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COMMENT

FOOD LABELING AND THE CONSUMER'S RIGHT TO KNOW: GIVE THE PEOPLE WHAT THEY WANT¹

David Alan Nauheim[†]

ABSTRACT

The average consumer would be surprised to find out that much of the food he buys has been irradiated, genetically modified, or cloned, or that it contains ingredients not listed on the label. Most consumers would believe that they have a “right to know” facts like this about the food they buy. The U.S. Supreme Court seems to agree. In *44 Liquormart, Inc. v. Rhode Island*, the Court said that:

The First Amendment directs us to be especially skeptical of regulations that seek to keep people in the dark for what the government perceives to be their own good. That teaching applies equally to state attempts to deprive consumers of accurate information about their chosen products: . . . “Some of the ideas and information are vital, some of slight worth. But the general rule is that the speaker and the audience, not the government, assess the value of the information presented.”

However the Food and Drug Administration (“FDA”) disagrees. Despite strong consumer interest, it refuses to mandate labeling of Genetically Modified foods or milk from cows injected with Recombinant Bovine Growth Hormone, and it has proposed eliminating mandatory labeling of irradiated foods.

The FDA argues that the Federal Food, Drug and Cosmetic Act (“FDCA”) does not give the FDA the authority to mandate labeling based on consumer interest. This interpretation has been upheld by the U.S. Court of Appeals for the D.C. Circuit in *Alliance for Bio-Integrity v. Shalala*. The court upheld the FDA’s interpretation of the FDCA based on the deference

¹ “Give the People What They Want” is the title of a 1981 album by the English rock group The Kinks.

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that courts must afford to an agency's interpretation of its own enabling statute. However, the D.C. Circuit did not consider whether consumers have a First Amendment right to receive accurate non-misleading information about food. Supreme Court jurisprudence suggests that such a right exists.

This Comment argues that the D.C. Circuit wrongly decided *Alliance for Bio-Integrity*. This Comment argues that the FDA should consider what a consumer reasonably wants to know when deciding what kind of information a food label must contain. This Comment concludes that the best way to vindicate the consumer's right to know is for Congress to amend the FDCA to require that regulators take into account the extent to which the labeling fails to reveal material facts that consumers reasonably desire.

Scientists will continue to develop more ways to manipulate food. These new technologies will continue to raise religious, moral, ethical, health, and safety issues. The consumers' right to know about their food will be an increasingly important issue. While mandatory labeling is often contrary to the interests of the food industry, this Comment argues the U.S. Constitution has made the choice for us—the First Amendment requires that government protect the consumers' right to receive accurate non-misleading information that they reasonably desire.

I. INTRODUCTION

A health-conscious consumer fills her grocery cart with what she thinks is healthy food—milk, corn, salmon, meat, potatoes, canola oil, almonds, and spinach. What she does not know is that her “healthy” food includes plants that have been genetically modified, a process which may have introduced unknown allergens and toxins. She does not know that her vegetables have been irradiated with ionizing radiation one million times more powerful than medical X-rays, destroying some of the nutritional content and causing chemical by-products that might cause cancer. She also does not realize that her milk contains antibiotics and growth hormones that may threaten her family's health. She does not know this because the labels do not say so. They do not say so because neither federal law nor state law requires food labels to contain the kind of information that most consumers would want to know.

This Comment will argue that consumers have a right to know what is in their food and that the current statutory and regulatory scheme should be amended to protect that right. Part II will set out the justification for the consumer's right to know and give examples of significant facts about food that the current regime does not require to appear on labels. Part III will

detail the current statutory and regulatory scheme and the case law that interprets it. Part IV will demonstrate that the FDA has authority to mandate food labeling based solely on the consumer's right to know, and it will also critique lower courts' decisions failing to require the FDA to so mandate. Part V will propose that Congress amend the FDCA so that a label will be deemed misleading unless it contains all of the information about a food product that an ordinary consumer would want to know. Part V will then address anticipated criticisms of that proposal. Part VI concludes this Comment.

II. BACKGROUND

A. *The Consumer's Right To Know*

That a consumer has the right to know what is in his food seems so evident that it does not need to be supported. However, a consumer's interest is sometimes contrary to the interests of industry and receives little weight from labeling regulators.² Thus, it is necessary to state the justification for the consumer's right to know.

A consumer's right to know is a part of a larger concept of health freedom. If we do not know what is in our food, how can we make healthy food choices?

At least some of the Founding Fathers were concerned that the government would restrict health freedom. Thomas Jefferson believed that the people—not the government—should make their own decisions about diet and medicine. He wrote, "Was the government to prescribe to us our medicine and diet, our bodies would be in such keeping as our souls are now."³ He also believed that government is not an elite group, who should decide what is best for society. Instead, the people should be informed so that they can make their own choices. He wrote, "I know no safe depository of the ultimate powers of the society but the people themselves; and if we think them not enlightened enough to exercise their control with wholesome

2. "The issue of labeling genetically modified foods is centered on the tension between a consumer's right to know and the bioengineering industry's interest in not labeling." Matthew Rich, *The Debate over Genetically Modified Crops in the United States: Reassessment of Notions of Harm, Difference, and Choice*, 54 CASE W. RES. L. REV. 889, 904 (2004).

3. THOMAS JEFFERSON, NOTES ON STATE OF VIRGINIA 159 (William Peden ed., Univ. of N.C. Press 1955) (1853).

discretion, the remedy is not to take it from them, but to inform their discretion by education.”⁴

Dr. Benjamin Rush,⁵ a physician and a founding father, reportedly believed that the U.S. Constitution should contain protections for health freedom:

Unless we put medical freedom into the Constitution, the time will come when medicine will organize itself into an undercover dictatorship. To restrict the art of healing to one class of men and deny equal privileges to others will constitute the Bastille of medical science. All such laws are un-American and despotic.⁶

Dr. Rush was referring to a monopoly on the practice of medicine, but the concept of health freedom—that the people should have the right to control their own health choices (and by implication their diet)—was implicit in his concern.

Many judicial pronouncements support the consumer’s right to know. Justice Scalia wrote, “The premise of the First Amendment is that the American people are neither sheep nor fools, and hence fully capable of considering both the substance of the speech presented to them and its proximate and ultimate source.”⁷ Justice Stevens wrote:

Precisely because bans against truthful, nonmisleading commercial speech rarely seek to protect consumers from either deception or overreaching, they usually rest solely on the offensive assumption that the public will respond “irrationally” to the truth. The First Amendment directs us to be especially skeptical of regulations that seek to keep people in the dark for what the government perceives to be their own good. That

4. Letter from Thomas Jefferson to William Charles Jarvis (Sept. 28, 1820), in 10 THE WRITINGS OF THOMAS JEFFERSON 161 (Paul L. Ford ed., G. P. Putnam’s Sons 1899).

5. Dr. Benjamin Rush was a physician and a signer of the Declaration of Independence. BENJAMIN RUSH, THE AUTOBIOGRAPHY OF BENJAMIN RUSH: HIS TRAVELS THROUGH LIFE TOGETHER WITH HIS COMMONPLACE BOOK FOR 1789-1813 (Greenwood Press 1970) (1948).

6. The author was unable to locate the exact source of this quotation, but this quotation is traditionally attributed to Dr. Rush. See, e.g., Christopher Mills, Comment, *Mainstreaming the Alternatives When Complementary and Alternative Medicines Become Westernized*, 13 ALB. L.J. SCI. & TECH. 775, 793 (2003).

7. *McConnell v. Fed. Election Comm’n*, 540 U.S. 93, 258-59 (2003) (Scalia, J., concurring in part and dissenting in part).

teaching applies equally to state attempts to deprive consumers of accurate information about their chosen products⁸

And most famously, Justice Jackson wrote, “If there is any fixed star in our constitutional constellation, it is that no official, high or petty, can prescribe what shall be orthodox in politics, nationalism, religion, or other matters of opinion or force citizens to confess by word or act their faith therein.”⁹

Three principles are clear in these three pronouncements:

- (1) It is not government’s role to decide what truth is.
- (2) The people are capable of deciding truth themselves.
- (3) Government should not keep information from the people.

Yet with food labeling policy, the government is doing just that—deciding what the truth is and keeping the public in the dark “for their own good.”

There have been several recent attempts in the U.S. to protect the consumer’s right to know. In 1962, President Kennedy sent Congress a “special message” declaring four basic consumer rights: the right to safety, the right to be informed, the right to choose, and the right to be heard.¹⁰ In 1980, California passed Proposition 65, which requires disclosure of carcinogens in consumer products.¹¹ Congress has given teeth to the “right to know” in some non-food contexts. For example, the Freedom of Information Act requires the U.S. Government to disclose information upon a written request, unless one of nine exceptions applies.¹² The Emergency Planning and Community Right-to-Know Act requires industry to report certain spills of toxic chemicals.¹³

In the food context, however, consumer rights bills have failed to gain traction in Congress.¹⁴ Under current federal law, a food label need only contain five things: the ingredients, the net weight, the name and address of the manufacturer, the name of the food, and certain nutritional

8. 44 *Liquormart, Inc. v. Rhode Island*, 517 U.S. 484, 503 (1996) (citations omitted).

9. *W. Va. State Bd. of Educ. v. Barnette*, 319 U.S. 624, 642 (1943).

10. Steve Keane, *Can a Consumer’s Right to Know Survive the WTO?: The Case of Food Labeling*, 16 *TRANSNAT’L L. & CONTEMP. PROBS.* 291 (2006).

11. Safe Drinking Water and Toxic Enforcement Act of 1986, *CAL. HEALTH & SAFETY CODE* §§ 25249.5-25249.13 (West 2005).

12. Freedom of Information Act, 5 U.S.C. § 1552 (2009) (codified in scattered sections of Title 5).

13. Emergency Planning and Community Right-to-Know Act, 42 U.S.C. § 11021 (2009).

14. See, e.g., Produce Consumers’ Right-to-Know Act, H.R. 1605, 107th Cong. (2001); Food Ingredient Right to Know Act, H.R. 1356, 107th Cong. (2001); Genetically Engineered Food Right to Know Act, H.R. 5269, 109th Cong. (2006).

information.¹⁵ Currently, the FDA claims that it does not have authority to mandate labeling based on consumer interest alone.¹⁶

B. What You Don't Know Might Hurt You: Examples of the FDA's Labeling Policy

This Part will look next at three controversial food technologies and the FDA's response to consumer demands for mandatory labeling of these technologies. Each of these food technologies is controversial for either safety, health, environmental, ethical, or religious reasons. In each of these examples, the FDA has ultimately sided with industry, concluding that there are no safety concerns, and that the FDA does not have the authority under the FDCA to mandate labeling.

1. Genetically Modified Organisms

Genetically Modified Organism ("GMO") is the name for what is created when a segment of Deoxyribonucleic Acid ("DNA") from one organism "is extracted and spliced into a recipient organism's preexisting DNA."¹⁷ This is done in order to introduce a favorable trait from one organism into another.¹⁸ DNA "can come from any organism," whether it is "microbial, animal, or plant."¹⁹ Scientists have, for example, developed GMOs that resist pests and disease better than conventional crops.²⁰

Fifty-four percent of Americans say they have never eaten GMOs.²¹ However, given that approximately seventy percent of processed foods in the U.S. contain GMOs, they are probably mistaken.²² Many Americans are

15. See Fred H. Degnan, *Biotechnology and the Food Label*, in LABELING GENETICALLY MODIFIED FOOD, THE PHILOSOPHICAL AND LEGAL DEBATE 17, 18-19 (Paul Weirich ed., 2007). Mr. Degnan is a partner with King & Spalding, which represents some of the giants in the food and pharmaceutical industry—which may explain his sympathy for the FDA's pro-industry policies. Kate & Spalding, *Biography of Frederick Degnan*, http://www.kslaw.com/bio/Frederick_Degnan (last visited Oct. 30, 2009).

16. See, e.g., *Stauber v. Shalala*, 895 F. Supp. 1178, 1193 (W.D. Wis. 1995). This Comment will argue that the FDA does have that authority. See *infra* Part III.B.

17. Matthew Rich, *supra* note 2, at 890.

18. Statement of Policy: Foods Derived From New Plant Varieties 57 Fed. Reg. 22,984, 22,986 (FDA May 29, 1992).

19. *Id.*

20. *Id.*

21. W.K. KELLOGG FOUNDATION, PERCEPTIONS OF THE U.S. FOOD SYSTEM: WHAT AND HOW AMERICANS THINK ABOUT THEIR FOOD 18 (2005) [hereinafter KELLOGG REPORT].

22. Robert Streiffer & Alan Rubel, *Genetically Engineered Animals and the Ethics of Food Labeling*, in LABELING GENETICALLY MODIFIED FOOD, THE PHILOSOPHICAL AND LEGAL DEBATE 61, 66 (Paul Weirich ed., 2007).

not aware of this fact, however, because the labels do not tell them—under current regulations, GMO labeling is voluntary.²³

Only thirty-two percent of Americans consider themselves knowledgeable about GMOs.²⁴ Nevertheless, a plurality (forty-seven percent) oppose the introduction of GMOs into the food supply, and a majority (fifty-two percent) say they are unlikely to eat GMOs.²⁵ Many consumers “are willing to pay [a substantial] premium for non-GM[O] foods.”²⁶ While most Americans do not know very much about GMOs, GMOs make them “cautious and uncomfortable.”²⁷

Why are consumers concerned? Some (thirty-seven percent) object to GMOs on religious grounds.²⁸ Gene splicing appears to violate Old Testament biblical laws.²⁹ Bioengineering also seems to usurp God’s role as the Creator.³⁰ Some just think it is immoral to play God with nature.³¹

23. “We are, therefore, reaffirming our decision to not require special labeling of all bioengineered foods.” Draft Guidance for Industry: Voluntary Labeling Indicating Whether Foods Have or Have Not Been Developed Using Bioengineering; Availability, 66 Fed. Reg. 4839, 4840 (FDA Jan. 18, 2001).

24. KELLOGG REPORT, *supra* note 21, at 16.

25. *Id.* at 18.

26. Philip G. Peters & Thomas A. Lambert, *Regulatory Barriers to Consumer Information about Genetically Modified Foods*, in LABELING GENETICALLY MODIFIED FOOD, THE PHILOSOPHICAL AND LEGAL DEBATE 151, 157 (Paul Weirich ed., 2007).

27. KELLOGG REPORT, *supra* note 21, at 17.

28. *Id.* at 21; *see Leviticus* 19:19 (“Do not mate different kinds of animals.”); *Deuteronomy* 22:9 (“Do not plant two kinds of seed in your vineyard; if you do, not only the crops you plant but also the fruit of the vineyard will be defiled.”).

29. *Leviticus* 19:19 (“Do not mate different kinds of animals.”); *Deuteronomy* 22:9 (“Do not plant two kinds of seed in your vineyard; if you do, not only the crops you plant but also the fruit of the vineyard will be defiled.”). *But see* Carl Feit, *Genetically Modified Food and Jewish Law (Halakhah)*, in GENETICALLY MODIFIED FOODS: DEBATING BIOTECHNOLOGY 123 (Michael Ruse & David Castle eds., 2002).

30. *Genesis* 1:1 (“In the beginning God created the heavens and the earth.”); *see also* Thomas O. McGarity, *Consumer Sovereignty, Federal Regulation, and Industry Control in Marketing and Choosing Food in the United States*, in LABELING GENETICALLY MODIFIED FOOD, THE PHILOSOPHICAL AND LEGAL DEBATE 128, 134 (Paul Weirich ed., 2007). *But see* Joe N. Perry, *Genetically Modified Crops*, in GENETICALLY MODIFIED FOODS: DEBATING BIOTECHNOLOGY 115, 115-21 (Michael Ruse & David Castle eds., 2002).

31. *See, e.g.*, HRH The Prince of Wales, *Reith Lecture 2000*, in GENETICALLY MODIFIED FOODS: DEBATING BIOTECHNOLOGY 11 (Michael Ruse & David Castle eds., 2002).

The idea that there is a sacred trust between mankind and our Creator, under which we accept a duty of stewardship for the earth, has been an important feature of most religious and spiritual thought throughout the ages. Even those whose beliefs have not included the existence of a Creator have, nevertheless, adopted a similar position on moral and ethical grounds.

Id. at 12.

Most (seventy-one percent), however, say that their view of GMOs is determined by GMOs' effect on their family.³² This may be an expression of concern about the safety of GMOs; twenty-seven percent of consumers believe that GMOs are "unsafe," and forty-two percent express "no opinion" on the question.³³

The FDA states that it is "not aware of any information showing that foods derived by [bioengineering] . . . present any different or greater safety concern than foods developed by traditional plant breeding."³⁴ However, given the government's track record on protecting consumer safety, consumers can be forgiven for having a "well-founded skepticism" of the FDA's assurance.³⁵

Critics point out that the FDA's claim that "there is no evidence of an adverse effect" is not the same as stating "there is no effect."³⁶ Critics also point out that researchers who dare to publish studies contrary to the commercial interest of industry do so at great peril.³⁷ Ironically, at the same time that the FDA declared the "safety" of GMOs, it also admitted that it was "unaware of any practical method to predict or assess the potential for new proteins in food to induce allergenicity"³⁸

32. KELLOGG REPORT, *supra* note 21, at 22.

33. *Id.* at 18.

34. Statement of Policy: Foods Derived From New Plant Varieties, 57 Fed. Reg. 22,984, 22,991 (FDA May 29, 1992).

35. McGarity, *supra* note 30, at 133. "A consumer who knows nothing about genetic engineering may know a lot about how 'miracle' drugs have caused catastrophic injuries, how nuclear power created a legacy of radioactive waste, and how the kudzu plan that was imported as an erosion control tool has taken over the rural South." *Id.*; *see also* Int'l Dairy Foods Ass'n v. Amestoy, 92 F.3d 67, 76-77 n.2 (2d Cir. 1996) (Leval, J., dissenting) ("[T]here are many possible reasons why a government agency might fail to find real health risks, including inadequate time and budget for testing, insufficient advancement of scientific techniques, insufficiently large sampling populations, pressures from industry, and simple human error. . . . In studying the frequency and seriousness of risks identified after approval, GAO found that of the 198 drugs approved by FDA between 1976 and 1985 for which data were available, 102 (or 51.5 percent) had serious postapproval risks, as evidenced by labeling changes or withdrawal from the market.").

36. Carl Cranor, *Different Conceptions of Food Labels and Acceptable Risks*, in LABELING GENETICALLY MODIFIED FOOD, THE PHILOSOPHICAL AND LEGAL DEBATE 201, 206 (Michael Ruse & David Castle eds., 2002).

37. *See, e.g.*, STEVEN P. MCGRIFFEN, BIOTECHNOLOGY: CORPORATE POWER VERSUS THE PUBLIC INTEREST 56-62 (2005) (detailing the intimidation, vilification, abuse, and ostracism of researchers who dare to challenge industry, as well as the immense influence industry wields over universities).

38. 57 Fed. Reg. at 22,987.

Critics also point out that food regulators do not require extensive testing of GMOs, as they do for chemical additives.³⁹ Instead, food regulators “[rely] on the doctrine of “substantial equivalence” to bypass the need for extensive testing.”⁴⁰ Essentially, the FDA “concluded that if a [GMO] is “substantially equivalent” to a non-GMO food that has a history of safe use, the [GMO] should not be regulated any more stringently” than the non-GMO food “simply because it is a product of bio-technology.”⁴¹ This policy is based on the assumption (instead of requiring evidence) that if a gene was safe in one plant, it “will be safe when transferred” via biotechnology “to another plant.”⁴²

Critics respond that GMOs are “*sui generis*,” and they therefore reject the FDA’s substantial equivalence theory.⁴³ They point out that the regulators are charged with promoting U.S. agricultural products as well as regulating them.⁴⁴ This conflict of interest calls into question the regulator’s judgments about “equivalence” and “substantiality.”⁴⁵ The Department of Agriculture has spent \$250 million to develop and promote agricultural biotechnology, and only \$1.6 million—less than one percent of the total—“was put into assessing the risks.”⁴⁶

In fact, there are valid reasons to be concerned about the safety of GMOs. When genes are spliced to create GMOs, unexpected toxins or allergens can be created.⁴⁷ “Genetic engineering crosses genes between unrelated species” that would not, and could not, crossbreed in nature.⁴⁸ It is difficult to know “whether a protein introduced into a food by genetic engineering is a potential allergen.”⁴⁹ Unforeseen, harmful mutations are

39. McGarity, *supra* note 30, at 131.

40. *Id.*

41. *Id.*

42. Cranor, *supra* note 36, at 201.

43. McGarity, *supra* note 30, at 131.

44. *Id.*

45. *Id.*

46. MARK SCHAPIRO, EXPOSED: THE TOXIC CHEMISTRY OF EVERYDAY PRODUCTS AND WHAT’S AT STAKE FOR AMERICAN POWER 90 (2007).

47. *See, e.g.*, Alliance for Bio-Integrity v. Shalala, 116 F. Supp. 2d 166, 170 (D.D.C. 2000).

48. Brian Tokar, *Genetic Engineering Is Too Dangerous to Be Used in Human Foods*, in FOOD: CURRENT CONTROVERSIES 120, 120 (Jan Grover ed., 2008).

49. Bob B. Buchanan, *Genetic Engineering and the Allergy Issue*, in GENETICALLY MODIFIED FOODS: DEBATING BIOTECHNOLOGY 213, 214 (Michael Ruse & David Castle eds., 2002).

more likely to occur with bioengineering than with traditional crossbreeding.⁵⁰

In one case, soya beans crossed with brazil nuts caused “allergic reactions in people sensitive to the nuts.”⁵¹ In another case, over 37 people were killed and 1500 were permanently disabled by a disease outbreak traced to a food supplement produced with GMO bacteria.⁵² The food supplement contained less than 0.1% of the toxic compound.⁵³ The U.S. Government declared that the GMO was not the cause, but the company involved blamed the GMO because the toxin was never found in the company’s non-GMO version of the product.⁵⁴

Changes in toxicity are also a concern. GMOs are sometimes specifically engineered to maximize their toxicity.⁵⁵ For example, it is considered desirable to make certain crops toxic to harmful pests.⁵⁶ It is not hard to imagine that this toxicity could also be a safety concern to humans.⁵⁷ Also, bioengineering can “inadvertently produce a plant in which the levels or bioavailability of important nutrients are altered in significant ways that could be harmful to human health.”⁵⁸

Some consumers oppose GMOs because of their risk to the environment. GMOs, through cross-fertilization, cross-pollinate indigenous native plants, diminishing biodiversity.⁵⁹ Cross-pollination from GMOs also threatens organic farmers. Once an organic crop is cross-pollinated with GMOs, it cannot be sold under an organic label. An organic farmer whose crop is crossbred with GMOs can no longer market his crop as organic, which destroys his investment and can result in financial disaster.⁶⁰

Another concern is that an herbicide-resistant/pest-resistant GMO could crossbreed with a weed, creating an unstoppable “super-weed.”⁶¹ Herbicide-resistant GMOs also raise another concern. The ability to clear fields of all weeds using herbicides that can be sprayed directly on

50. Peters & Lambert, *supra* note 26, at 168.

51. Tokar, *supra* note 48, at 120.

52. *Id.*

53. *Id.*

54. *Id.*

55. McGarity, *supra* note 30, at 130.

56. *Id.*

57. *Id.*

58. *Id.*

59. *Id.* at 132-33.

60. See, e.g., SCHAPIRO, *supra* note 46, at 87-88.

61. Norman C. Ellstrand, *When Transgenes Wander, Should We Worry?*, in GENETICALLY MODIFIED FOODS: DEBATING BIOTECHNOLOGY 325, 326 (Michael Ruse & David Castle eds., 2002).

herbicide-resistant GMOs will result in farmlands devoid of wildlife, jeopardizing birds and plants that depend on farmland for habitat.⁶²

Perhaps the most frightening environmental threat from GMOs is the possibility that a virus will be inadvertently inserted into a GMO, resulting in a super-virus that could wipe out crops or cause human and animal disease of tremendous power.⁶³

Ironically, despite the benefits of GMOs touted by their proponents, GMOs have proven a financial disaster for American farmers. American agriculture, once called the “breadbasket of the world,” could now be called a “basket case.” In 1996, prior to the widespread introduction of GMOs, the U.S. exported 3.15 million metric tons of corn to the (then) fifteen member states of the European Union (“EU”).⁶⁴ In 2005, that number had dropped to 33,000 metric tons—a *ninety percent reduction*. As less corn is exported, inventory of unsold corn rises, resulting in reduced corn prices.⁶⁵ By one estimate, American corn farmers are losing at least \$200 million a year.⁶⁶

As prices drop, farmers are compensated, at least in part, by \$35 billion in subsidies provided by the Commodity Credit Corporation.⁶⁷ This amounts to a personal subsidy by every American to the biotechnology industry.⁶⁸

Concern about GMOs caused the EU and the United Kingdom to put a moratorium on GMOs in 1996.⁶⁹ Today the EU requires labeling for any food in which 0.9% of the ingredients have been genetically engineered.⁷⁰ Some nations have rejected food aid out of concern that it may contain GMOs.⁷¹

Clearly, consumers have valid reasons to reject GMOs. Should food containing GMOs say so on the label? In one poll, ninety-three percent of

62. Tokar, *supra* note 48, at 122.

63. *Id.*

64. SCHAPIRO, *supra* note 46, at 98-99.

65. *Id.* at 99.

66. *Id.*

67. *Id.* at 100.

68. *Id.*

69. Jamie E. Jorg Spence, *Right To Know: A Diet of the Future Presently Upon Us*, 39 VAL. U. L. REV. 1009, 1023-24 (2005).

70. Commission Regulation 1829/2003, 2003 O.J. (L 268), Genetically Modified Food and Feed, 2003 O.J. (L 268), available at <http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=OJ:L:2003:268:0001:0023:EN:PDF> (last visited Nov. 6, 2009).

71. Both India and Zambia have rejected food aid from the U.S. because it may be contaminated with GMOs. Dinesh C. Sharma, *India's Poor Don't Need GM Aid*, BANGKOK POST (Mar. 13, 2003), available at http://www.agbioworld.org/newsletter_wm/index.php?caseid=archive&newsid=1611 (last visited Nov. 6, 2009).

respondents thought that the government should require that GMOs be labeled.⁷² While the long-term impacts of GMOs are not yet known, must consumers wait until there is proof sufficient to satisfy the FDA before they have a right to know of the presence of GMOs in their food?⁷³ Or is the mere possibility of harm enough to justify a consumer's right to know?⁷⁴ Would not the risk of consuming GMOs be more reasonable if it was done knowingly?⁷⁵ An act that would require mandatory labeling of GMOs failed to gain support in Congress.⁷⁶ However, this Comment argues that consumers—not the FDA—should be allowed to decide for themselves.

2. Irradiated Foods

Irradiated food is what it sounds like—food that has been bombarded with ionizing radiation.⁷⁷ High-energy gamma rays, electron beams, or X-rays, millions of times more powerful than standard medical X-rays, break apart the bacteria, such as *E. coli*, that are sometimes found in food.⁷⁸ Irradiation also destroys vitamins and minerals and kills all living cells in the irradiated food.⁷⁹

While irradiated food is not radioactive, eating irradiated foods can have effects that mimic those of actual radiation exposure.⁸⁰ Irradiation can create mutagens.⁸¹ Mutagens can cause gene mutations, polyploidy (an abnormal condition in which cells contain more than two sets of chromosomes), chromosome aberrations (often associated with cancer), and

72. McGarity, *supra* note 30, at 138.

73. Peters & Lambert, *supra* note 26, at 168-69.

74. “Vermont need not, furthermore, take the position that rBST is harmful to require its disclosure because of potential health risks. The mere fact that it does not know whether rBST poses hazards is sufficient reason to justify disclosure by reason of the unknown potential for harm.” *Int’l Dairy Foods Ass’n v. Amestoy*, 92 F.3d 67, 76 n.2 (2d Cir. 1996) (Leval, J., dissenting).

75. “A person’s voluntary embracing of a risky activity or exposure tends to make the exposure or activity acceptable.” Cranor, *supra* note 36, at 212.

76. Genetically Engineered Food Right to Know Act, H.R. 5269, 109th Cong. (2006), available at <http://www.govtrack.us/congress/billtext.xpd?bill=h109-5269> (last visited Nov. 6, 2009).

77. CHRISTINE HOZA FARLOW, D.C., *FOOD ADDITIVES: A SHOPPER’S GUIDE TO WHAT’S SAFE & WHAT’S NOT* 22 (rev. ed. 2007).

78. The Center for Food Safety, *Food Irradiation*, <http://truefoodnow.org/campaigns/food-irradiation> (last visited Nov. 5, 2009).

79. FARLOW, *supra* note 77, at 22.

80. *Id.*

81. The Center for Food Safety, *supra* note 78.

dominant lethal mutations (a change in a cell that prevents it from reproducing in humans cells).⁸² Also, many mutagens are carcinogens.⁸³

The irradiation process also causes chemical reactions that produce benzene and formaldehyde, chemicals that are suspected of causing cancer and birth defects.⁸⁴ Another study linked colon tumors in lab rats to a chemical *only* found in irradiated food.⁸⁵ In another study, irradiation of fruit juices caused low-level production of furans, which are similar to cancer-causing dioxin.⁸⁶ The FDA has never tested the safety of these byproducts.⁸⁷

Irradiation can also diminish vitamin content of food.⁸⁸ For example, irradiation can destroy up to eighty percent of vitamin A in eggs, up to ninety-five percent of vitamin A and lutein in green beans, and forty percent of beta-carotene in orange juice. Perhaps it is not surprising, then, that studies show that lab animals fed irradiated food experience stunted growth.⁸⁹ Irradiation also doubles the amount of trans fat in beef.⁹⁰

While irradiation may reduce unwanted pathogens in food, it does not address the underlying problem—the unsanitary food production that introduces those pathogens.⁹¹ In fact, some critics argue that irradiation actually creates a disincentive for producers to worry about contamination prevention, since it allows them to mask the unsanitary practices of factory farms.⁹²

In 1986, the FDA decided to require labeling of all irradiated foods.⁹³ The decision, it made clear, was “not based on any concern about the safety of the uses of radiation that are allowed under this final rule.”⁹⁴ The FDA apparently is not concerned by a number of studies showing the harmful

82. *Id.*

83. *Id.*

84. *Id.*

85. *Id.*

86. *Id.*

87. *Id.*

88. *Id.*

89. *Id.*

90. *Id.*

91. Marion Nestle, *New Technologies Supplant Old Precautions with High-Tech Shortcuts*, in *FOOD: CURRENT CONTROVERSIES* 102, 107 (Jan Grover ed., 2008).

92. The Center for Food Safety, *supra* note 78, at 2.

93. Irradiation in the Production, Processing, and Handling of Food, 51 Fed. Reg. 13,376, 13,388 (FDA Apr. 18, 1986).

94. *Id.*

effects of irradiation on food.⁹⁵ Instead, the FDA based the decision on the fact that “consumers view such information as important”⁹⁶ The FDA noted, “The large number of consumer comments requesting retail labeling attest to the significance placed on such labeling by consumers.”⁹⁷ It is important to note that later, the FDA would claim that it did not have authority under the FDCA to mandate labeling solely on the basis of consumer interest.⁹⁸

In 2007, the FDA proposed to change its rule on the labeling of irradiated food.⁹⁹ Under the proposed rule, irradiated food would not need to be labeled unless the irradiation “cause[d] a material change in a food’s characteristics.”¹⁰⁰ For example, if irradiation extended a food’s shelf life by delaying ripening, the food would have to be labeled.¹⁰¹ The FDA did not propose to require labeling unless the change in the irradiated food was not “within the range of characteristics ordinarily found in such foods.”¹⁰²

The FDA also proposed to allow irradiated foods to be labeled with the term “pasteurized.”¹⁰³ This is ironic, since the FDA once argued that labeling irradiated food as “pasteurized” would be “misleading.”¹⁰⁴ The FDA’s Orwellian explanation was that while past labeling policy focused on conveying to consumers whether a food had been processed, today the focus is on the results of the processing rather than the processing itself.¹⁰⁵

This rationale rings somewhat hollow. Consumers have long shown an interest in whether products have been produced in accordance with their political and social beliefs.¹⁰⁶ Hence, there are labels declaring: “Dolphin

95. For a compilation of negative irradiation research, including one 1968 FDA study where irradiated food caused internal bleeding in rats, see Dr. Joseph Mercola, *The Problems with Irradiated Food: What the Research Says*, http://www.mercola.com/article/irradiated/irradiated_research.htm (last visited Nov. 5, 2009).

96. 51 Fed. Reg. at 13,388. This decision is discussed more fully *infra* Part III.B.

97. 51 Fed. Reg. at 13,388.

98. *See infra* Part III.B.

99. Irradiation in the Production, Processing and Handling of Food, 72 Fed. Reg. 16,291, 16,294 (FDA proposed Apr. 4, 2007). This is a change from the stance previously taken by the Food Safety and Inspection Service of the FDA, which held that food irradiation was a “material fact” that must be reflected on the label. Irradiation of Meat Food Products, 64 Fed. Reg. 72,150, 72,157 (FDA Dec. 23, 1999).

100. 72 Fed. Reg. at 16,294.

101. *Id.*

102. *Id.* at 16295.

103. *Id.*

104. Irradiation of Meat Food Products, 64 Fed. Reg. 72,150, 72,158 (FDA Dec. 23, 1999).

105. 72 Fed. Reg. at 16,295.

106. Peters & Lambert, *supra* note 26, at 171.

Safe Tuna,”¹⁰⁷ “No Animal Testing,”¹⁰⁸ “No HFCs,”¹⁰⁹ and “Conflict Free Diamonds.”¹¹⁰

While the safety of irradiated foods is debatable, consumers are justified in wanting to know whether their food has been irradiated. If the FDA does not require labeling of irradiated food, consumers will not have a realistic means of avoiding it. Again, the government has decided what is safe and is keeping the consumer in the dark.

3. Recombinant Bovine Growth Hormone

Recombinant Bovine Growth Hormone (“rBGH”) is a synthetic hormone given to milk cows to increase their milk output.¹¹¹ It is the synthetic version of bovine somatotrophin (“bST”), a naturally occurring bovine growth hormone produced in the pituitary gland of all cattle.¹¹² A typical dairy cow’s output can be increased by as much as twenty percent a day when injected with rBGH.¹¹³ The FDA argues that milk from cows that have been given rBGH is indistinguishable from rBGH-free milk.¹¹⁴ However, there is mounting research that rBGH is not safe.¹¹⁵

rBGH’s adverse effects on cows were described by the court in *Stauber v. Shalala*:

107. Tuna labeled as “Dolphin Safe Tuna” was caught using methods that do not harm dolphins. Dolphin Safe Tuna, <http://www.earthisland.org/dolphinSafeTuna/consumer/> (last visited Nov. 5, 2009).

108. This label purports to inform the consumer that the product has not been tested on animals. While some consumer groups are skeptical of this claim, it does show that consumers have ethical concerns about their products. Bornfreeusa.org, What Do These Labels Really Mean?, <http://www.bornfreeusa.org/articles.php?more=1&p=451> (last visited Nov. 5, 2009).

109. The “No HFC” label indicates that the producer uses alternative refrigerants that do not contribute to global warming. Benjerry.com, Ben and Jerry’s: The Cleaner, Greener Freezer, <http://www.benjerry.com/activism/environmental/hc-freezer> (last visited Nov. 6, 2009).

110. A diamond is a “Conflict-Free Diamond” if its profits are not used to fund war, and if it is mined and produced under ethical conditions. The Conflict-Free Diamond Council, <http://www.conflictfreediamonds.org/learnmore.html> (last visited Nov. 5, 2009).

111. Int’l Dairy Foods Ass’n. v. Amestoy, 92 F.3d 67, 69 (2d Cir. 1996). Recombinant Bovine Growth Hormone (“rBGH”) is also known as Recombinant Bovine Somatotropin (“rBST”). *Id.*

112. *Stauber v. Shalala*, 895 F. Supp. 1178, 1183 (W.D. Wis. 1995).

113. Christina Cusimano, Comment, *RBST, It Does a Body Good?: RBST Labeling and the Federal Denial of Consumers’ Right to Know*, 48 SANTA CLARA L. REV. 1095, 1098-99 (2008).

114. *Id.* at 1096.

115. *Id.* at 1099-1105.

Use of [rBGH] may affect cows adversely in several ways. [rBGH] increases the risks of reduced pregnancy rates, ovarian cysts and uterine disorders, decreased lengths of gestation periods and lower birth weight of calves. [rBGH] increases the risk of retained placentas and twinning rates in cows. It may cause increased bovine body temperatures, indigestion, bloating, diarrhea, enlarged hocks, enlarged lesions and injection site swellings. Additionally, use of [rBGH] increases the risk of clinical and subclinical mastitis, a bacterial infection of the udder. In absolute terms, [rBGH] increases the risk of mastitis by about 0.1 case per cow per year. This risk is less than the risk of mastitis posed by seasonal change.¹¹⁶

The FDA claims that there are no adverse affects to humans.¹¹⁷ However, the General Accounting Office (“GAO”) has expressed concern that rBGH can indirectly lead to an increase in antibiotic residue in milk.¹¹⁸ This risk arises because rBGH increases the risk of mastitis,¹¹⁹ cows with mastitis are given antibiotics,¹²⁰ and this “may lead to high levels of antibiotic residue in milk,” not to mention increased pus content.¹²¹

Critics are also concerned that humans will have allergic reactions to the increased antibiotics.¹²² They are also wary about the decreased potency of antibiotics, such as penicillin, due to an acquired resistance from exposure to such antibiotics.¹²³ Farmers use over fifty different kinds of antibiotics to treat mastitis, some of which are not approved for dairy cows.¹²⁴ The GAO has concluded that there is no way to assess the degree to which current milk supplies are contaminated by these drugs.¹²⁵ The GAO ultimately recommended that approval of rBGH be withheld until the mastitis issue could be resolved.¹²⁶

116. *Stauber*, 895 F. Supp. at 1183.

117. *Id.* at 1185.

118. Cusimano, *supra* note 113, at 1100.

119. *Id.* One study showed that rBGH increased the risk of mastitis by 25%; another showed the increase to be 79%. *Id.*

120. *Id.*

121. *Id.* at 1101.

122. *Id.*

123. *Id.*

124. *Stauber v. Shalala*, 895 F. Supp. 1178, 1184 (W.D. Wis. 1995).

125. *Id.*

126. “The increased milk production triggered by the [rBGH] has lead to an outbreak of mastitis among cows, and increased residues of the antibiotics used to treat this condition could be showing up in milk and beef. Also, food products from cows treated with the

rBGH also poses a second threat to human health: insulin-like growth factor (“IGF-1”).¹²⁷

[IGF-1] is [a] protein hormone whose production is regulated at least in part by [bST]. It has the same biochemical composition in humans and cows and is present in all milk, human saliva and human digestive juices. [rBGH] increases the amount of IGF-1 in milk. IGF-1 is [removed] in the process of making baby formula, but it is not destroyed by pasteurization.¹²⁸

Monsanto, the maker of rBGH, has not conducted any long-term studies on the effect of increased levels of IGF-1 on humans.¹²⁹ Nevertheless, FDA concluded that the small amount of IGF-1 in cow’s milk from rBGH was unlikely to affect humans.¹³⁰

Whether out of concern either for human health or for the effect on cows, consumers have valid reasons to want to know whether their milk was produced with rBGH.¹³¹ Yet under current FDA regulations, rBGH labeling is voluntary.¹³² The FDA reasons that “there [is] no significant difference between milk from treated and untreated cows and, therefore, . . . under the [FDCA] the agency did not have the authority . . . to require special labeling”¹³³

Amazingly, the FDA concluded that consumer’s religious concerns about GMOs were invalid.¹³⁴ It recognized that “for religious or cultural reasons, consumers are interested in being able to identify the source of a

hormone have been commercially processed and sold to consumers without any warning labels.” Summary of the Government Accountability Office’s Report to Congress, *Bovine Growth Hormone: FDA Approval Should Be Withheld Until the Mastitis Issue Is Resolved* (Aug. 6, 1992), available at <http://www.gao.gov/products/PEMD-92-26> (last visited Nov. 5, 2009).

127. Cusimano, *supra* note 113, at 1102.

128. *Stauber*, 895 F. Supp. at 1185.

129. *Id.*

130. *Id.* For a summary of other research about the danger of rBGH, see Streiffer & Rubel, *supra* note 22, at 73.

131. See, e.g., CenterforFoodSafety.com, rBGH/rBST, <http://www.centerforfoodsafety.org/rbgh2.cfm> (last visited Dec. 18, 2008) (“CFS seeks to force the FDA to remove rBGH / rBST from the market through all available legal means.”).

132. Interim Guidance on the Voluntary Labeling of Milk and Milk Products from Cows That Have Not Been Treated with Recombinant Bovine Somatotropin, 59 Fed. Reg. 6279 (Feb. 10, 1994). To this author’s knowledge, no milk producer has yet voluntarily labeled its milk, “Contains rBGH!”

133. *Id.*

134. Food Labeling; Foods Derived From New Plant Varieties, 58 Fed. Reg. 25,837, 25,838 (FDA Apr. 28, 1993).

protein hydrolysate and determined that for these consumers the protein source of a protein hydrolysate is a material fact.”¹³⁵ However, the FDA reasoned that *for scientific reasons*, those religious concerns were invalid:

When using recombinant DNA techniques, scientists do not infuse the plant with the original genes that were removed from the animal. The animal genes are used to produce copies in the laboratory. Once the copies are transferred to the plant, they become an integral part of its genetic information, just like thousands of other genes that are present in the plant chromosome. There is a scientific basis to conclude that such genetic alterations do not change the essential nature of the plant, nor do they confer “animal-like” characteristics to the plant.¹³⁶

Thus, the FDA purports to decide what is of religious concern, and what is not. In 2000, the U.S. District Court for the District of Columbia held that the FDA’s GMO policy did not violate the First Amendment because it was a neutral law of general applicability.¹³⁷ However, one wonders whether the FDA’s reasoning could survive the so-called *Lemon Test*, which prohibits “excessive government entanglement with religion.”¹³⁸

Many milk producers, responding to consumer demand for milk free from artificial hormones, have labeled their milk “No Artificial Growth Hormones.”¹³⁹ Monsanto responded to the emerging threat by lobbying states to ban “rBGH-free” labeling.¹⁴⁰ Monsanto argues that such labeling is misleading because it implies that milk produced with rBGH is inferior.¹⁴¹

135. *Id.* (citation omitted).

136. *Id.* at 25,839.

137. *Alliance for Bio-Integrity v. Shalala*, 116 F. Supp. 2d 166 (D.D.C. 2000); *see infra* Part III.C.4. The Religious Freedom Restoration Act provides that “Government may substantially burden a person’s exercise of religion only if it demonstrates that application of the burden to the person[] is in furtherance of a compelling governmental interest; and[] is the least restrictive means of furthering that compelling governmental interest.” 42 U.S.C. § 2000bb-1 (1993).

138. “First, the statute must have a secular legislative purpose; second, its principal or primary effect must be one that neither advances nor inhibits religion, finally, the statute must not foster ‘an excessive government entanglement with religion.’” *Lemon v. Kurtzman*, 403 U.S. 602, 612-13 (1971) (citations omitted).

139. *See, e.g.*, CSMonitor.com, “Hormone-Free” Milk Spurs Labeling Debate: Some Say Chemical Company is Behind Efforts To Sink “rBGH-Free” Milk Choice, <http://www.csmonitor.com/Environment/2008/0421/p13s01-sten.html>. A label that declares what a food does not contain is called “absence labeling.” “Fat free” and “cholesterol free” are examples of absence labeling.

140. Andrew Martin, *Fighting on a Battlefield the Size of a Milk Label*, N.Y. TIMES, Mar. 9, 2008, at BU-7. Monsanto hired a Colorado consultant to form the group American

In Pennsylvania, Monsanto succeeded in persuading the legislature to ban “rBGH-free” labeling.¹⁴² Public outcry was so pronounced that the legislature reversed itself just one month later.¹⁴³ Nevertheless, other states have followed or are following suit. Ohio’s “no rBGH” labeling ban is the subject of a legal challenge.¹⁴⁴ Indiana and New Jersey have similar bans under consideration in their legislatures.¹⁴⁵

Ironically, while states move to ban “rBGH-free” labeling, and the FDA declares rBGH to be “safe,” Congress’s newly revamped cafeteria proudly boasts “hormone-free milk.”¹⁴⁶ Restaurant Associates, the manager of the congressional cafeteria, explained on its web site that “Recombinant bovine

Farmers for the Advancement and Conservation of Technology (“AFACT”), which lobbies legislatures to ban or restrict labels that indicate milk comes from untreated cows. AFACT claims to be led by dairy farmers, but it was funded and initiated by Monsanto.

141. *Id.* This argument has also been made by the FDA. Interim Guidance on the Voluntary Labeling of Milk in Milk Products from Cows That Have Not Been Treated with Recombinant Bovine Somatotropin, 59 Fed. Reg. 6279 (FDA Feb. 10, 1994). However, this is a dubious argument in light of *Tylka v. Gerber*, No. 96 C 1647, 1999 WL 495126 (N.D. Ill. 1999). In that case, plaintiffs argued that Gerber’s claims, including “Nutritionally, you can’t buy a better baby food than Gerber” were false and misleading advertising, since Gerber was using ingredients, such as starch and sugar, which rendered their products less nutritious than other brands. *Id.* at *2. The court held:

Nutrition is a nebulous concept, although quantifiable in some respects. With respect to the use of the term in Gerber’s advertisements, it cannot be said that the term reasonably misleads consumers. . . . Statements such as . . . “[n]utritionally, you can’t buy a better food than Gerber,” . . . add little to the daily informational barrage to which consumers are exposed. These statements fall within the supermarket sales pitch; they address such a large market that they bespeak caution, and should put the reasonable consumer on alert that the comments are meaningless sales patter.

Id. at *8.

142. *Id.*

143. Jane Akre, *Public Outcry Keeps Hormone Milk Labels in Pennsylvania*, RACHEL’S DEMOCRACY & HEALTH NEWS, Jan. 24, 2008.

144. Andrew Martin, *Consumers Won’t Know What They’re Missing*, N.Y. TIMES, Nov. 11, 2007, § 3, at 8, available at <http://www.nytimes.com/2007/11/11/business/11feed> (last visited Dec. 3, 2009).

145. Andrew Martin, *Fighting on a Battlefield the Size of a Milk Label*, N.Y. TIMES, Mar. 9, 2008, at BU-7. This author questions whether absence labeling bans could withstand the scrutiny announced in *44 Liquormart*: “The First Amendment directs us to be especially skeptical of regulations that seek to keep people in the dark for what the government perceives to be their own good.” *44 Liquormart v. Rhode Island*, 517 U.S. 484, 503 (1996). Perhaps this is why the FDA and FTC refused to ban GMO absence labeling when petitioned to do so by Monsanto. See *infra* notes 251-52 and accompanying text.

146. Marion Burros, *More House Salads, Whether the House Likes It or Not*, N.Y. TIMES, Jan. 16, 2008.

growth hormone, or rBGH, is injected into dairy cows to artificially increase their milk production. The hormone has not been properly tested for safety. Milk labeled rBGH-free is produced by dairy cows that never received injections of this hormone.”¹⁴⁷

This pronouncement did not escape the ire of dairy industry lobbyists, who demanded that the web site be changed—which it has.¹⁴⁸

So, while Congress sips rBGH-free milk in its own cafeteria, for the rest of us, rBGH labeling is voluntary, and in some states, rBGH absence labeling is forbidden. Considering, however, the fact that rBGH milk is banned in much of the world¹⁴⁹ (as well as the congressional cafeteria), the GAO’s recommendation that it not be approved, and the many studies warning of its dangers, it seems that the American consumer is justified in wanting to know whether his milk was produced with rBGH.

III. THE FDA’S REGULATION OF FOOD LABELING

A. *The Food, Drug, and Cosmetic Act (FDCA)*

The FDA’s authority to regulate food labeling derives from the Food, Drug, and Cosmetic Act of 1938. Section 403 of the FDCA provides that a food shall be deemed misbranded if “its labeling is false or misleading in any particular”¹⁵⁰ Section 201 provides that in determining whether a label is misleading,

there shall be taken into account (among other things) . . . the extent to which the labeling or advertising fails to reveal facts material in the light of such representations or material with respect to consequences which may result from the use of the article to which the labeling . . . relates under the conditions of use prescribed in the labeling . . . thereof or under such conditions of use as are customary or usual.¹⁵¹

Section 201 has two prongs. First, it requires that if a manufacturer opts to tell something about its product, it must tell the whole truth and provide all

147. *Id.*

148. The web site now reads: “Milk produced without synthetic rBGH is produced by dairy cows that never received injections of synthetic bovine growth hormone.” *Id.*

149. Peters & Lambert, *supra* note 26, at 173.

150. 21 U.S.C. § 343 (1938).

151. 21 U.S.C. § 321(n) (1938).

of the material information.¹⁵² Second, it requires disclosure of facts that are “material” to the “consequences” of consuming a food.¹⁵³

B. The FDA’s Interpretation of the FDCA

Under the current FDA policy, a fact is only considered material in two contexts: when it relates to an increased risk to consumer safety,¹⁵⁴ or when it relates to a “material consequence,” such as a change in a food’s organoleptic,¹⁵⁵ nutritional, or functional properties “that would not be noticeable at the point of purchase but could be apparent when consumed or cooked.”¹⁵⁶ Of course, whether there is an increased risk to consumer safety is determined by the regulator, and that decision will receive deference from a reviewing court because the reasoning behind labeling decisions are “characterized by scientific and technological uncertainty.”¹⁵⁷

However, the FDA has not always held that materiality is a condition precedent to considering consumer interest. As discussed *supra* Part II.B.2, the FDA has previously mandated labeling, based solely on consumer interest. In its 1986 decision to mandate labeling for all irradiated food, the FDA stated, “Whether information is material under section 201(n) of the act depends not on the abstract worth of the information but *on whether consumers view such information as important* and whether the omission of label information may mislead a consumer.”¹⁵⁸ The FDA reasoned that the “FDA has historically required the disclosure of a food processing agent whenever it is material to the processing of foods.”¹⁵⁹ It reasoned that if flour must be labeled as “bleached” when bleaching agents are used in processing, or as “bromated” when potassium bromate is used in the

152. Degnan, *supra* note 15, at 20.

153. *Id.*

154. *Id.* at 8 (citing 49 Fed. Reg. 13679 (Apr. 6, 1984) (pertaining to the FDA requirement in 21 C.F.R. § 101.17(d)(1) that a special warning statement appear on the label of protein products intended for use in weight reduction due to health risks associated with very low calorie diets)).

155. An organoleptic difference is one capable of being detected by a human sense organ. *Stauber v. Shalala*, 895 F. Supp. 1178, 1193 (W.D. Wis. 1995).

156. *Id.*; *see also* Irradiation in the Production, Processing and Handling of Food, 72 Fed. Reg. 16,291, 16,293 (FDA proposed Apr. 4, 2007).

157. *Environmental Defense Fund, Inc. v. Costle*, 578 F.2d 337, 339 (D.C. Cir. 1978).

158. Irradiation in the Production, Processing, and Handling of Food, 51 Fed. Reg. 13,376, 13,388 (FDA Apr. 18, 1986) (emphasis added).

159. *Id.*

processing, then irradiated food should be labeled as irradiated, if irradiation is used in processing.¹⁶⁰

The FDA also gave other examples where it has mandated labeling, not because of the “abstract worth of the information,” i.e., safety concerns or organoleptic changes, but rather based solely on “whether consumers view such information as important and whether the omission of label information may mislead a consumer.”¹⁶¹ The FDA noted that it had required labeling where a food is enriched or fortified, where orange juice is made from a previously concentrated ingredient, or where orange juice has been pasteurized.¹⁶² The FDA further noted that manufacturers of “[p]otato chips made from dehydrated potatoes, onion rings made from minced onions, and fish sticks made from minced fish are all required to disclose these material differences in processing.”¹⁶³

The FDA has also proposed mandating labeling due to religious and cultural concerns.¹⁶⁴ Consumers asked the FDA, for religious and cultural reasons, to require that labels state whether a protein hydrolysate is derived from animals or plants.¹⁶⁵ The FDA recognized that, “for religious or cultural reasons, some consumers wish to avoid foods or food ingredients that are of animal origin because their dietary convictions prohibit or discourage the consumption of such foods.”¹⁶⁶ The FDA, therefore, proposed a rule that would mandate labeling, concluding, “[T]he food source of a protein hydrolysate is information of material importance for a person who desires to avoid certain foods for *religious or cultural reasons*.”¹⁶⁷ The FDA later backtracked on this proposed rule.¹⁶⁸

If the FDA requires labeling in all of these situations, then it would seem perfectly consistent for the FDA to require labeling of GMOs, or of milk from cows that have been treated with rBGH. Thus, while the FDA currently claims that it does not have authority under the FDCA to mandate labeling based solely on consumer interest, this seems a dubious claim.¹⁶⁹

160. *Id.*

161. *Id.*

162. *Id.*

163. *Id.*

164. Food Labeling; Declaration of Ingredients, 56 Fed. Reg. 28,592, 28,600 (FDA proposed June 21, 1991).

165. *Id.*

166. *Id.*

167. *Id.* (emphasis added).

168. See *supra* notes 137-40 and accompanying text.

169. *Accord* Streiffer & Rubel, *supra* note 22, at 68 (“[C]laiming that the FDA’s authority is *limited* to requiring those kinds of information is inconsistent with the plain language of the FDCA itself.”) (internal citations omitted); McGarity *supra* note 30, at 139

C. *When Is a Label Misleading?: Legal Challenges to FDA Labeling Policy*

1. *Chevron Deference*

Stauber v. Shalala and *Alliance for Bio-Integrity v. Shalala*, discussed *infra*, demonstrate the deference that courts afford administrative agencies. An agency's statutory interpretation does not receive deference when Congress has spoken directly to the issue; in such a case, the will of Congress must be given effect.¹⁷⁰ However, where Congress has not specifically addressed the issue, agencies receive considerable deference; a court does not substitute its own judgment, but merely decides whether the agency's answer is "based on a permissible construction of the statute."¹⁷¹ Further, courts give "substantial deference" when an agency is interpreting its own enabling statute.¹⁷² Additionally, agency decisions requiring scientific judgment receive even further judicial deference.¹⁷³ And finally, common law rules of evidence require that reviewing courts confine themselves to the record that was before the agency, which forecloses challengers from bringing additional evidence showing the need for labeling.¹⁷⁴ Taken together, as demonstrated in *Stauber* and *Alliance for Bio-Integrity*, these rules stack the deck overwhelmingly in favor of the regulator. As a result, as the following cases demonstrate, any agency policy that is challenged in court is almost certain to be upheld.

2. *Central Hudson* Scrutiny

Regulation of food labels is a restriction on commercial speech, which must meet the *Central Hudson* test. Under *Central Hudson Gas & Electric Corp. v. Public Service Commission*, a court reviewing government restriction on food labeling must determine: "(1) whether the expression concerns lawful activity and is not misleading; (2) whether the

(arguing that the FDA could mandate labeling based solely on the fact that without a GMO label, a food will appear to be something that it is not, i.e, a food derived from non-engineered plants); see discussion *infra* Part IV.A. *But see* Degnan, *supra* note 15, at 27 (arguing that the FDA does not have authority to mandate labeling unless it determines that there is a safety concern).

170. "First, always, is the question whether Congress has directly spoken to the precise question at issue. If the intent of Congress is clear, that is the end of the matter; for the court, as well as the agency, must give effect to the unambiguously expressed intent of Congress." *Chevron, U.S.A., Inc. v. Natural Res. Def. Council, Inc.*, 467 U.S. 837, 842-43 (1984).

171. *Id.*

172. *Alliance for Bio-Integrity v. Shalala*, 116 F. Supp. 2d 166, 177 (D.D.C. 2000).

173. *Id.*

174. *Id.*

government's interest is substantial; (3) whether the labeling law directly serves the asserted interest; and (4) whether the labeling law is no more extensive than necessary."¹⁷⁵ The burden of proof is on the defendant to justify its labeling restriction, and that burden is not slight.¹⁷⁶ Thus, legislatures receive scrutiny, while unelected bureaucrats receive deference.¹⁷⁷

This Part will next review three examples of labeling decisions that were subjected to judicial review. In the following examples, the FDA's labeling decisions will receive deference and be upheld, while a state legislature's labeling decision will receive scrutiny and be overturned.

3. *Stauber v. Shalala*

In *Stauber v. Shalala*, a group of milk consumers challenged the FDA's refusal to require mandatory labeling of milk from rBGH-injected cows.¹⁷⁸ Plaintiffs argued that consumer interest alone could suffice to justify mandatory labeling.¹⁷⁹ The court refused to hear evidence of the danger of rBGH that had not been presented to the FDA.¹⁸⁰ Applying an arbitrary and capricious standard of review, it held that a finding of a material difference is a condition precedent to considering consumer interest.¹⁸¹ Consumer interest is only relevant upon

a determination that a product differs materially from the type of product it purports to be. If there is a difference, and consumers would likely want to know about the difference, then labeling is appropriate. . . . In the absence of evidence of a material difference between rBST-derived milk and ordinary milk, the use of consumer demand as the rationale for labeling would violate the Food, Drug, and Cosmetic Act.¹⁸²

The court cited no authority for this proposition except to note that this was the opinion of the FDA.¹⁸³ Thus, the *Stauber* court, following controlling

175. *Int'l Dairy Foods Ass'n v. Amestoy*, 92 F.3d 67, 72 (2d Cir. 1996) (citing *Central Hudson Gas & Elec. Corp. v. Public Serv. Comm'n*, 447 U.S. 557, 562-63 (1980)).

176. *Id.*

177. *See supra* Part III.C.1.

178. *Stauber v. Shalala*, 895 F. Supp. 1178, 1182 (W.D. Wis. 1995).

179. *Id.* at 1193.

180. *Id.* at 1189.

181. *Id.* at 1193.

182. *Id.*

183. *Stauber*, 895 F. Supp. at 1193. The court did not discuss the FDA's 1986 assertion that it had authority to label solely on the basis of consumer interest. *See generally id.*

U.S. Supreme Court precedent regarding deference to agencies, elevated an informal FDA policy to a rule of law: the FDA may not consider consumer interest in labeling decisions unless it first determines that a product differs materially from the type of product it purports to be.¹⁸⁴

4. *Alliance for Bio-Integrity v. Shalala*

In *Alliance for Bio-Integrity v. Shalala*, a coalition of groups and individuals, including scientists and religious leaders concerned about genetically altered foods, challenged the FDA's refusal to require mandatory labeling of GMOs as arbitrary and capricious.¹⁸⁵ They also raised challenges under the Free Exercise Clause and Religious Freedom Restoration Act ("RFRA").¹⁸⁶ The "[p]laintiffs produced several documents showing significant disagreements among scientific experts" regarding the safety of GMOs.¹⁸⁷ Like *Stauber*, however, the court confined itself to the record that was before the agency.¹⁸⁸

The plaintiffs argued that in its labeling decision, the "FDA should have considered the widespread consumer interest in having genetically engineered foods labeled, as well as the special concerns of religious groups and persons with allergies in having these foods labeled."¹⁸⁹ The court held, however, that the FDA's exclusion of consumer interest from the factors that determine whether a change is "material" constitutes a reasonable interpretation of the statute, and therefore is valid.¹⁹⁰ The court cited to *Stauber*, opining that a finding of a material difference is a condition precedent to considering consumer interest.¹⁹¹ It therefore held that because the "FDA has already determined that, in general, rDNA modification does not 'materially' alter foods [Thus,] the FDA lacks a basis upon which it can legally mandate labeling, regardless of the level of consumer demand."¹⁹² Thus, what began as an informal FDA policy became the rule of law in the influential D.C. Circuit.

The court rejected the Free Exercise argument, citing *Employment Division v. Smith*, because, it said, the FDA's policy was a neutral law of

184. *Id.*

185. *Alliance for Bio-Integrity v. Shalala*, 116 F. Supp. 2d 166, 170 (D.D.C. 2000).

186. *Id.*

187. *Id.* at 177.

188. *Id.*

189. *Id.* at 178.

190. *Id.* at 179.

191. *Id.*

192. *Id.* (footnote omitted).

general applicability.¹⁹³ The court also rejected the RFRA challenge because the plaintiff's religious beliefs were not "substantially burdened."¹⁹⁴

5. *International Dairy Foods Association v. Amestoy*

In *International Dairy Foods Association v. Amestoy*, a group of dairy manufacturers brought First Amendment and Commerce Clause challenges to a Vermont statute requiring dairy manufacturers to identify products which were, or might have been, derived from dairy cows treated with a synthetic growth hormone used to increase milk production.¹⁹⁵ The *Amestoy* court gave little deference to the Vermont legislature,¹⁹⁶ holding that it had not satisfied the second prong of the *Central Hudson* test, which requires that the state have a substantial interest in regulating the commercial speech.¹⁹⁷ The court held that "consumer curiosity alone is not a strong enough state interest to sustain the compulsion of even an accurate, factual statement."¹⁹⁸ The court reasoned that if consumer interest alone were enough to compel labeling, there would be no end to the information manufacturers may be required to disclose.¹⁹⁹ The court suggested that instead "consumers interested in such information should exercise the power of their purses by buying products from manufacturers who voluntarily reveal it."²⁰⁰

In a vigorous dissent, Judge Pierre Leval argued that Vermont's concern was substantial and went beyond mere consumer interest, including:

- (1) They consider the use of a genetically-engineered hormone in the production unnatural;
- (2) they believe that use of the hormone will result in increased milk production and lower milk prices, thereby hurting small dairy farmers;
- (3) they believe that

193. "Because it is not disputed that the Statement of Policy is neutral and generally applicable, Plaintiff's Free Exercise Claim must fail." *Id.* at 179-80 (citing *Emp. Div. v. Smith*, 494 U.S. 872 (1990)).

194. "While the Court recognizes the potential inconvenience the lack of labeling presents for Plaintiffs, Defendant's decision to mandate labeling of genetically modified foods does not 'substantially' burden Plaintiffs' religious beliefs." *Id.* at 181.

195. *Int'l Dairy Foods Assoc. v. Amestoy*, 92 F.3d 67 (2d Cir. 1996).

196. McGarity, *supra* note 30, at 146.

197. *Amestoy*, 92 F.3d at 73. One wonders if the result would have been different if it had been the FDA requiring labeling, rather than the Vermont legislature. The FDA would have been entitled to *Chevron* deference. *See supra* Part III.C.1.

198. *Amestoy*, 92 F.3d at 74.

199. *Id.*

200. *Id.*

the use of rBST is harmful to cows and potentially harmful to humans; and, (4) they feel that there is a lack of knowledge regarding the long-term effects of rBST.²⁰¹

Leval argued, “The mere fact that [Vermont] does not know whether rBST poses hazards is sufficient reason to justify disclosure by reason of the unknown potential for harm.”²⁰² He pointed out that while the FDA’s studies of rBST may have been thorough, “they could not cover *long-term* effects of rBST on humans.”²⁰³

He argued that the primary function of the First Amendment is to “advance truthful disclosure.”²⁰⁴ The true objective of the plaintiffs, Leval argued, is “concealment,” which “has little entitlement to protection under the First Amendment.”²⁰⁵

The real issue, Leval wrote, is “whether the First Amendment prohibits government from requiring disclosure of truthful relevant information to consumers.”²⁰⁶ To invoke the First Amendment to invalidate a law requiring disclosure of information to consumers, Leval argued, “stands the Amendment on its ear.”²⁰⁷ Leval detailed at length the U.S. Supreme Court’s commitment to “the free flow of commercial information,” citing *Virginia State Board of Pharmacy v. Virginia Citizens Consumer Council, Inc.*, and *44 Liquormart, Inc. v. Rhode Island*.²⁰⁸

Leval also took issue with the majority’s contention that “because the FDA has not found health risks in this new procedure, health worries could not be considered ‘real’ or ‘cognizable.’”²⁰⁹

[T]here are many possible reasons why a government agency might fail to find real health risks, including inadequate time and budget for testing, insufficient advancement of scientific techniques, insufficiently large sampling populations, pressures from industry, and simple human error.

To suggest that a government agency’s failure to find a health risk in a short-term study of a new genetic technology

201. *Id.* at 75-76 (Leval, J., dissenting).

202. *Id.* at 76.

203. *Id.*

204. *Id.* at 80.

205. *Id.*

206. *Id.*

207. *Id.* at 74.

208. *Id.* at 80-81 (citing *44 Liquormart, Inc. v. Rhode Island*, 517 U.S. 484 (1996); *Va. State Bd. of Pharmacy v. Va. Citizens Consumer Council, Inc.*, 425 U.S. 748 (1976)).

209. *Id.*

should bar a state from requiring simple disclosure of the use of that technology where its citizens are concerned about such health risks would be unreasonable and dangerous.²¹⁰

Leval pointed out the government's poor track record in determining product safety.²¹¹ He reasoned that "a government agency's conclusion regarding a product's safety, reached after limited study, is not a guarantee and does not invalidate public concern for unknown side effects."²¹² Finally, Leval comforted himself by noting the narrowness of the holding: "it applies only to cases where a state disclosure requirement is supported by no interest other than the gratification of consumer curiosity."²¹³

The plaintiffs in *Amestoy* also argued that the Vermont statute violated the Commerce Clause because the mandatory labeling would impede the free flow of interstate commerce.²¹⁴ While the court did not reach the Commerce Clause argument, the Commerce Clause may prove a potent obstacle to consumers' right-to-know labeling laws at the state level.²¹⁵

IV. ANALYSIS

A. *Can FDA Mandate Food Labeling Based Solely on Consumer Interest?*

In 1986, the answer was yes. At that time, the FDA claimed authority under sections 403(a), 201(n), and 409 of the FDCA to mandate food labeling based on consumer interest alone.²¹⁶ In 1994, the FDA said the answer was no, and this has been elevated to a rule of law.²¹⁷ Had the 1986 irradiation decision to mandate labeling of irradiated food been challenged in court, the FDA presumably would have argued that consumer interest *is* sufficient to give it the authority to mandate labeling under the FDCA. The reviewing court would have applied the same deference as the *Stauber* court and the *Alliance for Bio-Integrity* court, and as a result, the 1986 policy would have been elevated to a rule of law. But unfortunately for

210. *Id.* at 77.

211. "In studying the frequency and seriousness of risks identified after approval, GAO found that of the 198 drugs approved by FDA between 1976 and 1985 for which data were available, 102 (or 51.5 percent) had serious post-approval risks, as evidenced by labeling changes or withdrawal from the market." *Id.* at 77.

212. *Id.*

213. *Id.* at 81.

214. *Id.* at 69 (majority opinion).

215. *Id.* at 70.

216. *See supra* Part II.B.2; *see also* Irradiation in the Production, Processing, and Handling of Food, 51 Fed. Reg. 13,376, 13,388 (FDA Apr. 18, 1986).

217. *See supra* Part III.

consumer rights advocates, that did not happen. This raises the question, was the FDA wrong in 1986, or has it just changed its mind? Why did the FDA change policies from 1986 to 1994?²¹⁸

In 2007, the FDA answered this question as it explained why it was proposing to reverse its 1986 policy, which mandated labeling of irradiated foods.²¹⁹ The FDA stated, “In the past, FDA policies on irradiation labeling have focused on the fact that the food has been processed. . . . In recent years, FDA policies on the labeling of foods have focused *on the results of the processing of the food rather than the processing itself.*”²²⁰ Thus, the FDA’s turnaround on irradiated food labeling was triggered by a shift in policy, not by a lack of jurisdiction under the FDCA. The FDA has not argued that its 1986 policy was wrong, only that it has shifted its focus. The conclusion, therefore, is that the 1986 policy was a permissible interpretation of the FDCA; the FDA *does* have authority to mandate labeling based on consumer interest.²²¹

While the FDA’s labeling policy may have changed, the FDCA has not. Thus, if the FDCA allowed the FDA to make labeling policy on the basis of consumer interest in 1986, then it has the legal authority to do so today. It may be unwilling to do so for various reasons, but it is disingenuous for the FDA to claim that it does not have authority under the FDCA to do so,²²² since it has claimed legal authority to do so in the past.²²³

218. The FDA’s 1992 policy stated in *Alliance for Bio-Integrity* was the policy challenged in *Stauber*. See *Stauber*, 895 F. Supp. 1182, 1186 (W.D. Wis. 1995) (citing Interim Guidance on the Voluntary Labeling of Milk and Milk Products from Cows That Have Not Been Treated with Recombinant Bovine Somatotropin, 59 Fed. Reg. 6279, 6280 (FDA Feb. 10, 1994) (“In addition, the agency found that there was no significant difference between milk from treated and untreated cows and, therefore, concluded that under the Federal Food, Drug, and Cosmetic Act (the act), the agency did not have the authority in this situation to require special labeling for milk from rbST-treated cows.”)).

219. Irradiation in the Production, Processing and Handling of Food, 72 Fed. Reg. 16,291, 16,295 (FDA Apr. 4, 2007).

220. *Id.* (emphasis added).

221. See *supra* note 158.

222. This was the FDA’s position in *Stauber*, 895 F. Supp. at 1193; see also Interim Guidance on the Voluntary Labeling of Milk and Milk Products from Cows That Have Not Been Treated with Recombinant Bovine Somatotropin, 59 Fed. Reg. 6279 (FDA Feb. 10, 1994) (“In addition, the agency found that there was no significant difference between milk from treated and untreated cows and, therefore, concluded that under the Federal Food, Drug, and Cosmetic Act (the act), the agency did not have the authority in this situation to require special labeling for milk from rBST-treated cows.”).

223. See *supra* notes 93-97 and accompanying text.

One further question remains: the *Stauber* court and the *Alliance for Bio-Integrity* court elevated the 1994 policy into a rule of law—does this mean that the FDA’s 1986 interpretation cannot be revived?

Whether an agency that has been upheld by a court can reverse itself and still be entitled to *Chevron* deference is a question not yet addressed by the U.S. Supreme Court.²²⁴ However, we do know that agency decisions trump prior judicial interpretation, as long as they would otherwise qualify for *Chevron* deference.²²⁵ The FDA shifted its interpretation of the FDCA once from 1986 to 1994 and it was upheld—why could it not shift again? After all, regulators receive heightened deference when interpreting their own enabling statute.²²⁶

Heightened deference, however, is no guarantee of success in court. The majority in *Amestoy*, for example, showed little regard for the Vermont legislature when the majority concluded that Vermont’s “sole interest” in passing its rBST labeling statute had been “consumer curiosity,” when in fact the people of Vermont had cited multiple reasons, including “concerns about human health, cow health, biotechnology, and the survival of small dairy farms of Vermont.”²²⁷ Given the judicial branch’s unpredictableness when it comes to deference, it is not clear whether the FDA could go back to its 1986 interpretation without being overturned. Advocates of the consumer’s right to know, therefore, would be wiser to seek relief in Congress, rather than the courts. If Congress amends the FDCA to require regulators to consider the consumer’s right to know, the FDA could no longer argue that it did not have authority to base labeling decision thereupon.

224. Thomas W. Merrill, *Judicial Deference to Agency Action in 9* ENGAGE: J. FED. SOC. PRACTICE GROUPS 3, 18 (2008).

225. *Id.* (citing *Nat’l Cable & Telecomms. Ass’n v. Brand X Internet Servs.*, 545 U.S. 967, 982 (2005)).

226. *See supra* note 74.

227. *See Int’l Dairy Foods Ass’n v. Amestoy*, 92 F.3d 67, 76 (2nd Cir. 1996) (Leval, J., dissenting).

[The majority] simply disregards the evidence of Vermont’s true interests and the district court’s findings recognizing those interests. Nowhere does the majority opinion discuss or even mention the evidence or findings regarding the people of Vermont’s concerns about human health, cow health, biotechnology, and the survival of small dairy farms.

Id.

B. Stauber, Alliance for Bio-Integrity, & Amestoy—*Wrongly Decided?: A Critique*

The outcomes of *Stauber* and *Alliance for Bio-Integrity* were unfortunate for consumer rights advocates. However, both courts applied controlling precedent requiring substantial deference to agency decisions. When a court follows the law, it should be praised, not criticized. One could argue, however, that those courts should have considered the constitutional rights of a third party—the consumer.

As Judge Leval argued in *Amestoy*, to use the First Amendment to deny “disclosure of information consumers reasonably desire stands the Amendment on its ear.”²²⁸ “The benefit the First Amendment confers in the area of commercial speech,” Leval argued, “is the provision of accurate, non-misleading, relevant information to consumers.”²²⁹ In light of the U.S. Supreme Court’s holdings in *Virginia State Board of Pharmacy v. Virginia Citizens Consumer Council, Inc.*, and *44 Liquormart, Inc. v. Rhode Island*, Leval may be right.²³⁰

In *Virginia State Board of Pharmacy*, the Court struck down a ban preventing pharmacies from advertising drug prices.²³¹ The Court began its discussion with the principle that: “Freedom of speech presupposes a willing speaker. But where a speaker exists, . . . the protection afforded is to the communication, to its source and to its recipients both.”²³² The Court reasoned that “information is not in itself harmful, that people will perceive their own best interests if only they are well enough informed, and that the best means to that end is to open the channels of communication rather than to close them.”²³³ The Court held that Virginia may not accomplish its interests by “keeping the public in ignorance”²³⁴

While *Virginia State Board of Pharmacy*, which dealt with suppression of speech, is distinguishable from the question considered by this Comment—whether commercial speech can be compelled in the name of the consumer’s right to know—the principle is the same: the recipient of

228. *Id.* at 74.

229. *Id.* at 81.

230. *44 Liquormart, Inc. v. Rhode Island*, 517 U.S. 484, 516 (1996); *Va. State Bd. of Pharmacy v. Va. Citizens Consumer Council, Inc.*, 425 U.S. 748, 770 (1976).

231. *Va. State Bd. of Pharmacy*, 425 U.S. at 770.

232. *Id.* at 756 (emphasis added).

233. *Id.* at 770.

234. *Id.*

speech has a protected First Amendment interest and the government may not protect consumers by keeping them ignorant.²³⁵

In *44 Liquormart*, the Court struck down a state law that prevented liquor stores from advertising their prices.²³⁶ The Court reasoned that:

The First Amendment directs us to be especially skeptical of regulations that seek to keep people in the dark for what the government perceives to be their own good. *That teaching applies equally to state attempts to deprive consumers of accurate information about their chosen products: . . .* “Some of the ideas and information are vital, some of slight worth. But the general rule is that the speaker and the audience, not the government, assess the value of the information presented.”²³⁷

While *44 Liquormart*, like *Virginia State Board of Pharmacy*, addressed a ban on speech, not compelled labeling, the Court in both cases opined that courts should be especially skeptical of regulations that seek to keep people in the dark for what the government perceives to be their own good.

The Court has made clear, therefore, that recipients of commercial speech have a First Amendment right in receiving it, and courts should be skeptical of regulations that paternalistically prevent consumers from being provided with truthful information. The *Stauber* court and the *Alliance for Bio-Integrity* court can, therefore, be justifiably criticized for failing to consider the consumers’ First Amendment right to receive access to the speech they demanded. Under the Administrative Procedure Act (“APA”), a reviewing court must hold FDA regulations that violate the Constitution to be invalid.²³⁸

There is considerable support, therefore, for the view that *Stauber*, *Alliance for Bio-Integrity*, and *Amestoy* were wrongly decided. However, while a consumer’s right to know might be protected by the First Amendment, no court has squarely held so. Future courts are unlikely to make the jurisprudential leap argued for by Judge Leval. It is much safer to follow the path of *Stauber* and *Alliance for Bio-Integrity*. Furthermore, state

235. *Id.*

236. *44 Liquormart, Inc. v. Rhode Island*, 517 U.S. 484, 516 (1996).

237. *Id.* at 503-04 (emphasis added) (quoting *Edenfield v. Fane*, 507 U.S. 761, 767 (1993)).

238. See 5 U.S.C. § 706(2)(B) (2006) (“The reviewing court shall . . . hold unlawful and set aside agency action, findings, and conclusions found to be . . . contrary to constitutional right . . .”).

legislatures are not the places to vindicate the consumer's right to know, as *Amestoy* demonstrates.²³⁹ Congress, therefore, is the consumer's best hope.

V. PROPOSAL

Others have looked at individual situations where the consumer's right to know has been denied and have proposed solutions that would only apply to those specific situations.²⁴⁰ This Comment proposes a global solution that would require food regulators to consider what consumers reasonably want to know in every food labeling decision.

This Comment proposes that Congress, pursuant to its Commerce Clause power, amend section 201(n) of the FDCA to provide that: in determining whether a label is misleading, "there shall be taken into account the extent to which the labeling fails to reveal material facts that consumers reasonably desire to know" Admittedly, one can envision several criticisms of this proposal. This Part will attempt to anticipate and address the most obvious of them.

A. Criticisms Addressed

1. A "Reasonably Desire" Standard Is Too Vague and Invites Litigation

Critics will argue that the proposed statutory language is too vague—how can a court determine whether a fact is one that consumers "reasonably desire to know"? What this critic desires is a bright line rule. However, not everything in law lends itself to a bright line rule. Tort law has its "ordinary person"; contract law has its implied obligation of "good faith effort"; and corporate law has its "business judgment rule." All are vague standards; all invite litigation; yet all are deeply rooted in American law. Sometimes the law must eschew factors, bright line rules, and balancing tests in favor of reasonableness. It has done so successfully for hundreds of years; it can do so again here.

239. See *Int'l Dairy Foods Ass'n v. Amestoy*, 92 F.3d 67, 70 (2d Cir. 1996). The interstate Commerce Clause may represent a potential barrier to the enactment and enforcement of state consumer right to know legislation.

240. See, e.g., Cusimano, *supra* note 113, at 1121-24 (proposing that Congress mandate labeling of rBST products); Emily Robertson, Note, *Finding a Compromise in the Debate Over Genetically Modified Food: An Introduction to a Model State Consumer Right-To-Know Act*, 9 B.U. J. SCI. & TECH. L. 156, 170-76 (2003) (proposing a model act requiring disclosure of GMOs).

2. There Will Be No End to the Amount of Information That Consumers Will Demand

The majority in *Amestoy* argued that:

Were consumer interest alone sufficient, there is no end to the information that states could require manufacturers to disclose about their production methods. For instance, with respect to cattle, consumers might reasonably evince an interest in knowing which grains herds were fed, with which medicines they were treated, or the age at which they were slaughtered.²⁴¹

Several responses are possible to this critique. First, one could respond—so what? If consumers reasonably want to know it, an aversion to clutter is not a sufficient justification to deny them the access to pertinent information.

Second, there is a limit to what consumers will demand. As discussed *supra* Part II, there are valid reasons why a consumer would want to know whether milk comes from rBGH-injected cows. As of yet, no bills have been proposed, no lawsuits have been filed, and no petitions have been drafted, to compel slaughter age labeling, as the *Amestoy* majority mused.²⁴² Thus, the concern of the *Amestoy* majority is likely a non-issue; consumers will clamor for labeling of facts that are actually important to them, not trivialities.

Third, one could argue that this concern has a positive externality: the threat of compelled labeling will prevent manufacturers from putting things in their products that consumers would not want to consume. For example, the threat of compelled labeling might prevent liverwurst makers from including “snouts and ears” in their product.²⁴³ The free flow of information, aided by mandatory labeling, will make sellers more responsive to the desires of consumers—hardly a bad thing.

241. *Amestoy*, 92 F.3d at 74.

242. *Id.*

243. *See* Community Nutrition Inst. v. Block, 749 F.2d 50, 57 n.4 (D.C. Cir. 1984) (Scalia, Circuit J.).

Frankfurter labeling need not include esophagus even in the statement of ingredients. The fastidious reader will be comforted to know, however, that snouts and ears cannot be included unless the product name contains the phrase “with variety meats” or “with by-products.” Not so, of course, with liver sausage (liverwurst), where one takes his chances.

Id. (internal citations omitted).

3. Voluntary Labeling Is Sufficient To Protect Consumer Interests

The *Amestoy* majority argued that the consumer's right to know can be vindicated by market forces—consumers “should exercise the power of their purses by buying products from manufacturers who voluntarily reveal it.”²⁴⁴ The case for voluntarily labeling is compelling.²⁴⁵ However, it ignores the ugly reality that industry vigorously fights voluntary labeling in order to protect its own interests.

One dairy in Maine, citing the consumer's right to know, labeled its milk, “Our farmer's pledge: no artificial hormones.”²⁴⁶ Monsanto sued, arguing that the dairy's label implied its milk was superior, an inference that harmed Monsanto's business. That lawsuit was settled,²⁴⁷ but one can imagine the chilling effect on voluntary labeling.

In Oregon, biotech corporations spent \$5.3 million to successfully defeat a ballot initiative that would have required mandatory labeling of GMOs.²⁴⁸ Proponents of the initiative were only able to raise \$200,000.²⁴⁹

In February 2007, Monsanto petitioned the Federal Trade Commission and the FDA to “stop deceptive milk labeling and advertising.”²⁵⁰ The request was denied.²⁵¹ However, since then, Monsanto has sought to protect itself from voluntary labeling by lobbying for state legislative bans.²⁵² In

244. *Amestoy*, 92 F.3d at 74.

245. See, e.g., Peters & Lambert, *supra* note 26, at 174 (arguing that voluntary labeling enhances consumer autonomy at lower costs than a mandatory labeling scheme).

246. Kristen Philipkoski, *Monsanto v. Oakhurst Dairy: Does Monsanto Corporation Have the Right to Keep You from Knowing the Contents of Your Food?* (originally published in *Wired Magazine*, 2003), http://reclaimdemocracy.org/corporate_speech/monsanto_oakhurst_wired.html.

247. “The case was settled in 2003 when Oakhurst agreed to include language on its labels that explains that the FDA had found no significant difference between milk from cows that were given the hormone, and those that did not get the hormone.” Stephen J. Hedges, “Hormone Free” Milk Churns Up Quite a Stir, *CHARLESTON GAZETTE*, Apr. 23, 2007, at P1D.

248. Clark Wolf, *Labeling Genetically Engineered Foods: Rights, Risks, Interests, and Institutional Options*, in *LABELING GENETICALLY MODIFIED FOOD: THE PHILOSOPHICAL AND LEGAL DEBATE* 178, 178-79 (Paul Weirich ed., 2007).

249. *Id.* at 179.

250. Press Release, Monsanto, Federal Agencies Advised of Misleading Milk Labels and Advertising (Apr. 3, 2007), http://www.organicconsumers.org/artman2/uploads/1/FDA_FTC_FINAL_2.pdf (last visited Oct. 30, 2009).

251. Kara Sissell, *FTC Refuses Monsanto's Request for Dairy Inquiry*, *CHEMICAL WK.*, Sept. 12, 2007, at 45.

252. On this, Judge Leval was prophetic. He stated that “certain states, no doubt influenced by the rBST lobby, will ‘not allow any labeling concerning rBST.’” *Int'l Dairy*

October 2007, the Pennsylvania Agriculture Department, at Monsanto's request, banned labeling milk as free from rBGH.²⁵³ However, in January 2008, "a bombardment of consumer emails, letters and calls" persuaded the Governor to intervene and reverse the ban before it went into effect.²⁵⁴ As of March 2008, bans were being considered in New Jersey, Ohio, Indiana, Kansas, Utah, Missouri, and Vermont.²⁵⁵ Thus, one can see that voluntary labeling is not a viable solution.

In August 2008, Monsanto agreed to sell its rBGH business to Eli Lilly.²⁵⁶ It remains to be seen whether Eli Lilly will continue Monsanto's aggressive campaign against voluntary labeling. What is clear, however, is that when hundreds of millions of dollars in profits are on the line,²⁵⁷ the power of the purse alone is not sufficient to vindicate the consumer's right to know.

4. Does It Pass the *Central Hudson* Test?

The amendment to the FDCA proposed by this Comment would likely be considered a restriction on commercial speech, since, in some cases, it would force manufacturers to "speak" when they would prefer to remain silent. As discussed *supra* Part III.C.2, restrictions on commercial speech must pass the *Central Hudson* test: "(1) the food labeling regulation must concern lawful activity and not be misleading; (2) the government's interest must be substantial; (3) the labeling law must directly serve the asserted interest; and (4) the labeling law must be no more extensive than necessary."²⁵⁸

Critics will argue that the proposed amendment would fail this test. However, as this Comment has laid out above, there are ample moral, ethical, religious, and health reasons why consumers might desire certain

Foods Ass'n v. Amestoy, 92 F.3d 67, 80 n.6 (2d Cir. 1996) (Leval, J., dissenting) (quoting Affidavit of Ben Cohen at 3-4).

253. Jane Akre, *Public Outcry Keeps Hormone Milk Labels in PA*, Jan. 19, 2008, <http://www.injuryboard.com/national-news/public-outcry-keeps-hormone-milk-labels-in-pa.aspx?googleid=29144>; see also Dan Shapley, *Pennsylvania Allows Hormone-Free Milk Labelling: Monsanto is Lobbying States to Restrict Labelling*, THE DAILY GREEN, Jan. 17, 2008, <http://www.thedailygreen.com/healthy-eating/eat-safe/hormone-free-milk-47011701>.

254. Akre, *supra* note 253.

255. Andrew Martin, *Fighting on a Battlefield the Size of a Milk Label*, N.Y. TIMES, Mar. 9, 2008, at BU-7.

256. *Daily Briefing*, ATLANTA JOURNAL-CONSTITUTION, Aug. 21, 2008, at 2B.

257. *Id.*

258. Int'l Dairy Foods Ass'n v. Amestoy, 92 F.3d 67, 72 (2d Cir. 1996) (citing *Central Hudson Gas & Elec. Corp. v. Pub. Serv. Comm'n*, 447 U.S. 557, 566 (1980)).

information to appear on a label.²⁵⁹ And, as the representative of the people, when consumer concerns are material and reasonable, the government can be said to have a substantial interest in mandating labeling. Even critics would likely agree that mandatory labeling would directly advance this interest. Further, if a mandatory labeling regulation is crafted reasonably, it should easily pass the fourth prong, which requires that the regulation be no more extensive than necessary. Therefore, it seems that the amendment to the FDCA proposed by this Comment would easily survive *Central Hudson* scrutiny.

VI. CONCLUSION

Under the current law, regulators need not, and generally do not, consider consumer interest as a factor in deciding what must go on a label. However, the consumer's right to know, which is rooted in the First Amendment, requires that this situation be rectified. Due to unfavorable jurisprudence in the courts of appeals, unsympathetic regulators, and Commerce Clause issues, consumer interest litigation is unlikely to rectify this problem. The best way to vindicate the consumer's right to know, therefore, is for Congress to amend the FDCA to require regulators to take into account the extent to which the labeling fails to reveal material facts that consumers reasonably desire to know.

Scientists will continue to develop more ways to manipulate food. These new technologies will continue to raise religious, moral, ethical, health, and safety issues. The consumer's right to know about his food will be an increasingly important issue. While mandatory labeling is often contrary to the interests of the food industry, the U.S. Constitution has made the choice for us—the First Amendment requires the government to protect the consumer's right to receive accurate, non-misleading information the consumer reasonably desires to know.

259. See *supra* Part II.B.1.