue is lawful and not misleading, (2) the government has a substantial interest in restricting this speech, (3) the regulation directly advances the government's interest; and finally (4) the regulation is too extensive.⁹⁰ Application of this test in recent cases, however, demonstrates that it has essentially become a three-prong test.⁹¹ Before the test can be considered, the commercial speech at issue must be lawful and not misleading.⁹² Upon application of its test, the court in *Central Hudson* ultimately concluded that the advertising ban was unconstitutional.⁹³ Recently, courts have voided several FDA regulations through application of the *Central Hudson* test.⁹⁴

1. *Is the Commercial Speech at Issue Lawful and Not Misleading and is the Government's Interest Substantial?*

It has been established that labels constitute commercial speech;⁹⁵ thus, the application of the *Central Hudson* test is applicable to the regulation of

85. 447 U.S. at 558.

86. *Id.* at 559.

87. *Id.*

88. *Id.* at 560-61.

89. *Id.* at 566.

90. *Id.* Courts have often found application of this four-part test challenging. Noah & Noah, *supra* note 9, at 78.

91. Noah & Noah, *supra* note 9, n.67.

92. *Cent. Hudson Gas & Elec. Corp.*, 447 U.S. at 566.

93. *Id.* at 572. In applying the four-part test, the Court used the following reasoning. First, the Court held that the speech at issue was lawful and was not deceitful. *Id.* at 566. Second, the state's interest in the conservation of electricity was substantial. *Id.* at 568. Third, the effect that this ban would have on the conservation of fuel was speculative and did not validate the negative effects that the ban would have on the electric company. *Id.* at 569. Finally, the Court found that the Commission failed to demonstrate the ineffectiveness of a less restrictive approach. *Id.* at 570.

94. See *W. States Med. Ctr.*, 535 U.S. at 377 (finding an FDA regulation unconstitutional); see also *Wash. Legal Found.*, 13 F. Supp. 2d at 74 (invalidating an FDA regulation regarding off-label drug advertising); Hellman, *supra* note 34 (stating that courts are increasingly protective of manufacturer's commercial speech rights).

95. *Rubin*, 514 U.S. at 481.

food labels. The first prong of the test has been met; the labels at issue are not inherently misleading. Congress' impetus for enacting the NLEA was to improve consumers' dietary practices,⁹⁶ not to regulate misleading or unlawful food labels.

In evaluating the second prong of the test, the Court in *Posadas de Puerto Rico Assocs. v. Tourism Co.*⁹⁷ held that the government's interest is considered substantial when it pertains to "the health, safety and welfare" of its citizens.⁹⁸ In *Int'l Dairy v. Amestoy*,⁹⁹ a Vermont statute requiring dairy manufacturers to notify the public of any possibility that the product they were consuming was produced by a cow that had been given a synthetic growth hormone, did not pass the second prong of the *Central Hudson* test.¹⁰⁰ The statute did not relate to the government's health and safety concerns; rather, it was passed based upon the government's belief in the public's "right to know" about the possibility of the synthetic growth hormone.¹⁰¹ Unlike the statute at issue in *Int'l Dairy*, Congress enacted the NLEA to promote public health. The government's interest in enacting the NLEA was, therefore, substantial and the first two prongs of the *Central Hudson* test have been satisfied.

2. *The NLEA and the FDA Regulations Do Not Directly Advance the Government's Interest*

In order for a restriction of commercial speech to be upheld as constitutional, the government must demonstrate that "the harms it recites are real and that its restriction will in fact alleviate them to a material degree."¹⁰² If a regulation provides merely tenuous or remote support for the government's interest, it is unconstitutional.¹⁰³

The NLEA and FDA regulations at issue do not satisfy the third prong of the *Central Hudson* test. Research has shown that mandatory nutrition labeling only remotely improves the quality of American consumers' diets.¹⁰⁴

96. Enforcement Policy Statement on Food Advertising, 59 Fed. Reg. at 28,388.

97. 478 U.S. 328 (1986).

98. *Id.* at 341.

99. 92 F.3d 67 (2d Cir. 1996).

100. *Id.* at 73.

101. The court held that the public's "right to know" or curiosity did not justify the compelled disclosure of the fact at issue. *Id.* at 74.

102. *Edenfield*, 507 U.S. at 770-71. In *Edenfield*, the Florida Board of Accountancy prohibited Florida CPA's from promoting their services through "direct, in-person, uninvited solicitation." *Id.* at 763. The Supreme Court held the ban was unconstitutional. *Id.* at 765. The Florida Board had provided no significant proof that this ban directly advanced its putative interest in shielding consumers from fraudulent acts of CPAs. *Id.* at 771. Similarly, in *44 Liquormart*, 517 U.S. at 505, the Court held that a ban on advertisements that informed the public about alcohol prices was unconstitutional, as it did not directly advance the government's interest in reducing alcohol consumption.

103. *44 Liquormart*, 517 U.S. at 505 (citing *Cent. Hudson Gas & Elec. Corp.*, 447 U.S. at 564).

104. Nayga, *supra* note 26, at 40-41. In Nayga's article, he relied on data that the USDA collected from 1994 to 1996. *Id.* at 39. Nayga used this data to evaluate the impact

Nutrition label usage among consumers varies. Demographics play a major role in the extent to which American consumers actually *use* nutrition labels.¹⁰⁵ The Department of Agricultural, Food, and Resource Economics at Rutgers University completed a study on food product label usage.¹⁰⁶ Using a segment of New Jersey consumers as a control group,¹⁰⁷ the study demonstrated how demographic factors such as, “time constraints, the perceived role of dietary intake in maintaining individual health, literacy in English, a rudimentary understanding of nutrition, and the perceived benefits of nutritional information” can influence nutrition label usage.¹⁰⁸ Household size, age, place of residence, and gender were also found to be influential.¹⁰⁹

Ultimately, the study concluded that nutrition labels can influence the dietary practices of people who *currently* use labels.¹¹⁰ However, if the nutrition labels are not being used by certain segments of the population, the

of post-NLEA nutrition labels on the average American consumer’s diet. *Id.* The USDA measures “dietary quality” through application of the Healthy Eating Index (HEI). *Id.* This index spans from zero to one hundred. *Id.* at 40. Nayga and his group used the USDA data to demonstrate the impact of the nutrition information that food manufacturers place on their products as mandated by the NLEA. *Id.* at 40. One aspect of Nayga’s analysis pertained to the impact of the mandatory ingredient list found on NLEA compliant food labels. *Id.* Of all of the aspects of the food labels considered in the study, the list of ingredients had the most insignificant impact on a consumer’s HEI score. *Id.* at 41. The ingredient list increased the score by only 3.5 points. *Id.* For instance, if a consumer has, for example, an HEI score of 75, the score will increase to 78.5 based upon the inclusion of a full ingredient list on the foods consumed. Nayga concluded that, while nutrition labels do impact “dietary quality” this impact is “rather small.” *Id.* at 40-41. In an FDA statement analyzing the impact of these regulations, the Agency admitted that only a “small percentage” of consumers will use nutrition labels to alter their current purchasing habits. Regulatory Impact Analysis of the Final Rules to Amend the Food Labeling Regulations, 58 Fed. Reg. 2927, 2936 (Jan. 6, 1993).

105. Ramu Govindasamy & John Italia, *Evaluating Consumer Usage of Nutritional Labeling: The Influence of Socio-Economic Characteristics* 17-18 (Jan. 1999), <http://aesop.rutgers.edu/~agecon/pub/label.pdf>.

106. *Id.* at 1.

107. *Id.* at 3. This narrow segment of consumers was selected to avoid inconsistencies that may exist in a national study. *Id.* at 3-4. However, caution should be used in applying these results nationally. *Id.* at 18. The data used in this study was collected through the distribution of a survey completed at five grocery stores in New Jersey. *Id.* at 8-10.

108. *Id.* at 5.

109. *Id.* at 7. Other factors such as family size have a debatable effect on nutrition label usage. *Id.* at 13. This study, however, found that larger households spend less time looking at nutrition labels. *Id.* at 14. Additionally, younger consumers use nutrition labels with greater frequency than do older consumers. *Id.* at 15. The study also found that suburban residents are among the most frequent users of nutrition labels. *Id.* Female residents are also more likely to utilize nutrition labeling information than are their male counterparts. *Id.* at 11. See also Letter from Maureen L. Storey, Acting Dir., Ctr. for Food and Nutrition Policy, Va. Polytechnic Inst., to the Food and Drug Administration (Sept. 13, 2002), available at http://www.ceresnet.org/images/Misc/CFNP_First_Amendment_Comments_to_FDA.pdf (analyzing the results of federal diet, health, and nutrition knowledge surveys). Survey results showed that individuals that use these labels include women, people who already eat healthy foods, educated consumers, consumers with higher incomes, and consumers who must eat healthy foods due to a health condition. *Id.* at 6-7. These individuals, however, are not representative of the entire population.

110. Govindasamy & Italia, *supra* note 106, at 18.

extent to which they directly advance the government's goal is questionable at best.¹¹¹

A letter submitted to the FDA by Maureen L. Storey, 2002 Acting Director of the Virginia Polytechnic Institute's Center for Food and Nutrition Policy, also assessed the First Amendment concerns surrounding the NLEA by applying the *Central Hudson* test.¹¹² In addressing the third prong of the *Central Hudson* test, Storey demonstrated that while Congress and the FDA presume that consumers perceive nutrition to be of primary importance when purchasing food, this presumption is not supported by fact.¹¹³ Storey delineated the results of a USDA Diet and Health Knowledge survey conducted after the enactment of the NLEA.¹¹⁴ In this survey, consumers were asked to indicate the importance of certain food selection criteria.¹¹⁵ Despite the detailed nutrition information available on food products, nutrition was found to be less important to consumers than both food safety and taste.¹¹⁶ Certain consumers also indicated that there are other factors that can further lessen the importance of nutrition.¹¹⁷ For instance, lower income consumers reported that the availability of a coupon can devalue the impact of nutrition when making a purchase decision.¹¹⁸

Also outlined in Storey's letter were the results of the FDS's Food Label Use and Nutrition Education Survey. The results demonstrated that the increased availability of nutrition information has not translated into an increased emphasis on nutrition and the government's interest has not been directly advanced.¹¹⁹ Five months after the NLEA became effective, nearly half of all consumers were using these labels.¹²⁰ Nevertheless, over the next five years, label usage had not increased significantly.¹²¹ Based upon the multiple reasons stated, these regulations do not directly advance the government's interest and have not satisfied the third prong of the *Central Hudson* test.

111. *See id.* (stating that this policy restriction only affects current label users).

112. Storey, *supra* note 110, at 5.

113. *Id.* at 6-7. A USDA survey's results showed that factors other than nutrition, such as food safety and taste, are of primary importance to consumers when purchasing a food product. *Id.* at 7.

114. *Id.*

115. *Id.* The six characteristics were "food safety, nutrition, price, keeping quality, ease of preparation, and taste." *Id.*

116. *Id.* Only 62% of consumers said that nutrition was very important when making a food purchase decision. *Id.*

117. *Id.*

118. *Id.*

119. *Id.* The FDA's Food Label Use and Nutrition Education Survey showed that nutrition labels are primarily used to "avoid a specific ingredient." *Id.* at 8. Implicit in the results is the fact that when people purchase products for the first time, they are neither looking at the label nor are they using the labels when making food preparation decisions. *Id.*

120. *Id.* at 7.

121. *Id.* According to the FDA, in 1994, 52% of the population was reviewing product labels. *Id.* An independent study published in 1999 indicated that this number had only increased by 3%. *Id.*

3. *The Regulations That Have Been Placed on Food Manufacturers Are Too Extensive*

The fourth prong of the *Central Hudson* test is met when there is a “reasonable fit” between the government’s interest and the restriction on commercial speech.¹²² A government’s interest does not need to employ the “least restrictive” regulation; however, the regulation cannot be “substantially excessive” either.¹²³ If the government’s interest can be advanced in a less restrictive manner, that method should be used.¹²⁴

Recently, in *W. States Med. Ctr.*, the FDA’s restriction of compounded drug advertising was held unconstitutional.¹²⁵ The court held that the government’s goal could be achieved through less restrictive methods.¹²⁶ Similarly, the government’s interest in improving our nation’s diets can be advanced through less restrictive measures.

Compliance with the fourth prong of the *Central Hudson* test is particularly important in reference to manufacturers’ promotional efforts. The NLEA’s excessive regulations that compel a manufacturer to speak or to disclose certain information¹²⁷ will detrimentally affect food manufacturers’

122. *Bd. of Trs. of the State Univ. of N.Y. v. Fox*, 492 U.S. 469, 480 (1989).

123. *Id.*

124. *W. States Med. Ctr.*, 535 U.S. at 371; *Rubin*, 514 U.S. at 491; *United States v. Edge Broad. Co.*, 509 U.S. 418, 430 (1993).

125. *W. States Med. Ctr.*, 535 U.S. at 376-77.

126. *Id.* at 371-72. Through banning compounded drug advertising the government was attempting to advance two competing interests. *Id.* at 368. These interests were (1) the preservation of a new drug approval process and (2) securing the availability of compounded drugs to individuals for whom traditional drugs were ineffective. *Id.* The court suggested that the FDA implement alternate regulations that would not infringe upon the commercial speech rights of the affected pharmacists. *Id.* at 372. Two of the court’s suggestions involved regulating the volume of drugs that the pharmacists either compounded or wholesaled. *Id.* These solutions are examples of restrictions that can advance the government’s interest without restricting commercial speech. *See also Wash. Legal Found.*, 13 F. Supp. 2d at 73 (holding that the availability of “less burdensome alternatives” is a key consideration when evaluating the constitutionality of a restriction on commercial speech). The existence of less restrictive methods was also the impetus for invalidating four FDA sub-regulations in *Pearson v. Shalala*, 164 F.3d 650, 654 (D.C. Cir. 1999). In *Pearson*, all health claims placed on dietary supplements had to be approved by the FDA. *Id.* at 651-52. One such health claim requiring approval stated, “Consumption of antioxidant vitamins may reduce the risk of certain kinds of cancers.” *Id.* at 652. The court stated that the proposed health claim constituted commercial speech, and applied the *Central Hudson* test. *Id.* at 655-56. As in *Wash. Legal Found.* and *W. States Med. Ctr.*, the court in *Pearson* held that the regulation was unconstitutional as there were less restrictive ways to regulate the commercial speech at issue. *Id.* at 654. A “less draconian” regulation would require the use of disclaimers to eliminate any potentially misleading health claims. *Id.*

127. *See Riley v. Nat’l Fed’n of the Blind of N.C., Inc.*, 487 U.S. 781, 796-97 (1988) (discussing the extent to which the First Amendment protects “the decision of both what to say and what *not* to say”). The fact that the compelled statement is one of fact rather than opinion is not dispositive. *Id.* at 797. The constitutionality of laws that compel speech thereby restricting protected speech must be reviewed. *Id.* at 798. The information that manufacturers are required to place on food labels constitutes compelled speech. Such detailed disclosure of nutrition content places a burden upon protected corporate speech.

businesses. Additionally, the NLEA's strict regulation of product health claims will also hinder food manufacturer's promotional efforts.¹²⁸ As demonstrated, the NLEA and the regulations promulgated by the FDA are unconstitutional.

III. PROTECTING CORPORATE FIRST AMENDMENT RIGHTS WHILE IMPROVING SOCIETY'S HEALTH AND NUTRITION

The final section of this Comment proposes elimination of those aspects of the NLEA that infringe on corporate First Amendment rights¹²⁹ and suggests an alternative that the federal government can use to promote our nation's health and nutrition interests. An existing national education and marketing campaign called "5 A Day For Better Health" ("5 A Day")¹³⁰ is described and its effectiveness is discussed. The final proposal builds upon existing education and marketing programs.

A. Alternatives That Will Not Infringe on Corporations' First Amendment Rights

The federal government can pursue its goal of improving the dietary practices of our nation's citizens in a variety of ways. The government need not rely on the overly paternalistic system to which it currently subscribes.¹³¹ Some methods that have been used to further other governmental goals include the implementation of gang resistance educational and training programs, taxation of products such as cigarettes and alcohol in an effort to reduce consumption of these items, regulation of pesticides proven to cause birth defects, and the organization of health education programs.¹³² There

See, e.g., *Johanns v. Livestock Mktg. Ass'n*, 125 S. Ct. 2055, 2060 (May 23, 2005) (describing "true compelled speech" as speech in which a speaker must express a view with which he personally disagrees). In advertising its product, a manufacturer may not want to include detailed information on a product label. The manufacturer disagrees with the need to include such information. As long as the product labels comply with FTC standards, the manufacturers should not be compelled to alter them.

128. *See* Noah & Noah, *supra* note 9, at 67-68 (explaining the NLEA's test of the health claims included on product packages and labels).

129. 21 U.S.C. § 343 (q)(r).

130. Department for Health and Human Services, Centers for Disease Control and Prevention, 5 A Day, <http://www.cdc.gov/nccdphp/dnpa/5ADay/index.htm> (last visited Oct 16, 2005). This program encourages increased consumption of fruits and vegetables among U.S. consumers. Eat 5 to 9 A Day for Better Health, About the Program, <http://5aday.gov/about/index.html> (last visited Oct. 16, 2005).

131. *See* Economic Research Service/USDA, Mandatory Labeling, <http://www.ers.usda.gov/publications/aer793/aer793d.pdf> (last visited Nov. 14, 2004) (analyzing the effectiveness and propriety of food labels and the requirements imposed by regulation).

132. *Id.* One example of an education program that the federal government has established is the Comprehensive Smokeless Tobacco Health Education Act of 1986. 15 U.S.C. § 4401 (2000). This program is administered by the Secretary of Health and Human Services who has a duty to "develop educational programs and materials and public service announcements respecting the dangers to human health from the use of smokeless tobacco." § 4401(a)(1)(A). *See* Jendi B. Reiter, *Citizens or Sinners? The Economic and Political Inequity of "Sin Taxes" on Tobacco and Alcohol Products*, 29 COLUM. J.L. & SOC. PROBS. 443, 451 (1996) (discussing the federal government's

are numerous effective education and marketing programs that the federal government has either created or has contributed to financially.¹³³

Clearly there are a variety of ways for the government to pursue its objectives. The method that it has chosen to improve our nation's health, mandatory food labeling, is ineffective and paternalistic. In addition to the unconstitutional nature of the NLEA and the FDA regulations, the program lacks an education component. The program in its current form does not teach consumers how to understand food labels.¹³⁴ Nevertheless, inclusion of a labeling education component in this program would not alter the program's negative impact on the First Amendment rights of food manufacturers.

authority to impose so-called "sin taxes" on alcohol and tobacco products). Another federally operated education program is the Gang Resistance Education and Training ("G.R.E.A.T.") program. Bureau of Justice Assistance, Programs: Gang Resistance Education and Training (G.R.E.A.T) program, <http://www.ojp.usdoj.gov/BJA/grant/great.html> (last visited Oct. 16, 2005). The Bureau of Justice Assistance, which is a component of the U.S. Department of Justice, administers this program. *Id.* The program began as a combined effort between the Phoenix Police Department and the U.S. Department of Alcohol, Tobacco and Firearms. Phoenix.gov, Gang Resistance and Education Training — G.R.E.A.T., <http://www.phoenix.gov/POLICE/great1.html> (last visited Oct. 16, 2005). G.R.E.A.T. is a school-based program that works to prevent gang membership and violence among elementary and middle school children. Great-online.org, Welcome to the G.R.E.A.T. Web Site, <http://www.great-online.org> (last visited Oct. 16, 2005). Law enforcement officers visit schools and teach children nonviolent ways to solve problems. *Id.* In addition to school-based instruction, the "G.R.E.A.T." program includes a family component. Great-online.org, G.R.E.A.T. Families Training, <http://www.great-online.org/greatfamilies.htm> (last visited Oct. 16, 2005). Families are encouraged to attend seminars that educate parents about effective disciplinary measures, how to talk to their children about media violence, and about how to be good role models. *Id.* The program began in 1991, and by 1995 a study conducted by the U.S. Department of Justice demonstrated that the students involved in the program were victimized less, had an improved impression of police officers, and were increasingly involved in positive social activities. Great-online.org, History of the G.R.E.A.T. Program, <http://www.great-online.org/history.htm> (last visited Oct. 16, 2005).

133. One example of an educational program that the federal government contributes to is "McGruff the Crime Dog." National Crime Prevention Council, All About McGruff the Crime Dog, <http://ncpc.org/AllAboutMcGruff/index.htm> (last visited Feb. 16, 2005). This program uses public service advertising to communicate its crime prevention message. *Id.* The program began in 1980 and within 2 years, its slogan "Take a Bite Out Crime" was recognized by half of the American population. *Id.* These advertisements have proven to be a very cost effective method of spreading the government's crime prevention message. *Id.* The "McGruff" program targets children. *Id.* The program's spokesperson, the Crime Dog, visits schools to educate children about crime prevention. National Crime Prevention Council, All About McGruff the Crime Dog: Educators, <http://ncpc.org/AllAboutMcGruff/UsingMcGruff/educators.htm> (last visited Oct. 16, 2005). The program also supplies a variety of educational materials to children such as coloring and activity books, stickers and animated toys. *Id.*

134. Nayga, *supra* note 26, at 41.

B. 5 A Day

The “5 A Day for Better Health” program was created in 1991.¹³⁵ The program’s goals are multidimensional,¹³⁶ but its primary focus is increasing U.S. citizens’ consumption of fruits and vegetables to five to nine servings per day.¹³⁷ In support of its primary goal, “5 A Day” educates consumers about ways to incorporate more fruits and vegetables into their existing diets.¹³⁸ “5 A Day” receives both government funding and support from private entities.¹³⁹ The USDA is a government agency that provides financial support.¹⁴⁰

Rather than instituting a narrow approach such as the approach epitomized in the NLEA, “5 A Day” uses a variety of methods to spread its message.¹⁴¹ One such method involves publicity generated by the program’s industry partners.¹⁴²

The “5 A Day” message is broadcast on the radio through public service announcements, promoted to children through the use of games and school educational programs, and is available through an informative “kid friendly” website that also provides adults with information such as recipes that incorporate the use of fruits and vegetables.¹⁴³

The results of the “5 A Day” program are very promising.¹⁴⁴ From 1991 to 1997, the percentage of American adults who knew that they should eat at least five servings of fruits and vegetables every day doubled.¹⁴⁵ That

135. National Cancer Institute, 5 A Day for Better Health: About the Program, <http://www.5aday.gov/about/index.html> (last visited Oct. 16, 2005).

136. In addition to its main goal, the “5 A Day” program also attempts to educate Americans about the health benefits of eating fruits and vegetables, which include a reduced risk of “many cancers, high blood pressure, heart disease, diabetes, stroke, and other chronic diseases.” *Id.*

137. *Id.*

138. *Id.*

139. *Id.* The “5 A Day” program, began as a partnership between the National Cancer Institute and the Produce for Better Health Foundation. National Cancer Institute, 5 A Day for Better Health: About the Program — Partners, <http://www.5aday.gov/about/partners.html> (last visited Feb. 11, 2006). It is supported by the USDA, the American Cancer Society, the Centers for Disease Control, United Fresh Fruit and Vegetable Association, the National Alliance for Nutrition and Activity, and the Produce Marketing Association. *Id.*

140. *Id.* In addition to providing monetary assistance, the USDA supports “5 A Day” through its national school food assistance programs. 5 A Day: About the Program, Key Initiatives, http://www.5aday.gov/about/key_increase.html (last visited Feb. 16, 2005).

141. Department for Health and Human Services, Centers for Disease Control and Prevention, 5 A Day, *supra* note 130. The program includes education, communication, and research components. *Id.*

142. One example of an industry partnership is the Dole “We Make 5 a Day Fun” program. Dole 5 A Day, <http://www.dole5aday.com/> (last visited Oct. 16, 2005). Dole has a “kid-friendly” website and offers monthly online games that encourage children to eat fruits and vegetables in accordance with the “5 A Day” program. *Id.* The website also offers nutrition information for parents and educators. *Id.*

143. Department for Health and Human Services, Center for Disease Control and Prevention, 5 A Day, *supra* note 131.

144. *Id.*

145. *Id.* (citing the National Cancer Institute Omnibus Survey of Adults).

number has now increased fivefold.¹⁴⁶ Data collected by the Department of Agriculture demonstrated that in 1989–1991 American adults were consuming on average 3.9 servings of fruits and vegetables per day.¹⁴⁷ In 1996, the average American adult was consuming 4.6 servings of fruits and vegetables each day.¹⁴⁸ This means that adults are now receiving 92% of the recommended fruit and vegetable intake. The results of this program are far more promising than the aforementioned NLEA results.¹⁴⁹

C. *Proposed Education and Marketing Program:*
“Live Each Day the Healthy Way”

Programs such as “5 A Day”, the “Gang Resistance Education and Training” program (“G.R.E.A.T.”), and the “McGruff the Crime Dog” program all provide useful models for developing a full-range healthy living education and advertising campaign. This program can be instituted two different ways: first, the campaign can be initiated by a private organization that will receive funding from the federal government; and second, the federal government can initiate the program.¹⁵⁰ The latter method will be discussed in this proposal.

I. *Educational Component*

As in the “McGruff” and “G.R.E.A.T.” programs, a primary target of “Live Each Day the Healthy Way” will be school children. In “McGruff,” a “crime dog” visits schools to educate children about crime prevention,¹⁵¹ and in “G.R.E.A.T.,” uniformed police officers go to schools to talk to students about resisting gang involvement.¹⁵² The child education portion of the “Live Each Day the Healthy Way” program should also be delivered by an individual or character that children can trust. It is equally important that the “Live Each Day the Healthy Way” program play a dominant role in the classroom. This aspect of the program should be modeled after the “G.R.E.A.T.” program which uses thirteen, one-hour-long classroom sessions to spread its message.¹⁵³ The adult education portion of this program can be accomplished through a method similar to the one used in the “5 A Day” program. The “5 A Day” website includes nutrition information for adults as well as healthy recipe ideas.¹⁵⁴ Such information

146. National Cancer Institute, 5 A Day Background, *supra* note 136.

147. *Id.*

148. *Id.*

149. See *supra* notes 114–122 and accompanying text. Over the first seven years of the “5 A Day” program consumption of fruits and vegetables increased by 18%, *supra* note 131. Over the first five years of the NLEA’s implementation, label usage only increased by 3%, Storey, *supra* note 110, at 8. Clearly the “5 A Day” educational program is more effective.

150. See *supra* note 133 (discussing federal and private education programs). Private participation will still be encouraged in a federal program.

151. See *supra* note 134.

152. Great-online.org, *supra* note 133.

153. *Id.*

154. Department for Health and Human Services, Center for Disease Control and

will also be included on the “Live Each Day the Healthy Way” website.

2. *Marketing Aspect*

In order to generate awareness, an educational campaign must also be effectively marketed and promoted. In addition to broadcast advertising, several of the previously discussed programs use creative promotional methods such as the inclusion of online games and coloring books to indirectly convey the program’s message to children.

The promotional aspect of the “Live Each Day the Healthy Way” program will be the primary mode of adult program awareness. Television and radio advertising will encourage adults to visit the program’s website and collect useful nutrition information. Advertising will also help solidify the program’s message in the minds of children.

CONCLUSION

In conclusion, the NLEA and the food labeling regulations promulgated by the FDA are examples of overly paternalistic government regulations. The government instituted these regulations to protect the health of the American consumer. While the government clearly has a substantial interest in this goal, the method that it is currently using to accomplish this goal is unconstitutional.

The *Central Hudson* test forbids the government from restricting commercial speech through a method that does not directly advance its interest and is overly restrictive.¹⁵⁵ The NLEA and the FDA regulations do not sufficiently advance the government’s goal. These regulations restrict corporate First Amendment rights in an unconstitutional manner by requiring the inclusion of certain information on product advertising labels. A federally created education and marketing campaign is preferable to the current regulations. The campaign will advance the government’s substantial interest in creating a healthier society, while at the same time protecting corporate First Amendment rights.

Prevention, 5 A Day, *supra* note 131.

155. See *supra* Part II-B (defining the *Central Hudson* test).