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Fat America: The Need for Regulation Under the Food, Drug, and Cosmetic Act

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FAT AMERICA: THE NEED FOR REGULATION UNDER THE FOOD, DRUG, AND COSMETIC ACT

I. INTRODUCTION

In the past several years, Americans have begun to file suit against fast-food restaurants, such as McDonald's and Burger King, blaming them for health problems related to obesity.[1] One court has stated that most people in today's society are aware fast food is not healthy.[2] However, it is not so clear whether people truly understand the impact of fast food on their long-term health or whether the lack of nutritional value is within the knowledge of a reasonable customer.[3] Evidence has shown that Americans are overweight and obese and becoming more so over time.[4] There is no doubt that being overweight costs Americans both in money and in life span.[5] However, much can be done to increase the awareness level and education of the American people. The federal agency in charge of food safety and regulation, the Food and Drug Administration (FDA), is aware of the importance of this issue and recently held a forum on obesity, stating in the public notices that: "[h]elping

1. *See* Pelman v. McDonald's Corp., 237 F. Supp. 2d 512 (S.D.N.Y. 2003). In *Pelman*, parents brought an action on behalf of children against a fast-food corporation, alleging negligence and violations of state consumer protections laws in connection with children's over-consumption of fast-food products. *Id. See also* Geraldine Sealy, *Whopper of a Lawsuit: Fast-Food Chains Blamed for Obesity, Illnesses* (July 26, 2003), *at* http://www.abcnews.com. Sealy's article provides information about another lawsuit that was filed in New York by Caesar Barber, 56, who weighs 270 pounds, claiming that McDonald's, Burger King, Wendy's, and KFC jeopardized his health with greasy and salty food. *Id.* He stated in an interview, "[t]hey never explained to me what I was eating." *Id.*

2. "It is well-known that fast food in general . . . contain[s] high levels of cholesterol, fat, salt, and sugar, and that such attributes are bad for one." *Pelman*, 237 F. Supp. 2d. at 532.

3. *See id.* at 535. The plaintiffs argued that products are so altered that their unhealthy qualities are outside the knowledge of reasonable consumers by stating that ingredient lists show products contain many more additives and ingredients than an average person would consider. *Id.*

4. *See, e.g.*, Ali H. Mokdad et al., *The Spread of the Obesity Epidemic in the United States, 1991–1998*, 282 JAMA 1519 (1999); JK Binkley et al., *The Relation Between Dietary Change and Rising US Obesity*, 24 INT'L J. OBESITY 1032 (2000).

5. For evidence that obesity and overweight deaths are second only to cigarette smoking and that total costs attributed in 2000 amounted to $117 billion, see Press Release, U.S. Department of Health and Human Services, Overweight and Obesity Threaten U.S. Health Gains (Dec. 13, 2001*), available at* http://www.hhs.gov/news/press/2001pres/20011213.html [hereinafter Press Release].

consumers improve their diets is one of the nation's most pressing public health problems and an increasingly urgent part of FDA's activities. The consequences of poor diets . . . are endangering and diminishing the lives of millions of Americans."[6]

The best way to resolve the increasing litigation against fast-food restaurants is for the FDA to promulgate uniform regulations in this area. A reasonable amount of regulation could save the industry in legal fees and the consumer in health. This comment analyzes whether the FDA has authority over fast-food restaurants to require the industry either to label products with nutrition facts or to provide a warning to customers of the health consequences of consuming their products. Once fast-food regulations are uniform around the country, both the consumer and the industry will be protected, albeit in different ways.

A. The Problem of Obesity in America

In 2001, Department of Health and Human Services Secretary Tommy G. Thompson stated, "[o]verweight and obesity are among the most pressing new health challenges we face today."[7] Estimating that in 2002 obesity deaths were second only to tobacco related deaths, with 300,000 deaths annually, Surgeon General David Satcher gave a similar warning, stating, "[o]verweight and obesity may soon cause as much preventable disease and death as cigarette smoking."[8] In 2003, an estimated sixty-six percent of American adults were overweight or obese.[9] Data from the Centers for Disease Control and Prevention, "shows that 13 percent of children aged 6 to 11 are overweight—almost double the rate of two decades ago."[10] Trend data estimates that the percentage of persons classified as obese has increased "in every state, in both sexes, and across all age groups, races, educational levels, and smoking

6. Food and Drug Administration Obesity Working Group; Public Meeting Notice, 68 Fed. Reg. 58,117, 58,118 (Oct. 8, 2003) [hereinafter Meeting Notice]. Additionally, Congress has found that "there is a growing need for emphasis on the dissemination of information linking nutrition and long-term good health." Dietary Supplement Health and Education Act of 1994, Pub. L. No. 103-417, § 2(7), 108 Stat. 4325, 4326 (1994).

7. Press Release, *supra* note 5.

8. *Id*. The National Cancer Institute clarifies the difference between these terms defining obesity as different from being overweight. Overweight people tend to have excess body weight, which can come from fat, muscle, bone, and/or water retention. "People who are obese have an abnormally high and unhealthy proportion of body fat." National Cancer Institute, Obesity and Cancer: Questions and Answers (Mar. 16, 2004), *at* http://cis.nci.nih.gov/fact/3_70.htm.

9. Meeting Notice, *supra* note 6, at 58,117 (additionally stating that the number of adult Americans that suffered from obesity rose from less than twenty-three percent in 1992 to more than thirty percent in 1999–2000). *See also* Pelman v. McDonald's Corp., 237 F. Supp. 2d 512, 519 (S.D.N.Y. 2003) (estimating that in 1999, sixty-one percent of adults in the United States were overweight or obese).

10. Meeting Notice, *supra* note 6, at 58,117.

statuses. Rarely do chronic conditions such as obesity spread with the speed and dispersion characteristic of a communicable disease epidemic."[11] This yearly increase in the percentage of adults who are overweight began as early as 1960.[12] Furthermore, economic costs attributed to the problems related to being obese or overweight equaled $117 billion in the year 2000, suggesting weight-related expenditures account for nearly seven percent of United States health-care costs.[13] Overweight or obese people have an increased risk for coronary heart disease, type 2 diabetes, several types of cancers, and musculoskeletal disorders.[14]

Several theories exist to explain this continuing rise in overweight and obese Americans. One theory is that an increase in food eaten away from the home has occurred, especially fast food, which has contributed to the obesity and overweight problem.[15] Between 1980 and 1995, money spent in fast-food restaurants nearly doubled.[16] One author notes that Americans now spend more than $110 billion on fast food each year, and on any given day in the United States, almost one in four adults visits a fast-food restaurant.[17] One study, published in the International Journal of Obesity, concluded that trends in increased United States obesity and in increased consumption of food eaten away from home "are unlikely to be coincidental."[18] Food eaten away from home, and particularly fast-food consumption, are likely to be contributing factors to increased obesity.[19] Whatever the cause of obesity, the fact remains it has reached a hazardous level in the United States. A recent phenomenon of

11. Mokdad et al., *supra* note 4, at 1520. *See also* Katherine M. Flegal et al., *Prevalence and Trends in Obesity Among US Adults, 1999–2000*, 288 JAMA 1723, 1724 (2002) (finding that racial groups did not differ significantly in the existence of obesity or overweight for men, but that non-Hispanic black women had the highest prevalence among women).

12. Binkley et al., *supra* note 4, at 1032.

13. Press Release, *supra* note 5. *See* Meeting Notice, *supra* note 6 ("[*A*]*voidable* medical costs of obesity exceed $50 billion each year . . . .") (emphasis added); *see also* Mokdad et al., *supra* note 4, at 1519.

14. *Pelman*, 237 F. Supp. 2d at 520. *See* Dietary Supplement Health and Education Act of 1994, Pub. L. No. 103-417, § 2(4), 108 Stat. 4325, 4326 (1994) (finding that "healthful diets may mitigate the need for expensive medical procedures, such as coronary bypass surgery or angioplasty").

15. Binkley et al., *supra* note 4, at 1033.

16. *Id*.

17. ERIC SCHLOSSER, FAST FOOD NATION 3 (2001). Additionally, "[e]very month about 90 percent of American children between the ages of three and nine visit a McDonald's." *Id*. at 47.

18. Binkley et al., *supra* note 4, at 1032.

19. *See id*. at 1035 (finding that eating at fast food outlets significantly increased the body mass index for both males and females); *see also* Jane Brody, *We Need to Get Serious About Fighting Fat*, ST. LOUIS POST-DISPATCH, Jan. 26, 2004, at HF6 (noting a recent national study by the Agriculture Department and Harvard Medical School that found thirty percent of people surveyed ate fast food on a typical day and consumed 187 more calories, nine more grams of fat, and less fiber, fruits, and non-starchy vegetables than those who did not eat fast food that day).

fast-food litigation brought forth by obese consumers has demonstrated the beginning of a public movement to reverse this dangerous path.

This Comment will argue that the FDA has the legal authority to require fast-food restaurants to provide nutritional information or a warning to consumers. Part II will provide a background of the recent phenomena of consumers suing fast-food restaurants for obesity-related health problems and what action Congress has taken. Plaintiffs have brought forth several legal theories in an attempt to convince the justice system that the fast-food industry has broken the law. These theories include negligence, the claim that fast food is inherently dangerous, the failure of restaurants to warn of unhealthy attributes, and the addictive nature of fast food. The subsequent two Parts will provide a detailed analysis of whether the FDA has jurisdiction over fast-food restaurants and the extent of regulation that is permissible under the law. In Part V, there will be a critique of the rationale for regulating fast-food restaurants, focusing on whether it would benefit the American public and result in a reduction of the obesity epidemic.

II. PLAINTIFFS WAGE WAR AGAINST FAST-FOOD RESTAURANTS

Citizen actions blaming fast-food restaurants for obesity-related health problems have presented challenging issues for the courts because they include questions of personal responsibility, knowledge, public health, and the role of courts and society in addressing these types of problems. Consumers are beginning to seek relief for these injuries, but is that relief available through the tort system? The majority of "McLawsuits" have not made it far in the process and have been dismissed in the early stages, usually for a lack of specificity and failure to show proximate cause.[20] In one case, *Pelman v. McDonald's Corporation*, the judge found a lack of probable cause. Citing a failure to specify how often the plaintiffs ate at McDonald's, the *Pelman* court concluded that other factors could have affected the plaintiffs' weight and health.[21] The plaintiffs in this lawsuit presented several legal theories on which McDonald's should be held liable, including violation of consumer

20. Pelman v. McDonald's Corp., 237 F. Supp. 2d 512 (S.D.N.Y. 2003); *see also* Jonathan Wald, *Lawyers Revise Obesity Lawsuit Against McDonald's* (Feb. 21, 2003), *at* http://www.cnn.com/2003/LAW/02/21/obesity.lawsuit.

> Lawyers . . . couldn't get a federal judge to bite on their claims that McDonald's food was responsible for making their clients fat . . . . The original complaint was dismissed . . . by U.S. District Court Judge Robert Sweet, who said plaintiffs failed to show that McDonald's food was 'dangerous in any way other than that which was open and obvious to a reasonable consumer.'

21. *Pelman*, 237 F. Supp. 2d at 538. In the opinion, the judge stated that the potential for this type of lawsuit is great and that "the Court is cognizant of its duty 'to limit the legal consequences of wrongs to a controllable degree and to protect against crushing exposure to liability.'" *Id.* at 518 (quoting McCarthy v. Olin Corp., 119 F.3d 148, 157 (2d Cir. 1997)).

protection laws and negligence.[22] The following sections will discuss several of these theories in detail. First is an analysis of whether fast food is inherently dangerous, followed by a discussion of whether McDonald's had a duty to warn, and concluding with a brief examination on the alleged addictive nature of fast food.

1. Is Fast Food Dangerous?

One theory that is appearing in these "McLawsuits" is that fast food is "inherently dangerous."[23] In *Pelman*, the plaintiffs alleged that McDonald's owed them a duty because the dangers of the McDonalds' products were not within their common knowledge.[24] McDonald's argued it should not be held liable because the public is aware that fast food, like hamburgers and French fries, include high levels of certain ingredients, such as fat and sugar.[25] Additionally, McDonald's cited the *Restatement (Second) of Torts* claiming that the plaintiffs faced an extremely high standard of proof because their claims rested on injuries "resulting from excessive consumption of food."[26] McDonald's argued that any food involves some risk and that plaintiffs would need to demonstrate "[t]he article sold [is] dangerous to an extent beyond that which would be contemplated by the ordinary consumer who purchases it, with the ordinary knowledge common to the community as to its characteristics."[27] The court noted that the Restatement includes tobacco as a product, which even if over-consumed would not lead to liability; however, as successful tobacco litigation has shown, "the fact that excessive smoking was known to lead to health problems did not vitiate liability."[28] Recognition by the court of the paradox witnessed in tobacco litigation demonstrates that the door may not be completely shut on tort remedies for obese plaintiffs.

In *Pelman*, the court noted that to state a claim, the plaintiffs must allege that the products sold by McDonald's "are so extraordinarily unhealthy that they are outside the reasonable contemplation of the consuming public or that the products are so extraordinarily unhealthy as to be dangerous in their intended use."[29] The judge further contended, "[n]obody is forced to eat at McDonalds. . . . Even more pertinent, nobody is forced to supersize their meal

22. *Pelman*, 237 F. Supp. 2d at 516, 530.

23. *Id*. at 531 (alleging that "McDonalds' products are inherently dangerous because of the inclusion of high levels of cholesterol, fat, salt and sugar").

24. *Id*.

25. *Id*.

26. *Id*. at 531.

27. *Pelman*, 237 F. Supp. 2d at 531 (citing RESTATEMENT (SECOND) OF TORTS § 402A, cmt. i (1965)).

28. *Id.* at 532.

29. *Id*. (stating it is a known fact that fast food in general contains attributes that are bad).

or choose less healthy options on the menu."[30] However, the plaintiffs asserted that the products served by McDonald's have been so altered that the food's unhealthy character is outside the knowledge of the average consumer.[31] This argument was the subject of a controversy several years ago, when many angry vegetarians learned that McDonald's French fries contained a beef ingredient, as well as more saturated beef fat per ounce than a hamburger.[32] Ultimately in *Pelman*, the judge found "the Complaint fail[ed] to allege that the danger of the McDonalds' products were not well-known."[33] The court contemplated that McDonald's would owe a duty to its consumers and be subject to liability, if the dangers of these products were not commonly well-known.[34]

2. "Nobody told us fast food is unhealthy!"

Beyond claiming fast food is inherently dangerous, the plaintiffs in *Pelman* also tried to prove liability by alleging that McDonald's failed to warn of the unhealthy attributes of its products.[35] McDonald's again contended that the dangers of its products were known and that plaintiffs did not establish proximate cause.[36] The determination of whether an adequate warning is given is "often interwoven with the question of whether the defendant manufacturer has a duty to warn, and, if so, to whom that duty is owed."[37] One court has stated that, "a manufacturer may be liable for failing to warn against the dangers of foreseeable misuse of its product."[38] However, the *Restatement (Second) of Torts* states:

> [A] seller is not required to warn with respect to products, or ingredients in them, which are only dangerous, or potentially so, when consumed in excessive quantity, or over a long period of time, when the danger, or potentiality of danger, is generally known and recognized.[39]

30. *Id*. at 533.

31. *Id*. at 535 (contending that the average consumer would not know Chicken McNuggets actually contain twice the amount of fat per ounce as a hamburger).

32. Herbert G. McCann, *McDonald's Apologizes for Selling Fries with Beef Flavoring as Vegetarian*, *available at* http://www.mindfully.org/Food/McDonalds-Apologizes-Hindu5jun02.htm. *See also* Sealey, *supra* note 1 ("A similar lawsuit was filed against Pizza Hut for allegedly using beef fat in its Veggie Lovers' Pizza.").

33. *Pelman*, 237 F. Supp. 2d at 539–40.

34. *Id*. at 536. *See also* SCHLOSSER, *supra* note 17, at 121.

35. *Pelman*, 237 F. Supp. 2d at 540.

36. *Id*.

37. Cooley v. Carter-Wallace, Inc., 478 N.Y.S.2d 375, 376 (N.Y. App. Div. 1984). *See also* Andrulonis v. United States, 924 F.2d 1210, 1222 (2d Cir. 1991) (stating that a manufacturer would not be liable if risks were sufficiently obvious: "[t]he danger must be so apparent or so clearly within common knowledge that a user would appreciate the danger to the same extent that a warning would provide").

38. Liriano v. Hobart Corp., 700 N.E.2d 303, 307 (N.Y. 1998) (citations omitted).

39. RESTATEMENT (SECOND) OF TORTS § 402A cmt. j (1965).

The *Pelman* court held that the complaint failed to allege that the products consumed at McDonald's restaurants were dangerous "in any way other than that which was open and obvious to a reasonable consumer."[40] The judge further noted that the plaintiffs failed to allege that McDonald's had information that its products were more dangerous than a reasonable customer would expect.[41]

3. Addiction

A final attempt for finding fault with the McDonald's Corporation was the plaintiffs' allegation that McDonald's products are inherently dangerous because they are addictive.[42] The complaint did not specify what exactly is addictive, whether it is the combination of fats and sugars or some other additive that may work in the same manner as nicotine to induce addiction.[43] Researchers are currently investigating this exact hypothesis, that is, "whether large amounts of fat in combination with sugar can trigger a craving similar to addiction."[44] This finding would have some insight into explaining the fact that fast-food sales have climbed to more than $100 billion per year in the United States.[45]

At this point, *Pelman*, in addition to a handful of other lawsuits, seems to be an anomaly. However, plaintiffs have demonstrated a movement to find someone or something at fault for what has grown to be an American epidemic.[46] Laws are created in order to protect citizens when they are unable to protect themselves, but how far should society's responsibility extend? Regarding food and drink, Congress mandated that "all packaged foods sold at retail shall be appropriately labeled and have their contents described."[47] In addition, alcoholic beverages and cigarette labels must bear warning labels. The Nutrition Labeling and Education Act of 1990 (NLEA), which

40. *Pelman*, 237 F. Supp. 2d at 541.

41. *Id*. at 523. "[I]n order to state a claim, the Complaint must allege either that the attributes of McDonalds products are so extraordinarily unhealthy that they are outside the reasonable contemplation of the consuming public or that the products are so extraordinarily unhealthy as to be dangerous in their intended use." *Id.* at 532.

42. *Id*. at 542.

43. *Id*. (stating further that the complaint did not specify how often one would need to eat at McDonalds to become addicted).

44. *Id*. (quoting Sarah Avery, *Is Big Fat the Next Big Tobacco?*, RALEIGH NEWS & OBSERVER, Aug. 18, 2002, at 25A).

45. *Pelman*, 237 F. Supp. 2d at 542.

46. *See* Brody, *supra* note 19, at HF6 ("The recent suits by obese youngsters against McDonald's may sound laughable . . . . But the negative publicity that the suits attract to the company's high-calorie offerings may help others stop eating them before they, too, balloon into obesity.").

47. *Pelman*, 237 F. Supp. 2d at 516. *See also* Nutrition Labeling and Education Act of 1990, Pub. L. No. 101-535, 104 Stat. 2353 (1990) (codified in part at 21 U.S.C. § 343 (2000)).

standardized packaged food labels, "sought 'to ensure that consumers have access to information about food that is scientifically valid, truthful, reliable, understandable and not misleading. This information will enable consumers to make more healthful food choices.'"[48] If the NLEA was, in fact, an attempt to ensure that consumers have information regarding their food choices, then why was fast food, a large part of the food industry, left out? While these lawsuits continue to be brought to court, Congress is attempting to ban obesity related litigation that is costing the court system and the fast-food industry considerable time and money.

B. Legislative Reaction to Obesity Lawsuits

"McLawsuits" have received a great deal of negative publicity. Many feel that the plaintiffs should take personal responsibility for their actions and not attempt to blame the industry.[49] If a set of plaintiffs prevail in an obesity lawsuit, the floodgates of products liability litigation may open.[50] "If successful, fast-food suits could spawn attacks on other products and industries. Like Big Macs, many of the things that people enjoy consuming, if abused or over-used, can be dangerous and bad for our health: alcohol, fast cars, and television, for example."[51] In anticipation of this possibility, Congress passed two pieces of legislation in 2003 to stop these lawsuits. Senator Mitch McConnell (R-KY) presented the "Commonsense Consumption Act of 2003,"[52] and Representative Ric Keller (R-FL) presented the "Personal Responsibility in Food Consumption Act,"[53] both of which ban obesity-related lawsuits against the food industry. Representative Keller states:

> The gist of the legislation is that there should be common sense in a food court not blaming people in a legal court whenever there is an excessive consumption of fast food. Most people have enough common sense to realize

48. *Pelman*, 237 F. Supp. 2d at 517 n.1 (quoting Marilyn J. Schramm, *Constitutional Protection of Commercial Speech Under the* Central Hudson *Test as Applied to Health Claims*, 51 FOOD & DRUG L.J. 323, 328 (1996)).

49. *See* Lydia Saad, *Public Balks at Obesity Lawsuits*, The Gallop Organization (July 21, 2003), *available at* http://www.gallup.com/content/login.aspx?ci=8869 (finding the majority of those surveyed believe the fast food industry should not be held liable).

50. Kevin P. Allen, *Litigating Against Guilty Pleasures*, 5 LAW. J. 6 (2003).

51. *Id.* "[T]he more troubling aspect of the *Pelman* action and other fast-food lawsuits like it, is the risk that those suits, carried to their ultimate conclusion, present not only to life's guilty pleasures but also to the opportunity to resist those temptations." *Id.*

52. S. 1428, 108th Cong. (2003) ("To prohibit civil liability actions from being brought or continued against food manufacturers, marketers, distributors, advertisers, sellers, and trade associations for damages or injunctive relief for claims of injury resulting from a person's weight gain, obesity, or any health condition related to weight gain or obesity").

53. H.R. 339, 108th Cong. (2003) ("To prevent frivolous lawsuits against the manufacturers, distributors, or sellers of food or non-alcoholic beverage products that comply with applicable statutory and regulatory requirements").

> if they eat an unlimited amount of super size fries, cheeseburgers, milk shakes and chocolate sundaes, it may lead to obesity. In a country like the United States, where freedom of choice is cherished, nobody is forced to super size their fast food meals or choose less healthy options on the menu.[54]

Testifying in support of the bill at the hearing for the Common Sense Consumption Act was Dr. Gerard J. Musante, a clinical psychologist dedicated to fighting obesity. He stated, "Congress has rightly recognized the danger of allowing Americans to continue blaming others for the obesity epidemic. . . . The fact that we are addressing the issue here today is a step in the right direction. No industry is to blame and none should be charged with solving America's obesity problem."[55] Finally, most Americans appear to support this effort to stop obesity-related lawsuits.[56] The public seems to believe that failure to take personal responsibility is the culprit for the current state of American obesity.

But not all those testifying at the Congressional hearings supported the new legislation. John H. Banzhaf, III, a lawyer who has filed fast-food lawsuits, recognized that consumers do not receive enough information about their food, claiming that even "healthy" fast-food restaurants can be deceiving. He quoted a *Wall Street Journal* article that stated, "[w]hile the restaurant chains don't make any specific claims about the healthfulness or calorie content of their menu items, they nonetheless give consumers the impression

54. *Personal Responsibility in Food Consumption Act: Hearing on H.R. 339 Before the Subcomm. on Commercial and Admin. Law of the House Comm. on the Judiciary*, 108th Cong. 14 (2003) (statement of Rep. Keller, Member, House Comm. on the Judiciary), *available at* http://commdocs.house.gov/committees/judiciary/hju87814.000/hju87814_0.htm [hereinafter *Hearing on H.R. 339*].

55. *Common Sense Consumption: Super- Sizing Versus Personal Responsibility: Hearing on S. 1428 Before the Subcomm. on Admin. Oversight and the Courts of the Senate Comm. on the Judiciary*, 108th Cong. (2003) (statement of Dr. Gerard Musante, Founder, Structure House). Dr. Musante further explained his solution to the obesity problem by stating:

> Instead of squandering resources and defending needless lawsuits by pointing fingers, let us make everyone part of the solution. Let us encourage a national obesity summit where all the players are asked to come to the table and pledge their considerable resources towards creating a national mindset aimed at solving this problem. That would be in the interest of the American people.

Id.

56. Saad, *supra* note 49.

> Americans seem inclined to back the efforts of U.S. Sen. Mitch McConnell, who is leading the congressional charge to thwart obesity lawsuits against the food industry. According to a new Gallup Poll, nearly 9 in 10 Americans oppose the idea of holding fast-food companies legally responsible for the diet-related health problems of fast-food junkies.

Id.

that they are offering healthier food. . . . But consumers are being fooled."[57] In addition to suggesting alternatives to this legislation, Banzhaf stated, "[f]or all of these and other reasons, it is respectfully suggested that it is premature—if not presumptuous and preposterous—for Congress at this time to conclude that the one weapon against the war on obesity which appears to be having an impact should be eliminated."[58] Banzhaf suggested a variety of actions that could be taken by Congress before granting blanket immunity to the industry:

> Require that all fast food restaurants display information about the calories and fat in their menu items at the point of purchase when patrons are considering their choices while standing on [sic] line, not buried on a web site or on a hard-to find pamphlet or back wall. Several state bills to require this have been introduced, and Congressional action would avoid confusion due to lack of uniformity. [Or] [r]equire that all fast food restaurants provide appropriate warnings about the danger of eating fattening fast food too often.[59]

In conclusion, Banzhaf emphasized that these actions could be an alternative to litigation: "Should the fast food restaurants do these things—either voluntarily or as a result of uniform legislation—it would appear that they would largely insulate themselves from potential liability. This is a far better approach than simply granting them unearned immunity."[60]

While obesity litigation has gained the attention of Congress and the nation, these legislative responses have been insufficient. By passing laws preventing obesity lawsuits, Congress is conveying that no regulation of the industry is necessary and that stopping litigation is a solution. However, this "solution" does nothing to address the serious health problems that result from over-consumption of fast food. Congress appears to be siding with the fast-food industry by pre-empting lawsuits rather than supporting the consumer. The health issues must be addressed, which is why uniform FDA regulation of the industry is needed. The following section will prove that if it can be shown that fast food is adulterated and misbranded under the Food, Drug, and Cosmetic Act, the FDA does have authority to regulate the fast-food industry.

57. *Hearing on H.R. 339*, *supra* note 54, at 26 (statement of John Banzhaf, III) (citing Tara Parker-Pope, *That Veggie Wrap You Just Chowed Down is More Fattening than a Ham Sandwich*, WALL ST. J., Jan. 14, 2003, at D1). The article continued by stating, "making the healthy choice can be tough. Most restaurants don't display nutrition information inside the restaurant, and the menu offerings often are deceptive. . . . Nutritionists argue that calorie information should be available at the ordering counter." *Id*.

58. *Hearing on H.R. 339*, *supra* note 54, at 29 (statement of John Banzhaf, III). Banzhaf's suggestions to Congress, similar to those raised in this comment, regard other possibilities of how to regulate in this area. *Id.* at 29–30.

59. *Id*. at 30 (stating that PepsiCo has promised to provide warnings and McDonald's is doing something similar in France). Other suggestions included requiring all fast-food restaurants to provide nutritious alternative food choices for people who want to avoid the many fattening choices but because of convenience are forced to eat at fast-food establishments. *Id*.

60. *Id*. at 31.

III. DOES CURRENT LAW GIVE THE FDA JURISDICTION?

For the FDA to regulate the fast-food industry, the FDA must demonstrate legal jurisdiction. Given that the federal Food, Drug, and Cosmetic Act prohibits introducing adulterated or misbranded food into interstate commerce, to prove jurisdiction the FDA must show that fast-food restaurants serve food that has traveled in interstate commerce.[61]

A. Fast-Food Restaurants Serve "Food" as Defined by the Food, Drug, and Cosmetic Act

"Food" under the statutory definition includes, but is not limited to, the following products served in fast-food restaurants: hamburgers, chicken sandwiches, chicken nuggets, French fries, salads, ice cream, pie, cookies, and soda. The Food, Drug, and Cosmetic Act defines "food" to mean: "(1) articles used for food or drink for man or other animals, (2) chewing gum, and (3) articles used for components of any such article."[62] In fact, a "common-sense" standard prevails due to the absence of clear congressional guidance. One court has stated:

> [I]t is best to rely on statutory language and common sense. . . . The statutory definition of "food" in Section 321(f) is a term of art and is clearly intended to be broader than the common-sense definition of food . . . . Yet the statutory definition of "food" also includes in Section 321(f)(1) the common-sense definition of food. When the statute defines "food" as "articles used for food," it means that the statutory definition of "food" includes articles used by people in the ordinary way most people use food—primarily for taste, aroma, or nutritive value.[63]

The statutory definition is broad, and the previous list of foods, as well as any other item sold for consumption at a fast-food restaurant, certainly would fall under its scope as common-sense types of food.[64]

In addition, for purposes of the current analysis, food and food additives should be considered interchangeable. The statute defines food additives, which must be tested for safety, but also creates subcategories of different constituents, as well as exemptions for large classes of ingredients.[65] The

61. 21 U.S.C. § 331(a) (2000). Title 21 of the United States Code contains the Food, Drug, and Cosmetic Act, which is the main legislation regulating the food, drug, and cosmetic industries.

62. 21 U.S.C. § 321(f) (2000).

63. Nutrilab, Inc. v. Schweiker, 713 F.2d 335, 337–38 (7th Cir. 1983).

64. *See* United States v. O.F. Bayer & Co., 188 F.2d 555, 557 (2d Cir. 1951) (finding that because it is "common knowledge that green coffee beans are used to produce the roasted coffee beans. . . . [n]o evidence is necessary to establish that green coffee beans are a 'food' as defined by the statute").

65. 21 U.S.C. § 321(s) (2000). *See also* Richard A. Merrill, *Regulating Carcinogens in Food: A Legislator's Guide to the Food Safety Provisions of the Federal Food, Drug, and*

definition of a "food additive," including both artificial and natural substances, is "any substance the intended use of which results or may reasonably be expected to result, directly or indirectly, in its becoming a component or otherwise affecting the characteristics of any food []including any substance intended for use in producing [or] manufacturing."[66] The Food, Drug, and Cosmetic Act and the Food and Drug Administration Act grant the FDA the ability to regulate these food additives,[67] giving the FDA authority over *any* food product served at a fast food restaurant.

B. The FDA Can Regulate Adulterated or Misbranded Food Traveling in Interstate Commerce

The United States Constitution gives Congress the authority to regulate interstate commerce.[68] In turn, through the passage of the Food, Drug, and Cosmetic Act and the Food and Drug Administration Act,[69] Congress has granted the FDA authority to regulate food, drugs, and cosmetics that travel within interstate commerce so "that the public health and safety might be advanced . . . [and] to keep interstate channels free from deleterious, adulterated and misbranded articles of the specified types."[70] Section 331 of the Food, Drug, and Cosmetic Act provides that the following acts are prohibited: "[t]he introduction or delivery for introduction into interstate commerce of any food, drug, device, or cosmetic that is adulterated or misbranded . . . [and] [t]he receipt in interstate commerce of any food . . . that

Cosmetic Act, 77 MICH. L. REV. 171, 203–04 (1979). The exemptions are for ingredients that are "generally recognized as safe" by qualified experts. *Id*. at 204. Any food additive not generally recognized as safe must be shown to not adversely affect the health of consumers when used as intended. *Id*. Moreover, any food additive shown to induce cancer in animals or humans is prohibited. *Id*. The FDA requires any direct additive being used at high levels be tested for cancer through long-term animal feeding studies. *Id*. at 206.

66. 21 U.S.C. § 321(s). The FDA conditions its approval of food additives to assure safety and may "establish a regulation . . . prescribing, with respect to one or more proposed uses of the food additive involved, the conditions under which such additive may be safely used." This includes particular foods in which the additive may be used, the maximum quantity allowed, and any directions or other labeling requirements to assure consumer safety. 21 U.S.C. § 348(c)(1)(A) (2000).

67. The Food, Drug, and Cosmetic Act grants regulatory power to the Department of Health and Human Services, and the FDA is an enforcement agency within the Department. 21 U.S.C. §§ 348(c)(1)(A), 393(a)–(b) (2000). In some instances the FDA has used its authority under the food additives provision to force labeling requirements for finished foods that include the additive in its ingredients. *See* Merrill, *supra* note 65, at 206. For an example, see 21 C.F.R. § 172.110(c)(1) (2004).

68. U.S. CONST. art. I, § 8, cl. 3. "The Congress shall have power . . . [t]o regulate Commerce with foreign Nations, and among the several States, and with the Indian Tribes . . . ."

69. 21 U.S.C. §§ 348(c)(1)(A), 393(a)–(b) (2000).

70. United States v. Walsh, 331 U.S. 432, 434 (1947).

is adulterated or misbranded."[71] Congress designed the Food, Drug, and Cosmetic Act in part to ensure that the food we eat is safe, and to do this, the FDA may prohibit food that is misbranded or adulterated from entering interstate commerce.[72] Interstate commerce is defined in the statute as "(1) commerce between any State or Territory and any place outside thereof, and (2) commerce within the District of Columbia or within any other Territory not organized with a legislative body."[73] Courts have held that the "'shipment in interstate commerce' requirement is satisfied when adulterated articles held for in-state sale contain ingredients shipped in interstate commerce."[74]

In *United States v. An Article of Food*, it was argued that beverages seized in Puerto Rico were not subject to forfeiture because they were only going to be sold in Puerto Rico and not shipped in interstate commerce.[75] The court held that the items were properly seized because they contained an additive shipped in interstate commerce, based on the statutory language that provides: "[a]ny article of food . . . that is adulterated . . . when introduced into or while in interstate commerce *or while held for sale . . . after shipment in interstate commerce* . . . shall be liable to be proceeded against while in interstate commerce, or at any time thereafter . . . ."[76]

In another example, *United States v. 40 Cases*, blended oils were seized for allegedly being misbranded or adulterated under the Food, Drug, and Cosmetic Act.[77] The defendant argued that, although the variety of oils had been separately shipped in interstate commerce, the blended product existed in a completely different container and that the processing created a new product that was removed from federal regulation.[78] The court disagreed with these theories, relying on congressional legislation that subjected to condemnation "food which had been adulterated or misbranded after coming to rest within a

71. 21 U.S.C. § 331(a)–(c) (2000).

72. *See* Timothy K. Gilman & Brian R. McCormick, *Federal Food and Drug Act Violations*, 38 AM. CRIM. L. REV. 819, 820, 823 (2001); *see* Les v. Reilly, 968 F.2d 985, 986 (9th Cir. 1992).

73. 21 U.S.C. § 321(b) (2000).

74. United States v. An Article of Food . . . "Manischewitz . . . Diet Thins," 752 F.2d 11, 14 (1st Cir. 1985) (citing United States v. Dianovin Pharms., Inc., 475 F.2d 100, 102–03 (1st Cir. 1973)). *See infra* note 76 and accompanying text; s*ee also* Baker v. United States, 932 F.2d 813, 814 (9th Cir. 1991) ("[T]he 'shipment in interstate commerce' requirement [of the Food, Drug, and Cosmetic Act] is satisfied even when only [one] ingredient [used in the final product] is transported interstate.").

75. *An Article of Food*, 752 F.2d at 14.

76. *Id*. (quoting 21 U.S.C. § 334(a)(1) (2000)).

77. United States v. 40 Cases, 289 F.2d 343, 344 (2d Cir. 1961).

78. *Id*. at 345 (arguing that the new product "was not the same as the food transported in interstate commerce and therefore could not be seized as food held for sale after shipment in interstate commerce").

state but before being sold to a consumer."[79] Additionally, the court noted that the oil blend was created by components, all of which had been transported in interstate commerce.[80] In citing the Supreme Court, the opinion concluded that "Congress surely intended the provisions of the Food, Drug, and Cosmetic Act to apply to foods processed within a state, after shipment in interstate commerce, as was the case here. The statute must be read and applied broadly in order to effectuate its remedial purpose."[81]

An Article of Food and *40 Cases* both represent the notion that final products are not the only foods that can be regulated; rather, any food that has components that have traveled in interstate commerce falls within the statute.[82] The foods sold in fast-food restaurants travel between states, in interstate commerce, and therefore may be regulated by the FDA.[83] The majority of fast-food restaurant menus include hamburgers, French fries (or some other potato product), chicken, salads, cheese, and dairy products.[84] Presumably, the thousands of fast-food restaurants across the nation receive their products from various areas of the country through interstate commerce.[85] Therefore, the final "food" products sold to customers in fast-food chains fall within the jurisdiction of the Food, Drug, and Cosmetic Act and are subject to the regulations provided there. In addition to having the legal authority to regulate fast-food restaurants under the Food, Drug, and Cosmetic Act, the FDA should have a sincere interest in regulation to ensure that all consumers receive safe and healthy products. The following section will address the individual theories under which the FDA could regulate fast-food restaurants, as well as which actions are precluded under current law.

79. *Id*. ("[*E*]*nsuring* that such food meets minimum standards of purity and is not misbranded arises out of [Congress'] supervisory function over interstate commerce.") (emphasis added).

80. *Id*.

81. *Id*. at 346 (citing Kordel v. United States, 335 U.S. 345, 349 (1948)).

82. *See* United States v. An Article of Food, 752 F.2d 11, 14 (1st Cir. 1985); *see also 40 Cases*, 289 F.2d at 345–46.

83. *See* Pelman v. McDonald's Corp., 237 F. Supp. 2d 512, 523 (S.D.N.Y. 2003); *see supra* notes 67–70 and accompanying text. The *Pelman* opinion discusses the fact that a McDonald's Big Mac is the same at every outlet throughout the nation and the issue involves a national menu, leading to the conclusion that McDonald's Corporation ships ingredients throughout the fifty states. 237 F. Supp. 2d at 523.

84. For examples of other fast-food restaurants, see the menus from Burger King (http://www.bk.com/Food/index.aspx), Wendy's (http://www.wendys.com/food/Menu.jsp), and Taco Bell (http://www.tacobell.com/menu).

85. McDonald's states: "[O]n any given day, we proudly serve more than 46 million customers, in different countries from more than 30,000 different restaurant locations." *See* McDonald's Corp., McDonald's Means Food Quality, *at* http://www.mcdonalds.com/content/usa/eat/quality0.html (stating that products are shipped interstate and internationally to reach all of these locations).

IV. FAST-FOOD REGULATION: WHAT CAN THE FDA DO?

The FDA does, in fact, have jurisdiction over fast-food restaurants, but in what context? As will be discussed later in this comment, the Food, Drug, and Cosmetic Act has exempted restaurants from being required to label foods with nutritional content information.[86] However, there are alternative regulations that, if found to be violated by fast-food restaurants, give the FDA the power to regulate. Specifically, section 331 of the Food, Drug, and Cosmetic Act defines prohibited acts as:

> (a) The introduction or delivery for introduction into interstate commerce of any food, drug, device, or cosmetic that is adulterated or misbranded.
>
> (b) The adulteration or misbranding of any food, drug, device, or cosmetic in interstate commerce.
>
> (c) The receipt in interstate commerce of any food, drug, device, or cosmetic that is adulterated or misbranded . . . .[87]

If any of the foods served at fast-food restaurants are adulterated or misbranded, then under the Food, Drug, and Cosmetic Act, the FDA clearly has the right to take action. Section 334 states:

> Any article of food, drug, or cosmetic that is adulterated or misbranded when introduced into or while in interstate commerce or while held for sale . . . after shipment in interstate commerce . . . shall be liable to be proceeded against while in interstate commerce, or at any time thereafter, on libel of information and condemned . . . within the jurisdiction of which the article is found.[88]

Further, a misbranded or adulterated article under this section is subject to seizure.[89] The remaining sections will address the possibilities of classifying fast food as adulterated or misbranded within the Food, Drug, and Cosmetic Act. The next section will address whether fast food is adulterated. More specifically, is it considered a "deleterious substance" within the statutory definition? This will be followed by a discussion on food labeling and an influential provision added to the Food, Drug, and Cosmetic Act due to food safety concerns. The following section will analyze whether fast food may be misbranded. In conclusion, there will be a critical examination of what steps some fast food restaurants are currently taking in response to the growing concern over the obesity problem.

86. 21 U.S.C. § 343(q)(5)(A)(i) (2000) (stating that nutrition labeling requirements do not apply to food "[that] is served in restaurants or other establishments"). *See infra* notes 158, 177–80 and accompanying text.

87. 21 U.S.C. § 331(a)–(c) (2000).

88. 21 U.S.C. § 334(a)(1) (2000).

89. 21 U.S.C. § 334(b) (2000).

A. Is Fast Food Adulterated?

Under the Food, Drug, and Cosmetic Act, a food is deemed to be adulterated "[i]f it bears or contains any poisonous or deleterious substance which may render it injurious to health . . . or contains any added poisonous or added deleterious substance . . . that [are] unsafe within the meaning of section 346 of this title."[90] Various provisions throughout the Food, Drug, and Cosmetic Act focus on different types of food, although food elements certainly can fall into more than one category.[91] The main focus of this analysis is on food substances including, but not limited to: oil, animal lard, poultry products, sugar, salt, other chemicals, and beef—natural products or added substances used as ingredients combined into menu items, commonly known as "fast food." Although different fast-food chains offer a variety of menu items, the following fast-food products from McDonald's will be used as examples for analysis: Big Macs, McChicken Sandwiches, hamburgers, and French fries. The following sections offer an analysis of whether fast food is considered adulterated under the various measurements applied by the statute. First, section one will discuss whether fast food is considered "food" as defined by the FDA and if so, whether it is adulterated. The next two sections will analyze whether the tests used for "added substances" or "food additives" should be applied to fast food and what results may occur. Finally, the last section will analyze the authority granted to the FDA in this area and outline possible steps that may help the fast-food industry become part of the solution to the obesity problem, rather than a contributor.

1. Food

Several fast-food products, such as hamburgers, are considered products in themselves, rather than being combinations of "substances."[92] With such products, a higher standard exists to allege adulteration: The product must be shown to "*ordinarily* render it injurious to health."[93]

90. 21 U.S.C. § 342(a) (2000). A food will not be adulterated if "the substance is not an added substance . . . if the quantity of such substance in such food does not ordinarily render it injurious to health." *Id.*

91. As previously stated, for purposes of this analysis, the combined ingredients that make up the fast-food products may be considered food products or added substances. *See* Merrill, *supra* note 65, at 185.

92. The category of "food" emerges as the default, meaning those products that do not contain added substances or a variety of food additives can be simply classified as food. 21 U.S.C. § 321(f) (2000).

93. 21 U.S.C. § 342(a)(1) (emphasis added). Other statutory tests include the "may render injurious to health" test that is applied to added elements that are either necessary or unavoidable. *Id.* Food additives that are "necessary in the production of a food" or whose occurrence is "unavoidable" are regulated under § 346. Merrill, *supra* note 65, at 175 (noting these various tests were implemented along with the passage of the Food, Drug, and Cosmetic Act in 1938).

The leading case that defines "rendering a food injurious to health," *United States v. 1232 Cases American Beauty Brand Oysters*, held that "[i]t is the character, not the quantity of [a] substance that controls its ability to injure."[94] This case involved the FDA's seizure of oysters that contained shell fragments, apparently capable of injuring the mouth or lodging in the esophagus.[95] The court found that these shell fragments could not be removed from the oysters and that "there may be of necessity food products containing deleterious substances."[96] Further, millions of cans of the oyster product had been distributed without any complaint; therefore, the government did not meet its burden of proof of showing that the oysters were dangerous in ordinary use, leading the court to its conclusion that quantity does not control the injurious nature of a product.[97] This standard allows the FDA or a court to weigh the dangers of deleterious substances against beneficial effects of foods that contain poisonous, but harmless, elements.[98] Today, the legal measure of the danger of substances that occur naturally in foods remains the "ordinarily injurious" test.[99]

In reality, applying the ordinarily injurious test to fast food would likely yield a conclusion that the products are not adulterated within the meaning of the Food, Drug, and Cosmetic Act. The contention that fast food is a natural product is a weak one that would unlikely render fast food subject to this test anyway. If the FDA did use the "ordinarily injurious" test, the test should be applied to fast-food products that are served mostly in their natural state, such as beef and chicken. The consumption of these foods would have to be considered ordinarily injurious to a consumer's health to meet this test. For example, a McChicken Sandwich from McDonald's, which contains 430 calories and twenty-three grams of fat, must be considered injurious to health because of these attributes.[100] Meeting this high standard and showing the danger of the consumption of just one chicken sandwich is difficult.[101] The

94. 43 F. Supp. 749, 751 (W.D. Mo. 1942) (citation omitted).

95. *Id*. at 750.

96. *Id*.

97. *Id*. at 750–51.

98. *See* Merrill, *supra* note 65, at 188. Merrill points out that although it has been acknowledged that excessive consumption of caffeine could be injurious to health, the FDA clearly does not want to ban coffee; however, "[t]his does not mean that the FDA could not restrict the marketing of a food that naturally contains a constituent shown to be an animal carcinogen." *Id.*

99. *Id*. at 175.

100. McDonald's USA Nutrition Facts for Popular Menu Items, *at* http://www.mcdonalds.com/app_controller.nutrition.categories.nutrition.index.html (last visited Sept. 6, 2004) [hereinafter McDonald's Facts].

101. The *Pelman* court, in following this high standard, held that for McDonald's to be liable the plaintiff must allege the products are "so extraordinarily unhealthy as to be dangerous in their intended use." Pelman v. McDonald's Corp., 237 F. Supp. 2d 512, 532 (S.D.N.Y. 2003).

variety of elements combined to make fast food, when taken individually, will not meet the standard applied in *1232 Cases*, which focuses more on character than quantity. Certainly, one hamburger would not be considered "ordinarily injurious" because of its fat and calorie content.[102]

On the other hand, one argument for claiming that fast food is "ordinarily injurious" under the character standard applied in *1232 Cases* is that when combined and eaten in *excessive* amounts, hamburgers and other fast foods contain abnormally high amounts of saturated fat, calories, and cholesterol, which are proven to be injurious to health.[103] For example, a medium order of McDonald's French fries contains 350 calories and seventeen grams of fat.[104] When added to a Big Mac (which contains 600 calories and thirty-three grams of fat), one person has consumed fifty grams of fat, which is nearly 100% of the daily allowance suggested by the federal government.[105] However, the problem in applying this standard is that the FDA has not provided a clear definition of what it means to be ordinarily injurious, so difficulties arise in assessing whether fast food would qualify.

Case law does not seem to provide a standard "ordinarily injurious" test, other than that provided in *1232 Cases*, stating that character determines a product's ability to be injurious.[106] Because the Food, Drug, and Cosmetic Act does not explicitly prohibit the FDA from interpreting the statutory language,[107] if the FDA provided further definition of ordinarily injurious based on reasonable standards, both Congress and the courts would have to

102. However, hamburgers and other ground beef products have been shown to be ordinarily injurious, in fact deadly to health, in cases of E. coli or other food-borne illnesses, of which they are the primary source. According to the CDC, 200 people become sick from E. coli 0157:H7 every day and several die. JOHN ROBBINS, THE FOOD REVOLUTION 124 (2001).

103. *See* U.S. DEP'T OF AGRIC., NUTRITION AND YOUR HEALTH: DIETARY GUIDELINES FOR AMERICANS (5th ed. 2000) (stating that it is important to "[c]hoose a diet that is low in saturated fat and cholesterol and moderate in total fat"), *available at* http://www.health.gov/dietaryguidelines/dga2000/DIETGD.PDF [hereinafter DIETARY GUIDELINES FOR AMERICANS].

104. McDonald's Facts, *supra* note 100.

105. The dietary guidelines set forth by the government state the daily intake of fat grams should not be more than sixty-five grams for someone maintaining a 2,000 calorie diet, or not more than thirty percent of the normal diet. DIETARY GUIDELINES FOR AMERICANS, *supra* note 103. The amount of calories and fat would be increased by ordering large or "super size" French fries and a non-diet soda. *See* McDonald's Facts, *supra* note 100.

106. United States v. 1232 Cases Am. Beauty Brand Oysters, 43 F. Supp. 749, 751 (W.D. Mo. 1942).

107. However, the Food, Drug, and Cosmetic Act does permit the Secretary of Health and Human Services to promulgate regulations. *See* 21 U.S.C. § 341 (2000) ("Whenever in the judgment of the Secretary such action will promote honesty and fair dealing in the interest of consumers, he shall promulgate regulations fixing and establishing for any food . . . a reasonable definition and . . . a reasonable standard of quality . . . .").

defer to this interpretation.[108] The Supreme Court has provided: "[t]he power of an administrative agency to administer a congressionally created . . . program necessarily requires the formulation of policy and the making of rules to fill any gap left, implicitly or explicitly, by Congress."[109] Until the FDA gives further guidance on the definition of "ordinarily injurious," the current debate and the allegations set forth by the *Pelman* lawsuit rest on whether excessive or even moderate consumption of these fast-food products may brand them adulterated.[110]

2. Added Substances

Fast food is created from a variety of ingredients; therefore, it may be an easier argument to define fast food as "added" substances for purposes of the adulteration statute.[111] The FDA has stated that a substance is "added" if its presence is either attributable to man or if the substance is not an inherent, natural constituent of the food.[112] In this instance, the standard would be lowered to the "*may* render food injurious" to health standard.[113] Proving that fast-food products may render food injurious to health would not be difficult because the majority of products served at these restaurants contain excessive amounts of calories, fat, and cholesterol.[114]

Additionally, as argued in *Pelman*, the average consumer's misunderstanding of the numerous ingredients in the products may also render

108. Under the *Chevron* doctrine, "if the statute is silent or ambiguous with respect to the specific issue, the question for the court is whether the agency's answer is based on a permissible construction of the statute." Chevron U.S.A. Inc. v. Natural Res. Def. Council, Inc., 467 U.S. 837, 843 (1984). The Court further stated in *Chevron*:

> Such legislative regulations are given controlling weight unless they are arbitrary, capricious, or manifestly contrary to the statute. Sometimes the legislative delegation to an agency on a particular question is implicit rather than explicit. In such a case, a court may not substitute its own construction of a statutory provision for a reasonable interpretation made by the administrator of an agency.

Id. at 844 (citations omitted).

109. *Id*. at 843 (citing Morton v. Ruiz, 415 U.S. 199, 231 (1974)).

110. Under the Food, Drug, and Cosmetic Act, a court or the FDA would need to consider products such as hamburgers and chicken sandwiches to have such character that lead them to be "ordinarily injurious" to health. *See* 21 U.S.C. § 342(a) (2000). *See also 1232 Cases*, 43 F. Supp. at 751.

111. *See* United States v. Anderson Seafoods, Inc., 622 F.2d 157, 160 (5th Cir. 1980) (stating that congressional intent in the 1906 Act shows added "ingredient" is the same thing as added "substance").

112. *See* Cont'l Seafoods, Inc., v. Schweiker, 674 F.2d 38, 42 n.14 (D.C. Cir. 1983) (citing 21 C.F.R. § 109.3 (1977)). For example, without man adding oil to potatoes, they would not become French fries.

113. 21 U.S.C. § 342(a)(1) (emphasis added).

114. *See* McDonald's Facts, *supra* note 100; *see also* DIETARY GUIDELINES FOR AMERICANS, *supra* note 103 (providing basic health information).

the food injurious to health.[115] For example, McDonald's French fries are made not only from potatoes and vegetable oil but also from partially hydrogenated soybean oil, natural flavor (beef source), dextrose, and sodium acid pyrophosphate, and then they are cooked in partially hydrogenated vegetable oils (that may contain partially hydrogenated soybean oil, and/or partially hydrogenated corn oil, partially hydrogenated canola oil, cottonseed oil, sunflower oil, and corn oil), and then TBHQ and citric acid are added to help preserve freshness and dimethylpolysiloxane is added as an anti-foaming agent.[116] The commonly unknown added substances found in various fast-food products may be a reason the FDA would prefer to regulate under this standard.[117] Additionally, choosing to regulate fast food as added substances would give the FDA an easier comments process, excluding the necessity of formal public hearings.[118]

As stated, a food is considered adulterated "[i]f it bears or contains any poisonous or deleterious substance which may render it injurious to health."[119] The statute does make allowances for food substances that, although considered deleterious, are required in production or cannot be avoided even with sound manufacturing practices.[120] "[W]hen such substance is so required or cannot be so avoided, the [FDA] shall promulgate regulations limiting *the quantity* therein or thereon to such extent as [it] finds necessary for the *protection* of the public health . . . ."[121] Therefore, if fast-food products were

115. In *Pelman*, the plaintiffs argued that McDonald's products are so altered from the original state that the average consumer would not contemplate some of the unhealthy attributes the foods now possess. Pelman v. McDonald's Corp., 237 F. Supp. 2d 512, 535 (S.D.N.Y. 2003). Another argument brought up in the *Pelman* lawsuit was the contention that fast food is addictive, which if true would also likely render food injurious to health. Researchers are investigating fast food and addiction, rather, "whether large amounts of fat in combination with sugar can trigger a craving similar to addiction." *See id.* at 542 (citing Avery *supra* note 44). To date, there appears to be no scientific evidence to support that argument, and the *Pelman* court further found it would be unlikely for plaintiffs currently to be able to prove this addiction. *See Pelman*, 237 F. Supp. 2d at 542.

116. McDonald's USA Ingredients Listing for Popular Menu Items, *available at* http://www.mcdonalds.com/app_controller.nutrition.categories.ingredients.index.html (last visited Sept. 5, 2004) [hereinafter McDonald's Ingredients].

117. After all, in the spirit of the NLEA, Congress intended for consumers to have access to information about the products they eat. *See* Mara A. Michaels, Comment, *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, 327 (1995) ("Congress believed that if consumers were informed about the possible health benefits of foods, they would be better equipped to make appropriate food choices.").

118. For further information regarding which sections of the Food, Drug, and Cosmetic Act must go through a more formal hearing process, see 21 U.S.C. § 371 (2000).

119. 21 U.S.C. § 342(a)(1) (2000).

120. 21 U.S.C. § 346 (2000).

121. *Id.* (emphasis added).

deemed deleterious, and therefore adulterated by the FDA, these products would not necessarily be seized and banned.

3. Food Additives

Fast-food products can also be considered food additives and therefore receive a different statutory treatment than naturally occurring elements, despite presenting similar safety and regulatory problems.[122] Unfortunately, the process enacted by the statute does not guarantee that an additive will not be harmful to consumers, and the FDA's determination that a food additive is safe is somewhat uncertain.[123] Regulations concerning tolerance for poisonous or deleterious food additives are defined in § 346, which states:

> Any poisonous or deleterious substance added to any food, except where such substance is required in the production thereof or cannot be avoided by good manufacturing practice shall be deemed to be unsafe . . . when such substance is so required or cannot be so avoided, [there shall be] regulations limiting *the quantity* therein or thereon to such extent as [found] necessary for the *protection* of the public health, and any quantity exceeding the limits so fixed shall also be deemed to be unsafe for purposes of the application . . . of this title.[124]

The statutory definition of additive includes a "grandfather clause" that excludes substances that were used with approval before September 6, 1958, pursuant to the Food, Drug, and Cosmetic Act, the Poultry Products Inspection Act, or the Meat Inspection Act.[125] This exception exempts foods "generally recognized as safe" (GRAS) to prevent needless testing of ingredients that have been used for long periods of time without *evident* harmful effects, such as salt and sugar.[126] It also excludes most ingredients sanctioned, by either the

122. *See supra* notes 65–67 and accompanying text.

123. Merrill, *supra* note 65, at 207. "Most food additive petitions are eventually approved, and in twenty years only two have provoked demands for a formal hearing." *Id*. at 209.

124. 21 U.S.C. § 346 (emphasis added) (stating that if a regulation must limit the quantity of a substance in a food, that food will not be considered adulterated because it contains an added amount of the substance). The statute reads:

> In determining the quantity of such added substance to be tolerated in or on different articles of food the [FDA] shall take into account the extent to which the use of such substance is required or cannot be avoided in the production of each such article, and the other ways in which the consumer may be affected by the same or other poisonous or deleterious substances.

Id. The original wording of the Food, Drug, and Cosmetic Act did not include the terms "added," but it is clear that, "[w]hile Congress recognized that some potentially deleterious ingredients in food were ubiquitous, it wanted to enhance FDA control over consumer exposure." Merrill, *supra* note 65, at 196 n.89.

125. 21 U.S.C. § 321(s)(4) (2000). *See also* 21 U.S.C. §§ 451, 601 (2000).

126. Merrill, *supra* note 65, at 209–10 (emphasis added).

FDA or the Department of Agriculture for meat and poultry, for use in food before 1958.[127]

The statute defines two ways to evaluate safety of substances directly or indirectly added to food: through scientific procedures, or for substances used prior to January 1, 1958, through experience based on common use in food.[128] Although the Food, Drug, and Cosmetic Act does not seemingly allow considerations of the benefits of certain foods, an ingredient's utility does influence scientists' judgments.[129] Certain restrictions, including limits on levels, purpose, or source, serve as the basis for defining food safety; however, the FDA does not usually prescribe special labeling requirements for these ingredients or the food for which it is used, despite being included in the statutory requirements.[130] This loose system of defining foods as GRAS has allowed many food ingredients to come into common use through the *assumption* that they are under the GRAS label.[131] The GRAS category foods may be classified as "previously sanctioned," which because of approval prior to 1958, escape food additive status even though the additive might otherwise satisfy the requirements.[132] Because these sanctioned foods are not food additives under the statute, the basic adulteration provisions govern.[133]

The variety of products served in fast-food restaurants will likely fall within the food-additive categories. Several of the products are natural foods, such as grains, lettuce, and potatoes; however, the majority are substances used intentionally as food ingredients and would be considered GRAS. The remaining foods would fall under the "previously sanctioned" category, such as the meat products and poultry. One author examined the danger of exempting foods as food additives and GRAS foods when dealing with processed products: "[t]he Food and Drug Administration does not require flavor companies to disclose the ingredients of their additives, so long as all

127. *Id*. at 203–04.

128. 21 C.F.R. § 170.30(a)–(b) (2000) ("General recognition of safety requires common knowledge about the substance throughout the scientific community knowledgeable about the safety of substances . . . [and] recognition of safety based upon scientific procedures shall require the same quantity and quality of scientific evidence as is required to obtain approval of a food additive . . . .").

129. Merrill, *supra* note 65, at 211. The fact that salt has a preservative quality should not affect its determination. *Id.* However, it probably is taken into consideration. *See* Alexandra Greeley, *A Pinch of Controversy Shakes up Dietary Salt,* FDA CONSUMER MAGAZINE, Nov. 21, 1997, at 24 (discussing salt's presently known effects on sodium levels and possible effects on high blood pressure).

130. 21 C.F.R. § 184.1(f) (2000). *See also* Merrill, *supra* note 65, at 211.

131. Merrill, supra note 65, at 213.

132. *Id*. at 214–15. This is a limited exception, and these foods are still subject to other food-safety provisions. *Id*. at 215 n.164.

133. *Id*. at 216. If the FDA were able to show a previously sanctioned food is unsafe or is a carcinogen, basic adulteration provisions would allow seizure. *Id*.

the chemicals are considered by the agency to be GRAS . . . . This lack of public disclosure enables the companies to maintain the secrecy of their formulas."[134]

Despite fast food falling within this category, the FDA may choose not to regulate under this statute. The hearings process, briefly discussed in terms of added substances, is more stringent for food additives.[135] Specifically, the Food, Drug, and Cosmetic Act includes several statutes that require a formal hearings process; § 346 dealing with food additives is one such provision.[136] The FDA might be hesitant to regulate under this section in order to conserve the costs and time required to initiate the formal hearings process.

4. The Role of the FDA

No matter what category, whether a food, added substance, or additive, regulating adulterated food is an important function of the Food, Drug, and Cosmetic Act.[137] Part of this function is to identify dangers within the food arena, for instance a diet high in fat and calories that consists of fast food on a regular basis that can be linked to increased heart disease, cancer, and other illnesses.[138] Although the exact cause of cancer remains unknown, a great deal of scientific evidence links cancer to dietary habits.[139] The Department of Health and Human Services has stated: "[b]oth genetic and environmental risk factors may affect the risk of cancer. Risk factors include . . . overweight and obesity . . . and dietary factors."[140] Additionally, the federal government has named fat as the strongest cancer cause among dietary factors.[141] The possible link between cancer and a high-fat diet would seemingly meet the "*may* render it injurious to health" test discussed above, establishing fast food as

134. SCHLOSSER, *supra* note 17, at 125. Schlosser further states, "[t]he ubiquitous phrase 'artificial strawberry flavor' gives little hint of the chemical wizardry and manufacturing skill that can make a highly processed food taste like a strawberry." *Id*. at 125. In fact, the typical strawberry artificial flavor contains more than 45 different chemicals. *Id*. at 125–26.

135. *See* 21 U.S.C. § 371 (2000).

136. Whereas, the above-mentioned adulteration sections regulating food and added substances (§ 342) can be amended through a notice-and-comment hearings process, the food-additive section (§ 346) requires a formal public hearing. *See* 21 U.S.C. § 371(e)(1)–(3).

137. *See* 21 U.S.C. § 342(a) (2000).

138. *See* Press Release, *supra* note 5; *see also* AM. CANCER SOC'Y, CANCER FACTS & FIGURES 2003 (2003) (stating that in 2003, one-third of the expected cancer deaths will be "related to nutrition, physical inactivity, obesity, and other lifestyle factors and could also be prevented"), *at* http://www.cancer.org/docroot/STT/stt_0.asp [hereinafter CANCER FACTS & FIGURES].

139. *See* American Cancer Society, What Causes Cancer?, *at* http://www.cancer.org (last visited July 25, 2004); *see also*, 21 C.F.R. § 101.73(a)–(b) (2003).

140. 21 C.F.R. § 101.73(a)(1) (2003)

141. *Id.* at § 101.73(a)(2) ("Among dietary factors, the strongest positive association has been found between total fat intake and risk of some types of cancer.").

adulterated. Whether a food is labeled a substance or a food additive, it must be regulated by the FDA once it is determined to be a carcinogen.[142]

It is questionable why the FDA has not taken steps to begin the process of solving the "fat" problem or at least attempting to make the public more aware of it. Some fat is needed in the diet, but not the excessive amounts found in a diet that includes regular trips to McDonald's.[143] The FDA could regulate through limiting certain amounts of fats or oils used, regulating quantities served, or providing warning labels at restaurants that eating foods high in fat, calories, and cholesterol may be injurious to health.[144] A warning to the public that excessive consumption of fast food can lead to obesity-related illnesses could be accomplished through a poster in the store, a brochure near the register, or a disclaimer on the door. A warning, similar to that provided for alcohol and cigarettes, would ensure that consumers are aware of the dangers and enable them to make an informed decision on whether to eat the products.[145] A third, although less likely scenario, would be for the FDA to limit the sale of "super-sized" portions, in hopes of scaling back the amount of food consumed. By returning to smaller portion sizes, people would hopefully discover that extra large French fries and sodas are excessive and unnecessary.[146] If the FDA places limits on consumption or provides knowledge to the consumer, fast food likely will not have the opportunity to be injurious to people's health.

B. Less Stringent Laws Lead to Exceptions for Restaurants

Under the Food, Drug, and Cosmetic Act, the term "labeling" has a broad definition and consists of more than just what is written on a container or package.[147] "The term 'labeling' means all labels and other written, printed, or

142. *See* 21 U.S.C. §§ 348(c)(3)(A), 342(a) (2000).

143. *See* DIETARY GUIDELINES FOR AMERICANS, *supra* note 103.

144. There is simply no need to have super-sized hamburgers, French fries, and sodas. This country existed without service of these large quantities of food for many years. A study released in 2003 by the University of North Carolina noted this increase. "Portion sizes varied by food source, with the largest being consumed at fast-food establishments . . . . Between 1977 and 1996, portion sizes increased for salty snacks, desserts, soft drinks, fruit drinks, French fries, hamburgers, cheeseburgers, and Mexican food." David Williamson, *UNC Study Confirms that Food Portion Sizes Have Increased in U.S. Over Two Decades*, UNC NEWS SERVICES, Jan. 21, 2003, *available at* www.unc.edu/news/newsserv/archives/jan03/popkin011603.html. *See also* Brody, *supra* note 19 (stating that even if people would be satisfied with less, they will continue to eat more if the portions are larger).

145. In addition to providing consumer information, a warning label would decrease the possibility of consumer litigation alleging failure to warn. *See Hearing on H.R. 339*, *supra* note 54, at 30–31.

146. *See* Brody, *supra* note 19 ("A McDonald's meal that once had 540 calories now packs in 1550. The items are the same, but the portions have tripled.").

147. 21 U.S.C. § 321(m) (2000).

graphic matter (1) upon any article or any of its containers or wrappers, or (2) accompanying such article."[148] Further, the Supreme Court has held that "accompanying such article" is not restricted to mean labels that are on or in the article.[149] Therefore, any packaging, menus, or posters located in a fast-food restaurant would fall under this statutory definition and be available for regulation. Packaging would include any products that contain food items when sold to a consumer. Menus or posters would include the visual fast-food menus seen at the counter, and posters or reading material located on the restaurant walls or near the cash register. In determining if the various forms of labeling are misleading:

> [T]here 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 . . . with respect to consequences which may result from the use of the article to which the labeling . . . relates under the conditions of use prescribed . . . [or] as are customary or usual.[150]

The NLEA has further regulated labeling criteria for food, and in some instances narrowed the definition of "misbranded" under the Food, Drug, and Cosmetic Act.[151] To understand the state of food labeling today, a brief history of the NLEA will be provided in the following two sections.

1. Implementation of the Nutrition Labeling and Education Act of 1990

The enactment of the NLEA in 1990 has been the most significant development in food labeling law since Congress passed the Food, Drug, and Cosmetic Act in the late 1930's.[152] The legislation has had a large impact on food industry activities; however, the main purpose for its enactment was congressional concerns for the American consumer.[153] Two specific developments prompted passage of the NLEA: 1) There had been substantial scientific advances since the original Food, Drug, and Cosmetic Act had been passed, especially linking diet and disease prevention,[154] and 2) the food industry began to use this link for its own purposes and began flooding the

148. *Id.* "The term 'label' means a display of written, printed, or graphic matter upon the immediate container of any article . . . ." *Id.* at § 321(k).

149. Kordel v. United States, 335 U.S. 345, 349 (1948).

150. 21 U.S.C. § 321(n) (emphasis added).

151. Nutrition Labeling and Education Act of 1990, Pub. L. No. 101-535,104 Stat. 2353 (codified as amended in part at 21 U.S.C. § 343 (2000)).

152. *The Impact of the Nutrition Labeling and Education Act of 1990 on the Food Industry*, 47 ADMIN. L. REV. 605, 606 (1995) [hereinafter *Impact of the NLEA*].

153. *Id.*

154. *Id.*

market with food labels, some with misleading health claims.[155] Prior to passage of the NLEA, in order for the FDA to prevail in an enforcement action against a false or misleading label, the agency had to prove the connotation was false or misleading, after first establishing exactly what the statement implied to consumers.[156] However, under the NLEA, enforcement became much easier because any deviation from the wording provided under the FDA's regulations would render the product liable to a charge of false or misleading labeling.[157]

In addition to broader enforcement by the FDA, the NLEA amended the Food, Drug, and Cosmetic Act in several other ways. First, and most importantly, it expanded coverage of nutrition labeling to all packaged food products governed by the FDA, excluding restaurants and retail establishments that prepared and served food on-site.[158] Nutrition information given on food labels were now required to include the serving size ("an amount customarily consumed"), the number of servings in the container, and the total number of calories.[159] It also imposed limitations on nutrient and health claims, such as "low sodium" or "fiber helps prevent cancer."[160] Generally, the food industry welcomed this legislation that created national food labeling requirements. The industry thought it would lead to reduced costs, easier compliance, effective consumer education, and minimized interference with interstate distribution.[161] Through increased regulations and national uniformity, the NLEA created a new relationship between consumers, food manufacturers, and the FDA.

155. *Id*. Therefore, in addition to informing consumers, Congress felt a need to eradicate the American market of misleading information. *Id*.

156. Geoffrey M. Levitt, *FDA Enforcement Under the Nutrition Labeling and Education Act*, 48 FOOD & DRUG L.J. 119, 119 (1993).

157. *Id*.

158. *Impact of the NLEA*, *supra* note 152, at 606. *See also* 21 U.S.C. § 343(q)(5)(A)(i)–(ii) (2000).

159. 21 U.S.C. § 343(q)(1)(A)–(C) (2000). Additionally, each serving size must include the amount of fat, saturated fat, cholesterol, sodium, carbohydrates, sugars, fiber, and protein. *Id*. at § 343(q)(1)(D).

160. Pub. Citizen, Inc. v. Shalala, 932 F. Supp. 13, 15 (D.D.C. 1996). *See also*, 21 U.S.C. § 343(r)(1)(A)(B) (2000) (proclaiming on a label that the product is linked to the prevention of a particular health risk or disease is considered a "health-related claim," and a label that asserts a level of a particular nutrient in the product is a "nutrient level claim").

161. *Impact of the NLEA*, *supra* note 152, at 607.

2. The NLEA Imposes Separate Standards for Nutrient and Health Claims

Despite positive reaction from the industry, some complained about the new regulations.[162] Representatives of the food industry were unsuccessful in lobbying Congress and were unable to eliminate the increased monitoring of health and nutrient claims on food labels embedded in the NLEA.[163] The new regulations included the requirement that food labels characterizing a nexus between a nutrient and a health-related condition had to meet the requirements of the regulations set forth in the statute.[164] Congress specifically exempted restaurants from the uniform labeling requirements set forth in the NLEA; however, as noted above, debate regarding the regulation of nutrient and health claims in restaurants remained. In the final amendments, the FDA concluded that they would only regulate claims made on restaurant signs or posters but not claims made on menus.[165] The decision was based on the fact that menus are subject to change and these requirements may deter restaurants from providing any nutrition or health-related information on their menus.[166]

In the process of implementing the NLEA, the FDA received numerous comments and even faced litigation regarding the proposed labeling of nutrient and health claim standards that would apply to restaurant foods or foods sold in other establishments that were ready for human consumption.[167] Some

162. *Id*. at 607–08. In addition to lobbying for less stringent health claim monitoring, the industry was successful in lobbying for national pre-emption of all other state legislation regarding food labeling. *Id*. at 608.

163. *Id*. The NLEA has provided the Secretary of Health and Human Services with the ability to determine whether a nutrient, mineral, or vitamin not required should be placed on the label to assist consumers. 21 U.S.C. § 343(q)(1)–(2).

164. *See* 21 U.S.C. § 343(r) (2000). Requirements for authorization include scientific evidence published by a governmental agency linking the relationship, a notification submitted to Health and Human Services, and that the claim be stated in an accurate manner. *Id.*

165. *Shalala*, 932 F. Supp. at 15. *See generally* 21 C.F.R. pts. 20–21.

166. *Shalala*, 932 F. Supp. at 15. The court felt restaurants would be deterred from making claims because the regulations state that once a restaurant makes a nutrient or health claim, it must be able to provide the consumer with the information regarding the claim. *Id*. *See also* 21 C.F.R. § 101.10 (2003) ("Nutrition labeling in accordance with § 101.9 shall be provided upon request for any restaurant food or meal for which a nutrient content claim . . . or a health claim . . . is made [except on menus]"). The author disputes the FDA's reasoning that menus often change, and therefore regulation would be too difficult. It is not a viable argument against requiring menu labeling in fast-food restaurants. Although the menus do occasionally change, the majority of fast-food restaurants have the same menu for years at a time, in every location. As most restaurants now have websites listing all of the nutrition information, requiring this information either on fast-food menu boards, in a pamphlet next to cash registers, or on posters near the menu listings, does not seem to be as troublesome as it may be for a small local restaurant. For examples of menus, see http://www.mcdonalds.com; http://www.wendys.com; http://www.burgerking.com.

167. *See Shalala*, 932 F. Supp. at 13.

comments alleged that Congress did not intend the proposed health claim regulations to apply to restaurant foods.[168] Because Congress exempted restaurants from the labeling requirements, some claimed that Congress also intended restaurants to be exempt from restrictions placed on health or nutrient content claims.[169] On the opposing side, many argued that Congress' failure to make specific exemptions for health and nutrient content claims in restaurants implies that Congress intended for restaurants to be fully subjected to these restrictions.[170] The regulations guiding the NLEA state that foods served in restaurants are exempt from the general labeling requirements section provided that "the food bears no nutrition claims or other nutrition information in any context on the label or in labeling or advertising."[171] The FDA concluded that the 1990 amendments did not completely exempt restaurants from the health and nutrient content claim requirements, but restaurants would not be regulated in the same manner as packaged foods.[172]

The leading case disputing FDA's decision and challenging the menu exemption was brought by Public Citizen. The suit argued that FDA lacked the authority to excuse restaurant menus from labeling requirements.[173] The plaintiff argued the statute barred the menu exemption and that the FDA has acknowledged that menus are governed by the NLEA's nutrition and health claim labeling requirements.[174] In addition, the plaintiff argued that because nearly thirty percent of the American diet is composed of foods eaten away from home and that menus often make false representations about their nutritional values, the restaurant exception is irresponsible.[175] The court reasoned that exemptions not listed should not be implied, and there is no language in the statute to suggest that Congress contemplated allowing restaurants to make nutrition and health claims with no requirements for regulation.[176] Although 21 U.S.C. § 343(q) exempts restaurants from the

168. Food Labeling: General Requirements for Health Claims for Food, 58 Fed. Reg. 2478, 2515 (Jan. 6, 1993) (to be codified at 21 C.F.R. pts 20, 101) [hereinafter Food Labeling].

169. *See id*. (meaning restaurants would not be restricted from making claims regarding cholesterol, fat, and fiber content).

170. *Id*.

171. 21 C.F.R. § 101.9(j)(2)(i) (1998).

172. *See* Food Labeling, *supra* note 168 ("FDA believes that the provisions of the 1990 amendments pertaining to health claims clearly encompass restaurant food wherever a health claim is made (except . . . when the claim is made on a menu).").

173. *Shalala*, 932 F. Supp. at 15.

174. *Id*.

175. *Id*. at 15–16.

176. *Id*. at 16–17. Defendants argued the FDA has authority to make this exception and, additionally, the FDA could create the exception as part of an enforcement priority. *Id*. at 16.

general labeling requirements,[177] 21 U.S.C. § 343(r) exempts restaurants only from certain provisions and states that certain sub-clauses "do not apply to food which is served in restaurants."[178] The court found regulations exempting restaurant menus from the health claim provision to be contrary to the meaning of the statute and required all restaurant menus to be included under FDA regulations for these types of claims.[179] Currently, if a restaurant menu claims a dish is "low fat" or "lowers cholesterol," the restaurant must be able to provide the nutritional information upon request by the consumer.[180]

B. Is Fast Food Misbranded?

Under the Food, Drug, and Cosmetic Act, a food is considered misbranded if it falls within any of sixteen different categories.[181] For purposes of this analysis, two of these misbranding categories will be discussed: false or misleading labels and lack of nutrition information provided to consumers.[182] As previously mentioned, the purpose of the Food, Drug, and Cosmetic Act is "to protect consumers who under present conditions are largely unable to protect themselves."[183] A food is deemed misbranded if "its labeling is false or misleading in any particular."[184] One court has stated, "[i]t is not necessary to show that anyone was actually misled or deceived, or that there was any intent to deceive."[185] The following section will analyze whether fast-food restaurants are in violation of the Food, Drug, and Cosmetic Act because no information is provided regarding the food products, except for the generalized name, such as Big Mac or McChicken Sandwich.[186] Subsequently, there will

177. "[General labeling requirements] shall not apply to food—(i) which is served in restaurants or other establishments in which food is served for immediate human consumption or which is sold for sale or use in such establishments." 21 U.S.C. § 343(q)(5)(A)(i) (2000).

178. *Shalala*, 932 F. Supp. at 16 (citing 21 U.S.C. § 343(r)(5)(B) (2000)).

179. *Shalala*,, 932 F. Supp. at 18.

180. *See id*. ("All restaurant menus [must] be included under FDA regulations for the labeling of nutrient content and health claims.").

181. *See* 21 U.S.C. § 343(a)–(q) (2000) (including categories such as: false or misleading label, misleading container, package form, representation as to standard of quality and fill of container, color additives, and nutrition information).

182. *See* 21 U.S.C. § 343(a), (q). The various mediums used by fast food restaurants will be analyzed, such as posters, menus, and packaging.

183. Kordel v. United States, 335 U.S. 345, 349 (1948).

184. 21 U.S.C. § 343(a)(1).

185. United States v. An Article of Food . . . "Manischewitz . . . Diet Thins," 377 F. Supp. 746, 749 (E.D.N.Y. 1974). "[T]he test is not the effect of the label on a 'reasonable consumer,' but upon 'the ignorant, the unthinking and the credulous' consumer." *Id*. at 749 (citing United States v. An Article of Food—Sudden Change, 409 F.2d 734, 740 (2d Cir. 1969)).

186. As any consumer is aware, fast-food products uniformly come in boxed containers or paper wrapped with either the restaurant name or the generic name of the food inside. *See* McDonald's USA Introduces New Packaging, *at* http://www.mcdonalds.com/usa/good/environment/packaging.html.

be a brief discussion of what function the FDA should take in the arena of food labeling regulation.

1. Fast Food is Misbranded Despite the Restaurant Exception

Although the Food, Drug, and Cosmetic Act has exempted restaurants from needing to provide nutritional information on labels, fast food may still be misbranded and in violation of the law. As stated previously, to determine misleading labeling, the law provides, "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" will be taken into consideration.[187] The law appears to provide two ways for labeling to be misleading: first, through a misrepresentation on the label, and second, through a failure to reveal certain facts about the article.

The labeling of fast foods clearly is misleading under § 321(n) because of representations made on labels and failure to reveal material facts that could result in serious consequences from using the article. The labels "chicken sandwich" or "French fries" suggest the name of certain ingredients, such as chicken and potatoes, but they are misleading because dozens of other ingredients not contemplated by the consumer are included.[188] In *Pelman*, the plaintiffs contended that food products have been so altered "that their unhealthy attributes are now outside the ken of the average reasonable consumer."[189] The plaintiffs stated that while Chicken McNuggets may seem healthier because they include chicken instead of beef, they actually have twice as much fat per ounce as a hamburger.[190] Additionally, French fries, which average consumers interpret to be potatoes cooked in hot oil, include a variety of acids, hydrogenated oils, and most unusually, a natural flavor derived from a

187. 21 U.S.C. § 321(n) (2000).

188. *See* McDonald's Ingredients, *supra* note 116 (grilled chicken, not including the bun, actually contains over twenty ingredients including different types of cheeses and oils). *See* Potato Chip Inst. v. Gen. Mills, Inc., 333 F. Supp. 173 (D. Neb. 1971) for a case involving use of the word "potato chip" and whether it was misleading. The opinion stated:

> [The FDA declared] that use of "potato chip" for a product of dehydrated potatoes would not be considered misleading, if accompanied by a prominent declaration of the basic dehydrated or fried ingredient and if the product is made from dried potatoes and only such other ingredients as are used in traditional potato chips. The insistence upon a declaration acknowledges that without it some misleading might result.

Id. at 180.

189. Pelman v. McDonald's Corp., 237 F. Supp. 2d 512, 535 (S.D.N.Y. 2003). The court points to a McDonald's ingredient list and explains that Chicken McNuggets, "rather than being merely chicken fried in a pan, are a McFrankenstein creation of various elements not utilized by the home cook." *Id.*

190. *Id.* This information is available from the McDonald's website, although selective stores do have nutrition posters. *See* McDonald's Facts, *supra* note 100.

beef source.[191] As demonstrated by a recently settled lawsuit, most vegetarians would likely be appalled by this information.[192] Until 1990, McDonald's cooked French fries in a mix "of about 7 percent soy oil and 93 percent beef tallow," giving their fries, "more saturated beef fat per ounce than a McDonald's hamburger."[193] When this became known, McDonald's was sued by groups of vegetarians, including consumers that did not eat meat for religious reasons.[194] Ultimately the case settled for ten million dollars—split among Hindus, vegetarians and other groups—and McDonald's apologized for portraying its French fries as vegetarian.[195]

2. The Role of the FDA

Eating foods that consumers assume to be something they are not could result in serious consequences, namely those that are linked to being overweight and obese.[196] Some consumers believe that their food choices, such as chicken rather than beef, result in a healthier diet, when the reality is somewhat different.[197] As stated previously, the purposes of food labels, the NLEA, and the Food, Drug, and Cosmetic Act are to better protect consumers from exactly this situation. Even though restaurants are currently exempt from having to list calorie and fat content or ingredients on their products, the spirit of the Food, Drug, and Cosmetic Act seems inconsistent with the FDA's tendency to completely turn a blind eye to fast-food restaurants and allow them to continue deceiving the American public. The FDA should find certain fast-food products misbranded under the statute for the reasons stated above, and require either disclosure of ingredients or nutritional information. These steps are necessary to educate the American public regarding their food choices and to begin reversing the obesity epidemic that has taken control of this nation.

Requiring fast-food restaurants to have nutrition and ingredient information on hand in the establishment will provide consumers with the knowledge required to make informed decisions. If consumers are aware of the unhealthy ingredients in the food, as well as the high calorie and fat content, and they still choose to eat the product, at least the decision was made on a knowledgeable basis. Undoubtedly, the FDA does not intend to keep people from consuming fast food; rather, it intends to make consumers aware

191. *Pelman*, 237 F. Supp. 2d at 535.

192. *See* McCann, *supra* note 32. McDonald's issued an apology letter press release on their website on June 1, 2002, but it is no longer available.

193. SCHLOSSER, *supra* note 17, at 120.

194. McCann, *supra* note 32.

195. *Id.*

196. In addition, as demonstrated, it could lead to offending certain religious groups. *Id.*

197. The *Pelman* court stated it is a question of fact "as to whether a reasonable consumer would know . . . that a Chicken McNugget contained so many ingredients other than chicken and provided twice the fat of a hamburger." *Pelman*, 237 F. Supp. at 535.

of what they are eating and the contributions—or lack thereof—that the food is making to their daily diet. Many fast-food restaurants do hang posters that include nutrition information near the menu. Making this a uniform requirement for the fast-food industry would ensure consumers have all the knowledge needed to make an informed decision, in any state in the country.

Uniform regulation would put an end to any chance of plaintiffs winning an obesity-related lawsuit. If fast-food restaurants provide nutritional information or a warning to consumers, no argument would prevail in a courtroom. As stated, any of the arguments used in the *Pelman* lawsuit, such as failure to warn or the sale of inherently dangerous food, would become moot. Additionally, uniform regulation by the FDA is a better option than simply banning the "McLawsuits" because regulation provides a benefit to the consumers as well, which is the apparent goal of the Food, Drug, and Cosmetic Act.

D. FDA Regulation of Tobacco Versus Fast Food

Congress may attempt to argue that the FDA does not have jurisdiction over the fast-food industry, which is reminiscent of the tobacco debate that has taken place in the United States during the last half-century.[198] Debate over tobacco regulation has been the subject of numerous lawsuits and has cost the industry and the government millions of dollars. Plaintiffs have won billions of dollars from the tobacco industry after filing suit for injuries sustained from smoking cigarettes.[199] Congress created a regulatory scheme for tobacco, assuming that neither the FDA nor any other agency had jurisdiction over tobacco products. The Supreme Court concluded that, "[r]egardless of how serious the problem an administrative agency seeks to address . . . it may not exercise its authority, 'in a manner that is inconsistent with the administrative structure that Congress enacted into law.'"[200] Agencies are given deference to

198. Also reminiscent of this phenomenon is the fact that today American deaths from obesity rank second only to deaths from illnesses related to smoking cigarettes. *See* Press Release, *supra* note 5. Some attorneys wonder if fast-food lawsuits could be the next "big tobacco." TODD G. BUCHHOLZ, BURGER, FRIES AND LAWYERS: THE BEEF BEHIND OBESITY LAWSUITS 6 (2003).

199. *See, e.g.*, FDA v. Brown & Williamson Tobacco Corp., 529 U.S. 120 (2000). Opponents of fast-food lawsuits see the cases as another way for lawyers to make money.

> Litigators, eager to replicate the swath of remunerative tobacco lawsuits, have focused on the rapidly increasing girth of American consumers as a problem to be addressed in the nation's courts. Purveyors of fast foods like burgers, tacos, soft drinks and the like, typically companies whose pockets compare favorably to those of Big Tobacco, are the targets of trial lawyers eager to find a lucrative villain to sue.

BUCHHOLZ, *supra* note 198, at 1.

200. *Brown & Williamson*, 529 U.S. at 125 (quoting ETSI Pipeline Project v. Missouri, 484 U.S. 495, 517 (1988)).

interpret statutes; however, the agency and reviewing court must "give effect to the unambiguously expressed intent of Congress."[201]

In *Food and Drug Administration v. Brown & Williamson Tobacco Corporation*, tobacco manufacturers, retailers, and advertisers brought an action challenging the FDA's attempt to regulate tobacco products.[202] The *Brown & Williamson* Court held, that "Congress has clearly precluded the FDA from asserting jurisdiction to regulate tobacco products."[203] If the FDA did have jurisdiction over tobacco, it would be forced to remove tobacco products from the market for violation of the Food, Drug, and Cosmetic Act, and the Court has found this option to be against congressional intent.[204]

Regulation of fast food is unlike the jurisdiction battle created in tobacco regulation. Even though restaurants are currently exempted under the Food, Drug, and Cosmetic Act from being required to provide nutritional labeling on their menus, as stated previously, the FDA does have jurisdiction and could argue the right to regulate under other provisions of the Food, Drug, and Cosmetic Act. The Supreme Court stated, "we fully recognize that 'regulatory agencies do not establish rules of conduct to last forever,' and that an agency must be given ample latitude to 'adapt their rules and policies to the demands of changing circumstances.'"[205] The FDA may regulate fast-food restaurants without banning them, which was impossible in the case of tobacco.[206] The Food, Drug, and Cosmetic Act is not as stringent as the restrictions provided in tobacco regulation, and the FDA currently has enforcement powers in the areas of misbranding and adulteration of foods. The Supreme Court held that if "an agency rule is rational, based on consideration of relevant factors, and within the scope of the authority delegated to the agency," a reviewing court may not invalidate it.[207] Therefore, if the FDA can set forth rational reasoning, such as described in this Comment, based on a combination of factors relating to this issue, then a sound policy change can occur. The FDA has several policy

201. *Id.* at 125–26 (quoting Chevron U.S.A. Inc. v. Natural Res. Def. Council, Inc., 467 U.S. 837, 842–43 (1984)).

202. *Id.* at 129–30.

203. *Id*. at 126. The FDA argued that because tobacco was the leading cause of preventable deaths in the United States, the only way to reduce addiction levels would be prevention among children and adolescents. *Id.* at 127–28.

204. *Id. at* 137–39. Additionally, the Court concluded that Congress had several opportunities to give the FDA authority over tobacco and chose not to do so. "[T]his is not a case of simple inaction by Congress that purportedly represents its acquiescence in an agency's position. To the contrary, Congress has enacted several statutes addressing . . . tobacco and health, creating a distinct regulatory scheme for cigarettes and smokeless tobacco." *Id*. at 155.

205. Motor Vehicle Mfrs. Ass'n v. State Farm Mut. Auto. Ins. Co., 463 U.S. 29, 42 (1983) (citation omitted).

206. Under the regulations discussed, it is possible for the FDA to place restrictions on fast food restaurants without having to ban the products sold. *See* 21 U.S.C. §§ 342–343 (2000).

207. Motor Vehicle Mfrs. Ass'n, 463 U.S. at 42.

options that, if implemented, may result in the reduction of unhealthy fast food consumed by Americans, in turn leading to healthier lifestyles and an end to lawsuits that blame the fast-food industry for obesity-related health issues.

V. CONCLUSION

The FDA must adapt to the changes that have occurred in the fast-food industry. Due to increased portion sizes and lack of knowledge regarding ingredients and risks, some sort of regulation is needed to combat the obesity problem that is growing in America. Although some fast-food restaurants have begun to respond to the increasing concern over the obesity problem,[208] regulation is still necessary in order to ensure widespread positive changes. In 2004, McDonald's launched a Happy Meal for adults — the McDonald's "Go Active! Happy Meal."[209] This meal included a salad, a fountain drink of choice or bottled water, a pedometer to track daily steps, and a booklet containing a walking log.[210] McDonald's estimate was that ten million Happy Meals would be distributed to customers across the country; however, the meal was only available for a limited time and did not become a fixed menu item.[211] This demonstrates that although McDonald's is aware of the problem and is slowly taking steps to improve its image, it is not willing to make permanent changes.[212]

In addition, McDonald's is undoubtedly the largest fast-food chain and has the money to promote such programs. FDA regulation is needed because

208. McDonald's recently introduced a balanced-lifestyles platform for children. A press release states that the platform "is focused on food choices, education and physical activity. The platform is designed to educate, assist and engage children in ways that change individual behavior and help them build healthy habits that result in better food/energy balance in their lives." Press Release, McDonald's Corp., McDonald's Launches Balanced Lifestyles Commitment for Children & Celebrates Results of "McDonald's Go Active! American Challenge" with Bob Greene (May 25, 2004), *available at* http://www.mcdonalds.com/usa/news/current/conpr_05252004.html [hereinafter McDonald's Press Release].

209. *Id*.

210. *Id*.

211. *Id*.

212. For example, McDonald's pledged in 2002 to switch to a lower-fat cooking oil in its French fries by February of 2003. In 2004, with McDonald's yet to make the change, a lawsuit was brought against McDonald's for failing to reduce the fat in its French fries. McDonald's cited concerns over customer satisfaction and product quality as reasons for the delay. Associated Press, *McDonald's Hit With Lawsuit Over Fat in French Fries*, BOSTON HERALD, July 9, 2004, *available at* http://news.bostonherald.com/national/view.bg?atricleid=35013. McDonald's also stated the company will be phasing out "Super" menu items by the end of 2004. "The burger giant said it has begun phasing out Supersize fries and drinks in its more than 13,000 U.S. restaurants and will stop selling them altogether by year's end, except in promotions." Associated Press, *Supersize It? Forget it! McDonald's Dumps Big Meals*, N.Y. DAILY NEWS, March 3, 2004, *available at* http://www.newyorkdailynews.com/front/breaking_news/story/170006p-148430c.html.

smaller food chains may not take the initiative to follow in the footsteps of McDonald's by attempting to offer healthier options. If there is industry-wide regulation, then fast-food restaurants will have no choice but to act in the best interest of the consumer. The industry will be moving in the right direction in terms of public health, and the government will be taking proper steps to educate and protect its citizens.

The FDA has jurisdiction to regulate in the fast-food industry and can accomplish it in a way that benefits the American public without harming the fast-food industry.[213] As stated throughout this Comment, FDA regulation of fast-food restaurants is legally granted under the Food, Drug, and Cosmetic Act. By demonstrating that substances added to fast food may render consumption injurious to health, the FDA would have jurisdiction to regulate through warnings or limited serving sizes. Additionally, the FDA may find fast food misbranded and its labeling insufficient to provide consumers with knowledge of what they are eating, and it may mandate some type of labeling either on a menu or posted in a restaurant. Through FDA monitoring, fast-food restaurants would have a safety shield against lawsuits brought by angry citizens. Fast-food establishments could boast about their concern for the American public and claim their food is part of a manageable diet, as long as consumers know that over-consumption is unhealthy. Consumers, in turn, would gain essential knowledge regarding the food choices they regularly make. The availability of the nutrition information in every establishment would allow customers to understand the food content and ingredients of what they are eating and reasonably incorporate their knowledge into the rest of their diet. With government warnings that fast food should not be over-consumed, people may begin to acknowledge how food choices affect their health.

Now that obesity-related health problems are the number two killer in the United States, the government has a duty to warn of any contributing risks. Although one cannot predict whether FDA regulation would affect the obesity problem, there is little argument that regulation would contribute to its expansion. The gravity of this issue is just coming to fruition, and the government should take the leading position and learn from the mistakes made through tobacco litigation. The Food, Drug, and Cosmetic Act strives to provide consumers with knowledge and the ability to make informed decisions

213. In fact, such steps could help the industry by demonstrating to consumers their interest in health. It should be noted that McDonald's has begun to take steps in this direction. *See* McDonald's Press Release, *supra* note 208. However, these options are not widespread throughout the country and the problem *remains* lack of knowledge regarding the other products discussed in this Comment.

regarding their food choices. The FDA has a legal right under the law to deem fast food adulterated and misbranded under the theories indicated above.

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