COMMENT

LABELING LIMBO: WHY GENETICALLY MODIFIED FOODS CONTINUE TO DUCK MANDATORY DISCLOSURE*

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I. INTRODUCTION

> "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 that control with a wholesome discretion, the remedy is not to take it from them, but to inform their discretion."
>
> Thomas Jefferson[1]

With advancements of science come implications of law, and genetic engineering is the quintessential example. The new millennium has already witnessed incredible new developments in genetics and biotechnology.[2] But each new development presents a comparable controversy. One associated controversy concerns the labeling of genetically modified foods, and it poses the following question: Should Americans be afforded the opportunity to make informed decisions concerning whether to consume genetically modified foods, or does the current U.S. regulatory framework provide sufficient and appropriate protection to consumers such that mandatory labeling is unnecessary and only amounts to constitutionally and administratively volatile consequences? As this loaded question may suggest, the answer to date is not pleasing to concerned citizens critical of genetically modified foods; the federal

1. MATT RIDLEY, GENOME: THE AUTOBIOGRAPHY OF A SPECIES IN 23 CHAPTERS 286 (2000).

2. On June 26, 2000, scientists announced the completion of a rough-draft map of the entire human genome. *Id.* at 6. In January 2001, two companies, Syngenta and Myriad Genetics, announced the completion of the first crop genome. Andrew Pollack & Carol Kaesuk Yoon, *Rice Genome Called a Crop Breakthrough*, N.Y. TIMES, Jan. 27, 2001, at A10.

government provides no mandatory labeling protection,[3] but with valid justification, as discussed in this Comment.

While humans have used selective breeding to alter the traits of crops and livestock for thousands of years, modern biotechnological discoveries now allow us to alter traits directly at the gene level through genetic engineering.[4] An in-depth scientific discussion of genetic engineering is beyond the scope of this Comment, but it is important to recognize the end result—a genetically modified ("GM") organism.[5]

Much of modern food is genetically modified in some way. Up to forty-five percent of the major crops grown in the United States are genetically modified,[6] including soybeans, corn, and canola, which are used in many food products available in U.S. supermarkets.[7] Furthermore, livestock may be grown with growth hormones or fed GM foods in an attempt to increase their size, production, or nutritional qualities.[8] With such a significant portion of U.S. food being derived from some form of genetic modification, public debate over the related risks and benefits is equally significant.[9]

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3. Statement of Policy: Foods Derived from New Plant Varieties, 57 Fed. Reg. 22,984 (May 29, 1992) [hereinafter 1992 Statement of Policy] (refusing to mandate labeling).

4. SHELDON KRIMSKY & ROGER P. WRUBEL, AGRICULTURAL BIOTECHNOLOGY AND THE ENVIRONMENT: SCIENCE, POLICY, AND SOCIAL ISSUES 9 (1996).

5. Throughout this Comment, "GM" refers to the human alteration of the genotype of an organism, particularly food, through mutagenic techniques or recombinant DNA ("rDNA") techniques, such as hybridization, chemical or radiation-induced mutagenesis, cell or protoplast fusion, embryo rescue, somaclonal variation, or other methods not occurring naturally that amount to the formation of an organism. *See* 1992 Statement of Policy, *supra* note 3, at 22,985–22,986 (describing these techniques). At the most basic level, rDNA techniques involve inserting "pieces or strands of foreign genetic material [into an organism] in an effort to change or supplement one or more of the [organism's] traits." Sophia Kolehmainen, *Precaution Before Profits: An Overview of Issues in Genetically Engineered Food and Crops*, 20 VA. ENVTL. L.J. 267, 269–72 (2001) (detailing the process involved in genetically engineering plants and crops).

6. Lara Beth Winn, *Special Labeling Requirements for Genetically Engineered Food: How Sound Are the Analytical Frameworks Used by FDA and Food Producers?*, 54 FOOD & DRUG L.J. 667, 667 (1999).

7. *See* Kolehmainen, *supra* note 5, at 269–70 (reporting that GM crops constitute more than sixty million acres of U.S. farmland, and that these crops are used in products ranging from "Kellogg's and General Mills cereals to Heinz ketchup, Carnation chocolate milk, Coca-Cola, and Beech Nut baby food").

8. *See, e.g.*, Int'l Dairy Foods Ass'n v. Amestoy, 92 F.3d 67, 69 (2d Cir. 1996) (describing the FDA-approved use of recombinant Bovine Somatotropin ("rBST"), a synthetic growth hormone that increases milk production by cows).

9. For instance, during the last few congressional sessions, numerous bills directed at governing GM products have been proposed to the U.S. Congress, all of which have failed to gain approval. *See* Pew Initiative on Food and Biotechnology, Legislation Tracker 2003, *at* http://pewagbiotech.org/resources/factsheets/legislation/ (last visited Mar. 4, 2005) (listing bills proposed at both the state and federal levels); *see also infra* Part IV.C

The risks and benefits associated with GM foods are divisive, encompassing human, environmental, and economic issues.[10] But a closer look at the GM-food debate reveals more than risk-benefit issues. A closer look reveals (1) emotionally charged consumers demanding mandatory labeling despite the absence of a legitimate risk to human health;[11] (2) an arguably efficient and sufficiently protective federal regulatory scheme;[12] (3) a deeply rooted Food and Drug Administration (FDA) policy position that requires more than consumer demand to mandate labeling under its statutory authority;[13] and (4) various constitutionally volatile and statutorily preemptive hurdles facing legislatively compelled labeling.[14] Consumers and public interest groups enraged by the revelations just described have mounted attacks on the U.S. nonmandatory labeling policy through legislative lobbying, litigation, and voter referendums, though with little success.[15] Despite a lack of success, attempts to effect change continue, attempts that breed this Comment's underlying thesis: Consumers are unaware of their protections and unaware of their alternatives.

This Comment aims to ease consumers' fears by informing them of their existing protections and alternatives and helping them understand the limitations that mandatory GM-food labeling faces. Part II sets the stage for the GM-food-labeling debate by introducing the competing arguments and elaborating on the risks and benefits associated with GM foods. Part III outlines the regulatory framework currently used in the United States to govern GM foods and provide consumer protection. Part IV discusses various hurdles unlikely to be overcome by

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(analyzing the most recent legislative proposals of the 108th congressional session).

10. *See* Margaret Rosso Grossman, *Biotechnology, Property Rights and the Environment*, 50 AM. J. COMP. L. 215, 217–23 (Supp. 2002) (outlining the risks and benefits associated with GM foods); Kolehmainen, *supra* note 5, at 272–83 (same); Carie-Megan Flood, Note, *Pollen Drift and Potential Causes of Action*, 28 J. CORP. L. 473, 477–82 (2003) (same); *see also infra* Part II.B–C (elaborating on the risks and benefits).

11. *See infra* Part IV.A–B (discussing consumers' limited rights to know what is in the products they eat).

12. *See infra* Part III (detailing the role of federal agencies in the regulation of GM foods).

13. *See infra* Part III.C (elaborating on the FDA's current position regarding the labeling of GM foods).

14. *See infra* Part IV (reviewing various impediments to compelled GM-food labeling).

15. *See, e.g.*, Secretary of State, State of Oregon, Ballot Measure Statement, Measure 27 (Sept. 5, 2002) (attempting to achieve voter approval for mandatory labeling of GM products in Oregon); The Ctr. for Food Safety, Legal Actions, *at* http://www.centerforfoodsafety.org/legal_acti.cfm (last visited Mar. 4, 2005) (listing recent GM-food litigation). See *infra* Part IV for a complete discussion of these activities.

legislatures attempting to mandate labeling of GM foods, absent sufficient evidence of risk to human health. Finally, Part V concludes that the current U.S. regulatory framework is sufficient to protect against potential risks and highlights other avenues of protection available to consumers. In addition, Part V proposes that to inform the discretion of the people properly, as Thomas Jefferson advised, the government and the GM-food industry must do more to ease consumer fear of GM foods through advertising and education.

II. WEIGHING THE RISKS AND BENEFITS OF GENETIC MODIFICATION

A. Setting the Stage of the Labeling Debate

Before analyzing GM-food regulation and labeling, it is important to understand the breadth and depth of the GM-food debate. The debate involves scientists and activists, consumers and politicians, farmers and manufacturers, international and intranational commercial entities, all branches of government, and numerous nongovernmental public interest organizations.[16] Supporters, primarily the federal government and the GM-food industry, argue that GM foods are safe, that consumer fear is unfounded and based on speculative risks, and that labeling is unnecessary and perhaps more costly than beneficial.[17] Critics argue that the safety of GM foods is too uncertain, that no long-term studies have been done, that the benefits do not outweigh the potential environmental and public health risks, and that individuals have a right to know whether their food is genetically modified.[18] Public sentiment regarding these competing positions seems to favor GM-food critics, but why?

Negative public sentiment regarding GM foods likely relates to uncertainty and lack of knowledge.[19] Even when consumers do

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16. *See* Julie Teel, *Rapporteur's Summary of the Deliberative Forum: Have NGOs Distorted or Illuminated the Benefits and Hazards of Genetically Modified Organisms?*, 13 COLO. J. INT'L ENVTL. L. & POL'Y 137, 138 (2002) ("The [GM-food] debate has environmental, public health, trade, intellectual property, socio-economic, cultural, and ethical dimensions that transcend political boundaries.").

17. *Id.* at 137–38; *see also infra* Part III.C.4 (detailing the reasoning behind current FDA policy).

18. *See* Teel, *supra* note 16, at 137, 140–44 ("Largely, the debate between critics and supporters of [GM foods] is fueled by divergent views on risk perception, assessment, and management.").

19. Kolehmainen, *supra* note 5, at 275–77 (suggesting that unpredictability causes a great deal of concern about GM crops and citing various studies designed to increase consumer knowledge).

receive information about GM foods, they are vulnerable to the high-impact marketing of public interest groups and "media sensationalism."[20] Combining this lack (or tainted form) of GM-food knowledge with a lack of GM-food labeling in the United States leaves consumers vulnerable.[21] Without doing much to support the current regulatory policy or even supplant the public's lack of knowledge concerning GM foods, the federal government and the GM-food industry have done little to respond to their critics.[22] On the other hand, many significantly persuasive public interest organizations have united to influence the regulation, development, and marketing of GM foods, and more importantly, the FDA's current approach to labeling.[23] These organizations include: Mothers for Natural Law,[24] The Campaign to Label Genetically Engineered Foods,[25] The Center for Food Safety,[26] the Union of Concerned Scientists,[27] the Genetically Engineered Food Alert,[28] the Council for Responsible

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20. *See* Charles A. Deacon & Emilie K. Paterson, *Emerging Trends in Biotechnology Litigation*, 20 REV. LITIG. 589, 599 (2001) (arguing that incomplete consumer alert stories about GM products give consumers a fear of victimization that leads to increased litigation).

21. *See* Kolehmainen, *supra* note 5, at 277.

22. *See* Teel, *supra* note 16, at 137 (identifying the lack of an adequate government response to the public's concerns).

23. *See* Kolehmainen, *supra* note 5, at 275 (listing nonprofit and advocacy organizations collaborating to inform the public about GM foods); *see also* Emily Marden, *Risk and Regulation: U.S. Regulatory Policy on Genetically Modified Food and Agriculture*, 44 B.C. L. REV. 733, 753–55 (2003) (same).

24. Mothers for Natural Law promotes "rigorous pre-market safety testing, mandatory labeling and a moratorium on [GM] foods." *See* Mothers for Natural Law, About Mothers for Natural Law, *at* http://www.safe-food.org/-campaign/about.html (last visited Mar. 4, 2005). In 1998, the group initiated a petition drive calling for mandatory labeling of GM foods, which amassed nearly 500,000 signatures, many from prominent figures and corporations opposed to GM foods. *Id.*

25. The Campaign focuses on lobbying Congress and the President to pass legislation requiring GM-food labels. *See* The Campaign to Label Genetically Engineered Foods, About Us, *at* http://www.thecampaign.org/aboutus.php (last visited Mar. 4, 2005).

26. The Center for Food Safety works to protect human health and the environment from harmful food production techniques and to guide policymakers in their food safety decisions by engaging in legal, scientific, and grassroots initiatives. *See* The Ctr. for Food Safety, About Us, *at* http://www.centerforfoodsafety.org/about_us.cfm (last visited Mar. 4, 2005).

27. This alliance of more than 100,000 citizens and scientists uses scientific expertise and citizen advocacy to disseminate scientific findings publicly in hopes of altering policy at all levels. *See* Union of Concerned Scientists, About UCS, *at* http://www.ucsusa.org/ucs/about (last visited Mar. 4, 2005).

28. The Genetically Engineered Food Alert is "a coalition of seven organizations united in their commitment to testing and labeling genetically engineered food." *See* Genetically Engineered Food Alert Campaign Ctr., Who Is Genetically Engineered Food Alert?, *at* http://www.gefoodalert.org/takeaction/html/whoisgefoodalert.htm (last visited Mar. 4, 2005).

Genetics,[29] Greenpeace,[30] and many others.[31] With this support, it seems GM-food critics are winning the marketing battle within the debate, which has forced legislators to address the moral, legal, and economic implications involved.[32] From litigation[33] to voter referendums,[34] debate over GM foods is not going away. Public fear of GM food remains and perhaps grows, but is this fear warranted?

B. Benefits of Genetic Engineering

To appreciate fully the GM-food-labeling debate, it is important to recognize the numerous benefits that genetic engineering technology provides. In general, genetic engineering provides economic advantages to biotech seed manufacturers and farmers by improving crop resistance to herbicides and pesticides, and it provides great social and medical advantages to poor countries and malnourished individuals by manipulating the expression of specific crop traits.[35]

Genetically engineering crops for pesticide resistance is a primary example of a GM method used by GM-seed manufacturers. This process often involves using the naturally occurring soil bacterium Bacillus thuringiensis ("B.t."), which produces a protein that acts as a natural insecticide that farmers commonly spray on crops to prevent insect damage.[36] By inserting the genetic material that triggers B.t. production directly into the crop's genetic code, genetic engineers create crops with an

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29. *See* Council for Responsible Genetics, About CRG, *at* http://www.gene-watch.org/pages/about.html (last visited Mar. 4, 2005).

30. *See* The True Food Network, About Us, *at* http://www.truefoodnow.org/aboutus/ (last visited Mar. 4, 2005) (explaining the Network's role as part of Greenpeace's Genetic Engineering Campaign before becoming an independent organization in 2003).

31. *See generally* Teel, *supra* note 16, at 162–66 (surveying the impact nongovernmental organizations have on the GM-food debate and providing a table of websites of these organizations).

32. On July 25, 2003, six bills relating to GM organisms were introduced in the House in the 108th Congress. The bills as proposed can be found at http://thomas.loc.gov. See *infra* Part IV.C for a discussion of the relevant bills.

33. *See, e.g.*, Alliance for Bio-Integrity v. Shalala, 116 F. Supp. 2d 166, 181 (D.D.C. 2000) (dismissing claims by plaintiffs challenging the FDA's 1992 Statement of Policy); *see also infra* Part IV.B (analyzing this litigation).

34. *See* Secretary of State, State of Oregon, Ballot Measure Statement, Measure 27 (Sept. 5, 2002) (seeking to require labeling of GM foods); *see also infra* Part IV.C (summarizing the Oregon voter referendum).

35. *See* Kolehmainen, *supra* note 5, at 272–73 (detailing these benefits); Grossman, *supra* note 10, at 218 (same).

36. Kolehmainen, *supra* note 5, at 273.

"internalized insecticide," thereby preventing farmers from having to use more expensive spray versions on their crops.[37]

Using a similar technique, the biotech company Monsanto markets Roundup Ready crops (including corn, soy, and canola) that are genetically engineered to resist the damaging effects of the herbicide Roundup.[38] Roundup is an herbicide sprayed to kill weeds, but it also has the potential to kill surrounding crops in the process.[39] Able to resist the herbicide, Roundup Ready crops prevent crop damage and increase yields, resulting in temporal and economic advantages for farmers.[40] Furthermore, GM crops such as Roundup Ready crops protect water supplies from chemical run-off and may ease consumer health concerns associated with eating insecticide-treated foods.[41]

Another form of genetic engineering with numerous benefits involves directly manipulating the gene expression of crops. This method increases world food supplies by improving the hardiness of crops and increases food shelf life by extending ripening periods.[42] Moreover, this form of genetic engineering makes certain foods healthier and more nutritious by supplementing the foods with additional vitamins and nutrients that are lacking in the foods' unaltered forms.[43]

But, as already stated, these benefits are not without consequence. And where the federal government and GM food industry have failed to increase public support for and awareness of these benefits, GM-food critics have rushed to expose potential risks, whether supported by evidence or not.[44] The problem for GM-food supporters is that legitimate evidence of risk is not required for the formation of legitimate fear; arguably, genuine public fear can arise without any basis at all and can shadow the benefits that GM foods offer. On the contrary, the problem for GM-food critics is that this shadowing effect alone, while enough to increase public demand for a right to know, is not sufficient for

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37. *Id.* at 273–74.

38. *See id.* at 273; *see also* Flood, *supra* note 10, at 477–78.

39. Flood, *supra* note 10, at 477–78.

40. *Id.* at 478.

41. *Id.*

42. *See* Kolehmainen, *supra* note 5, at 274 (describing the supposedly extended shelf life and improved flavor of the FLAVR SAVR tomato engineered by Calgene).

43. *See* Flood, *supra* note 10, at 479 (discussing the advantages that "nutritionally enhanced" food crops provide to third world countries that rely on a single crop as their primary source of food); Grossman, *supra* note 10, at 218 (observing the nutritional benefits of GM "golden rice that produces [beta]-carotene, a precursor to the vitamin A needed to preserve vision in young Asian children whose food staple is rice").

44. *See supra* notes 22–32 and accompanying text.

mandatory labeling; the courts and statutes demand legitimate evidence of risk.[45]

C. Exposing the Public's Fear of GM Foods

Like the benefits above, fears of GM foods relate to the environment, the economy, and human safety, regardless of whether evidence exists to validate these fears.[46] Researchers have performed numerous studies to determine the potential threats that GM foods pose to human safety, many of which indicate that GM foods are safer than perceived.[47] However, one commentator contends that "[t]hese experiments show that attempts at genetic modification of plants are truly experiments in the sense that results can be predicted but never guaranteed."[48] These inconsistencies are corroborated by studies investigating the potential ill effects genetic modification may have on wildlife—some find harm, others don't.[49] What is certain, however, is that no studies have shown sufficient evidence of risk to *human* health to necessitate a shift in current labeling policy.[50] Nevertheless, it is important to understand consumer fear and

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45. *See, e.g.*, 1992 Statement of Policy, *supra* note 3, at 22,991 (finding no legitimate evidence of human health risk sufficient to require labeling of GM-foods as a class under the FDA's statutorily granted authority); Int'l Dairy Foods Ass'n v. Amestoy, 92 F.3d 67, 73–74 (2d Cir. 1996) (holding that consumer curiosity alone is not enough to allow a state to compel dairy manufacturers to label their products—a "real" harm must exist); Alliance for Bio-Integrity v. Shalala, 116 F. Supp. 2d 166, 179 (D.D.C. 2000) (suggesting that the FDA does not have the authority to mandate labeling based solely on consumer demand).

46. *See generally* Flood, *supra* note 10, at 479–80 (discussing the potential risks of genetic engineering); Kolehmainen, *supra* note 5, at 275–81 (same); Amelia P. Nelson, Note, *Legal Liability in the Wake of* StarLink™*: Who Pays in the End?*, 7 DRAKE J. AGRIC. L. 241, 245–50 (2002) (same). Although the risks and concerns giving rise to the public's fear of GM foods encompass many facets, this Comment intends to elucidate only the potential threats to human safety, thereby relating to the overall issue of whether GM foods should or even can be labeled for the benefit of individual consumers.

47. *See, e.g.*, Steven H. Yoshida, *The Safety of Genetically Modified Soybeans: Evidence and Regulation*, 55 FOOD & DRUG L.J. 193, 206 (2000) (reviewing and analyzing published data from GM-soybean studies and concluding that GM soybeans are equivalent to non-GM soybeans).

48. Kolehmainen, *supra* note 5, at 276–77 (citing a 1999 study in which rats were fed GM potatoes and experienced stunted growth and depressed immune systems).

49. *See* Flood, *supra* note 10, at 479 (reporting that one study found that pollen from GM B.t. corn could kill the larvae of Monarch butterflies, but that a counter study by the biotech industry found that the risks to Monarch butterflies were minimal); *see also* Thomas P. Redick & Christina G. Bernstein, *Nuisance Law and the Prevention of "Genetic Pollution": Declining a Dinner Date with Damocles*, 30 ENVTL. L. REP. 10,328, 10,331 (2000) (discussing the same studies).

50. *See infra* note 144 and accompanying text (reporting the FDA's continuing position and the American Medical Association's supporting position that no scientific evidence exists to mandate labeling of GM foods as a whole).

whether fear or curiosity alone should be sufficient to require GM-food labels.

1. Human Health Risks. Risks to human health form the backbone of the call to label GM foods. To begin, scientists argue that herbicide-resistant GM crops could cross-pollinate with weeds, resulting in a hardier species of "superweeds," and that pests could become resistant to the B.t. contained in GM crops, creating a species of "superbugs."[51] To handle these super species, farmers would have to use chemicals with increased strength and toxicity, presumably creating a vicious cycle of increasingly stronger chemicals and increasingly hardier weeds and bugs.[52] Arguably, administering stronger chemicals to crops would increase the toxicity of the crops humans eat.[53]

Critics also argue that the use of antibiotic resistant "marker genes" in the genetic modification process may exacerbate the already mounting problem of resistance to antibiotics in humans and animals.[54] Antibiotic resistant genes are inserted into GM plants to mark the success of a genetic transfer, but the resistant trait can similarly transfer to the bacteria existing within the mouths and intestines of humans and animals consuming and digesting these GM plants.[55] Exposing essential bacteria to antibiotic resistant genes in this way may significantly inhibit the ability to control disease.[56]

Uncontrolled exposure to allergens is another human health risk posed by GM foods. In 1996, researchers in Nebraska reported that transferring foreign genetic material with allergenic traits to other GM foods can cause the newly created GM food to take on those allergenic properties.[57] Considering the serious threat that food allergies present to many humans, this

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51. Flood, *supra* note 10, at 479–80 (reporting these risks).

52. *See id.*

53. *Cf. id.* (discussing the environmental risks of this cycle).

54. Kolehmainen, *supra* note 5, at 277. In order to determine whether a foreign gene has successfully entered a recipient cell through rDNA transfer techniques, scientists add another foreign element to the recipient cell known as a "marker gene." *Id.* Scientists typically use a bacterial gene for antibiotic resistance as the marker gene because it allows them to expose a recipient cell to an antibiotic; if the recipient cell survives, the genetic transfer is deemed successful. *Id.*

55. *Id.*

56. *Id.*

57. Julie A. Nordlee et al., *Identification of a Brazil-Nut Allergen in Transgenic Soybeans*, 334 NEW ENG. J. MED. 688, 691 (1996). The researchers investigated the allergenicity of a soybean that was genetically modified for improved nutritional quality by inserting a foreign protein taken from a brazil nut. *Id.* The researchers determined that individuals allergic to brazil nuts would also be allergic to the GM soybean. *Id.*

risk is particularly frightening.[58] Usually, consumers allergic to certain substances can protect themselves by monitoring the ingredients in the foods they eat through food labels.[59] Without GM-food labels, however, it is possible that consumers may unknowingly ingest GM foods to which they are allergic because they have no ability to monitor a label for adverse GM ingredients.[60]

An example of how potentially threatening GM foods can reach innocent consumers is evidenced by the recent StarLink™ corn seed disaster.[61] StarLink, a GM corn seed manufactured by Aventis CropScience, is genetically modified with the Cry9C protein to produce an internal insecticide.[62] Because Cry9C may cause allergic reactions in humans, the Environmental Protection Agency (EPA) did not approve the corn for human consumption and instead limited its use to animal feed and nonfood industrial purposes.[63] The EPA set up a protective protocol intended to prevent StarLink corn from getting into the human food supply, but despite this protocol, traces of StarLink wound up in numerous human food products containing corn.[64] Interestingly, a great debate existed (and continues to exist) concerning whether the Cry9C protein contained in StarLink corn could truly trigger an allergic reaction in humans.[65] In fact, no actual cases of personal injury have been identified,[66] and the Centers for Disease Control and Prevention (CDC) found that among those individual consumers claiming allergic injury in a nine million dollar settlement arising out of the StarLink saga,

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58. *See* Kolehmainen, *supra* note 5, at 278 ("Eight percent of children in the United States suffer from food allergies, with symptoms ranging from mild unpleasantness to sudden death.").

59. *Id.*

60. *See id.* (conceiving problems facing consumers with allergies that have no GM-food label to monitor).

61. For a detailed review of the StarLink saga, see D.L. Uchtmann, StarLink™—*A Case Study of Agricultural Biotechnology Regulation*, 7 DRAKE J. AGRIC. L. 159 (2002).

62. Deacon & Paterson, *supra* note 20, at 592–93.

63. *Id.* at 592; Uchtmann, *supra* note 61, at 161–62; *see infra* Part III.B (discussing the EPA's regulatory role in approving GM products).

64. Uchtmann, *supra* note 61, at 162. The EPA's protective protocol required a buffer zone of 660 feet to be placed around StarLink corn fields to prevent pollen drift from StarLink plants, and corn grown within the buffer zone was also limited to nonhuman food uses. *Id.* Nevertheless, StarLink corn "co-mingled with large quantities of other corn in the harvesting, transportation, storage and marketing processes," and Cry9C DNA was eventually found in foods used for human consumption, such as taco shells. *Id.*

65. *Id.*

66. Thomas P. Redick, *Biopharming, Biosafety, and Billion Dollar Debacles: Preventing Liability for Biotech Crops*, 8 DRAKE J. AGRIC. L. 115, 129 (2003) (reporting a lack of human allergic reaction to StarLink corn).

not a single one had physical evidence to prove an allergic reaction to the StarLink corn.[67] However, even if StarLink or any other GM food is not found to cause allergic reactions, the labeling debate is not necessarily moot. The controversy survives on the individual's right to know and right to protect himself from *potentially* harmful GM products. This situation begs the question: Is personal autonomy legally sufficient to mandate GM-food labels?[68]

2. Economic Risks in the Labeling Debate. Not only does the StarLink saga evidence how a *potential* human allergen can reach consumers without warning, it also exemplifies the economic damage that can result.[69] For instance, the European Union (EU) refuses to accept corn shipped from the United States because the shipments may contain StarLink or some other GM ingredient not yet approved in the EU.[70] In the past two years, "The U.S. grain industry has lost virtually all of the $200 million annual export market for sale of corn to the EU."[71] Even starving nations refuse to accept GM foods produced in the United States because of a lack of labeling.[72] Obviously, the U.S. GM-food policy affects import and export economics.

GM-food risks come in many forms, all of which create public fear and raise the call for mandatory labeling, regardless of the existence of risk to human health. Unfortunately for GM-food critics, an established risk to human health is the key to labeling in the United States, and to date that key simply has not been found.[73] As the following Parts of this Comment illustrate, a lack

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67. *Id.* at 147 (citing Michael Howie, *CDC Reports StarLink Not Cause of Allergic Reactions*, FEEDSTUFFS, June 18, 2001, at 1). Even without sufficient evidence, these settlements indicate that personal injury and economic loss will be compensated. *Id.* at 129.

68. *See infra* Part IV (answering "no" to this question).

69. For a general discussion of the economic implications surrounding GM organisms, see Redick, *supra* note 66, at 116–17, 127–30.

70. Redick & Bernstein, *supra* note 49, at 10,332. Essentially, the EU has no way to ensure that non-GM corn has not been contaminated or cross-pollinated with GM corn because the United States does not mandate labeling of GM corn. *Id.*

71. Richard A. Repp, Comment, *Biotech Pollution: Assessing Liability for Genetically Modified Crop Production and Genetic Drift*, 36 IDAHO L. REV. 585, 593 (2000). Discussion of the EU's GM-food labeling approach under the international consortium on food safety (the Codex Alimentarius) is beyond the scope of this Comment. For such a discussion, see generally A. Bryan Endres, *"GMO": Genetically Modified Organism or Gigantic Monetary Obligation? The Liability Schemes for GMO Damage in the United States and the European Union*, 22 LOY. L.A. INT'L & COMP. L. REV. 453 (2000).

72. *See* James Lamont, *Zambia Turns Away GM Food Aid for Its Starving*, FIN. TIMES, Aug. 19, 2002, at 4 (reporting Zambia, Mozambique, and Zimbabwe's adamant refusal to accept U.S. food aid because of public health and safety concerns).

73. *See infra* Part III.C.4 (discussing the FDA's findings).

of human health risk also typifies numerous other hurdles that continue to prevent the successful passage of a mandatory labeling law.

III. FEDERAL REGULATION OF GM FOODS: A COORDINATED FRAMEWORK

The following discussion examines GM-food regulation in the United States. Although much of this regulation does not pertain to labeling directly, it is important to outline how the entire regulatory framework provides oversight and protection to consumers, thereby undermining the need for labeling.

In 1986, the Office of Science and Technology Policy (OSTP), an executive agency, issued the Coordinated Framework for Regulation of Biotechnology ("Coordinated Framework"), which established the regulatory structure that currently governs all GM products in the United States.[74] Instead of enacting specific regulatory measures to deal with biotechnology, the Coordinated Framework proclaimed that existing federal statutory authority and regulation was sufficient to deal with the emerging risks and concerns associated with genetic engineering.[75] Thus, GM products are regulated in a piecemeal fashion by the EPA, the FDA, and the United States Department of Agriculture (USDA).[76]

After the Coordinated Framework was established, the OSTP issued a policy statement defining the scope, direction, and implementation of responsibility within the regulatory scheme.[77] The statement emphasized a science-based risk assessment of GM-product governance on the grounds that such an approach "is scientifically sound, properly protects public health and the environment against risk, and avoids hindering safe innovations."[78] Consumers may find solace under this approach

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74. Coordinated Framework for Regulation of Biotechnology, 51 Fed. Reg. 23,302 (proposed June 26, 1986).

75. *Id.* at 23,302–23,303; *see also* Marden, *supra* note 23, at 738–39 (chronicling the Coordinated Framework's design).

76. Coordinated Framework for Regulation of Biotechnology, 51 Fed. Reg. at 23,303; *see also* Endres, *supra* note 71, at 459 ("In contrast to the European Union's pro-active approach to [GM-food] regulation and liability issues, no single federal statute in the United States regulates [GM foods] directly."); U.S. Regulatory Agencies Unified Biotechnology Website, Welcome, *at* http://usbiotechreg.nbii.gov/ (last visited Mar. 4, 2005).

77. Exercise of Federal Oversight Within Scope of Statutory Authority: Planned Introductions of Biotechnology Products into the Environment, 57 Fed. Reg. 6753 (proposed Feb. 27, 1992) [hereinafter Exercise of Federal Oversight]; *see also* Marden, *supra* note 23, at 740 (describing implementation of the Coordinated Framework).

78. Exercise of Federal Oversight, *supra* note 77, at 6755; *see also* Marden, *supra* note 23, at 741–42. The scientific principles listed in the Oversight document are not

because, in assuring that the most current information is available to inform regulatory decisions, U.S. regulatory agencies (and even GM-product developers) rely on peer-reviewed scientific literature, the National Academy of Sciences and other scientific entities, public meetings, meetings of scientists addressing specific issues and products, and other forms of scientific advisory panels.[79] As detailed below, each agency within the Coordinated Framework governs GM foods through different authority and with separately enacted regulations.

A. USDA Regulation

The USDA, acting through the Animal and Plant Health Inspection Service (APHIS), regulates development and field testing of GM plants and other organisms under the newly enacted Plant Protection Act.[80] Before a new GM crop can enter commerce, APHIS regulations require a field testing permit or, if an exemption applies, prerelease notification and review.[81] Prior to field testing, APHIS evaluates the environmental impact of the GM crop.[82] Then, if field testing results in no adverse effects (usually determined after several years of review), a GM crop developer can petition APHIS for "nonregulated status," which allows the crop to enter the market.[83] Although USDA regulation does not directly involve labeling, it does ensure that consumers and the environment are provided oversight protection against adverse effects of new GM crops.[84]

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formal authority, but they do serve to guide federal agencies in their regulation. *Id.* at 742 (listing the five principles stated in Exercise of Federal Oversight).

79. *See* Sally L. McCammon, *Ensuring Safe Food*, ECON. PERSP., May 2002, at 9, 11 (emphasizing use of this science-based approach), *at* http://usinfo.state.gov/journals/ites/0502/ijee/ijee0502.pdf. This Comment does not address another form of consumer concern known as the Capture Thesis, which posits that regulators like the FDA, EPA, and USDA are improperly influenced by those they are supposed to regulate, such as food manufacturers. *See* Steven P. Croley, *Public Interested Regulation*, 28 FLA. ST. U. L. REV. 7, 12–13 (2000).

80. Agricultural Risk Protection Act of 2000, Title IV—Plant Protection Act, Pub. L. No. 106-224, 114 Stat. 358, 438 (codified as amended at 7 U.S.C. §§ 7701–7772 (2000 & Supp. II 2002)); McCammon, *supra* note 79, at 10. Initially, the USDA derived its authority to prohibit or restrict movement of plants, plant products, biological control organisms, and other products from the Federal Plant Pest Act, 7 U.S.C. §§ 150aa–150jj (repealed 2000), and the Plant Quarantine Act, 7 U.S.C. §§ 151–164a, 166–167 (repealed 2000); the new law continues this authority. 7 U.S.C. § 7712; Grossman, *supra* note 10, at 224. Furthermore, those regulations enacted by the USDA to govern GM products continue to do so until superseded. 7 U.S.C. §§ 7754, 7758(c); Grossman, *supra* note 10, at 224.

81. Grossman, *supra* note 10, at 224.

82. *Id.*

83. *Id.*; *see also* McCammon, *supra* note 79, at 10.

84. Grossman, *supra* note 10, at 224.

B. EPA Regulation

The EPA regulates GM products through the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA),[85] the Toxic Substance Control Act (TSCA),[86] and the Federal Food, Drug, and Cosmetic Act (FFDCA).[87]

Under the TSCA, the EPA determines whether chemical substances—including micro-organisms—present unreasonable health or environmental risks, although the TSCA's application to GM products is limited.[88]

Under the FFDCA, the EPA governs pesticide residues in or on food.[89] The EPA must establish tolerance levels for these pesticide residues and ensure "a reasonable certainty that no harm will result from . . . all anticipated dietary . . . and other exposures."[90] The EPA may exempt products from the tolerance requirement, and in fact most GM foods are exempted when the agency concludes that the foods do not endanger public health or that there is reasonable certainty that dietary exposure to the GM foods will not cause harm.[91] Thus, consumers can be confident that GM pesticide products have been reviewed for safety and efficacy by the EPA, even if this regulation does not provide consumers with knowledge regarding whether they are eating GM foods.[92]

The EPA relies most heavily on FIFRA, which provides the agency with authority to regulate "any plants with pesticide properties, or microorganisms intended for use as pesticides."[93] FIFRA requires EPA registration of GM products with pesticide properties, whereby the EPA "'balance[s] the potential human and environmental risks against the potential benefits to society'" in determining whether to grant a field testing permit for the governed GM product.[94] Registration allows the EPA to

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85. 7 U.S.C. §§ 136–136y.

86. 15 U.S.C. §§ 2601–2692.

87. 21 U.S.C. §§ 301–397; McCammon, *supra* note 79, at 10.

88. Grossman, *supra* note 10, at 224–25 & n.70.

89. 21 U.S.C. § 321(q)(2). This includes plants, such as B.t. corn, inserted with genetic materials that result in the expression of pesticide traits. Endres, *supra* note 71, at 480.

90. 21 U.S.C. § 346a(c)(A)(ii); Grossman, *supra* note 10, at 225.

91. Grossman, *supra* note 10, at 225 (explaining the EPA's exemption standard).

92. Endres, *supra* note 71, at 480.

93. *Id.*; 7 U.S.C. §§ 136(b), 136a. "'[P]esticide' is defined broadly to include any substance 'intended for preventing, destroying, repelling, or mitigating any pest' or 'intended for use as a plant regulator, defoliant, or desiccant.'" Marden, *supra* note 23, at 776 (quoting 7 U.S.C. § 136(u)).

94. Endres, *supra* note 71, at 480 (quoting Mary Jane Angelo, *Genetically*

collect data on the human and environmental effects of the GM product in order to establish proper labeling of the product (i.e., what it can and cannot be used for) prior to its entrance into the market.[95] Thus, almost all GM foods containing pesticide properties (e.g., StarLink corn seed) must undergo registration and labeling according to EPA guidelines.[96]

Admittedly, while FIFRA's regulations provide consumers and farmers with some security, the recent StarLink saga indicates that the system can break down when manufacturers act negligently with regard to EPA guidelines.[97] StarLink also indicates, however, that in most instances tort law can fill gaps in consumer protection resulting from manufacturer negligence by forcing manufacturers to abide by regulations through liability and large damage settlements. For instance, despite the fact that no individual consumer could provide evidence of actual allergic injury in the StarLink saga, the seed manufacturer still provided compensation to those individual claimants in the form of a nine million dollar settlement.[98] This indicates that even when consumers have no legal ground upon which to stand, personal injury will be compensated.[99] In this way, tort law forces manufacturers to adjust their behavior to avoid liability resulting from a breakdown in FIFRA protection.[100]

C. FDA Regulation

The FDA is the agency most directly charged with assuring GM-food safety.[101] The FDA's primary authority to ensure food

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Engineered Plant Pesticides: Recent Developments in the EPA's Regulation of Biotechnology, 7 FLA. J.L. & PUB. POL'Y 257, 264 (1996)); 7 U.S.C. § 136a. The EPA standards require GM-product registrants "to submit extensive information on the pesticide, as well as its environmental fate, potential toxicity to humans and other animals, and its potential for ecological disruption." Marden, *supra* note 23, at 776–77; *see* 40 C.F.R. §§ 152.80–.119 (2004) (stating the EPA pesticide regulations).

95. Grossman, *supra* note 10, at 225; *see supra* notes 63–64 and accompanying text (noting the labeling of StarLink corn).

96. Grossman, *supra* note 10, at 225.

97. *See supra* Part II.C.1 (introducing the StarLink saga). StarLink was deemed a pesticide by the EPA, which triggered regulation under FIFRA. *See In re* StarLink Corn Prods. Liab. Litig., 212 F. Supp. 2d 828, 833–34 (N.D. Ill. 2002) (analyzing FIFRA governance of StarLink corn).

98. *See supra* notes 66–68 and accompanying text (mentioning existence of this settlement despite the CDC's inability to find evidence of allergic injury to humans).

99. *See* Redick, *supra* note 66, at 129.

100. Of course, tort liability arises only after an injury has occurred, which undermines its initial ability to prevent the injury. The initial injury, however, has already occurred through the StarLink saga—food manufactures are now on notice of the liability resulting from their negligent behavior.

101. *See* Grossman, *supra* note 10, at 225.

safety and effectiveness derives from the FFDCA, specifically the provisions that prohibit food adulteration and govern food additives[102] and the provisions that govern food labeling.[103]

1. Adulterated Foods. The FFDCA prohibits the adulteration of food and the introduction of adulterated foods into interstate commerce.[104] A food is adulterated if it "bears or contains any poisonous or deleterious substance which may render it injurious to health."[105] Unless a food contains attributes subjecting it to regulation as an additive, the FDA only requires notification, rather than approval, before commercial distribution of an *un*adulterated food.[106] Food manufacturers are charged with warranting that their food product complies with the safety standards implicit in the definition of adulterated foods.[107] As a check on adherence to these standards, the FDA is authorized to seize foods and to enjoin or criminally prosecute food manufacturers failing to comply.[108]

2. Food Additives. The FFDCA prohibits the addition of "unsafe" additives to food, or the introduction of unapproved food additives into interstate commerce, because this would create "adulterated" food.[109] If a food contains a novel or unusual ingredient or attribute, it is subject to extensive premarket review and must be approved as a food additive prior to entering commerce.[110] The food additive approval process requires a food manufacturer to submit a petition containing "substantial scientific evidence of safety according to the tenets set out in 21 C.F.R. part 171."[111] Final FDA approval requires "reasonable

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102. 21 U.S.C. §§ 342, 348 (2000). Following publication of the Coordinated Framework, the FDA informally stated that these provisions were sufficient to ensure the safety of GM foods, thereby removing the need to enact new regulations. Marden, *supra* note 23, at 745–46.

103. 21 U.S.C. §§ 321(n), 343.

104. 21 U.S.C. § 331(a).

105. 21 U.S.C. § 342(a)(1). Also, a food is adulterated if it contains an unsafe pesticide residue (i.e., one that exceeds a tolerance level or exemption established by the EPA). 21 U.S.C. § 346a.

106. Grossman, *supra* note 10, at 225 (emphasizing the difference between "approval" and "notification").

107. *See* 1992 Statement of Policy, *supra* note 3, at 22,985, 22,988 (reiterating the food industry's concomitant responsibility to ensure food safety).

108. *Id.* at 22,988; *see* 21 U.S.C. §§ 331(b), 332, 333, 334 (providing these remedies).

109. 21 U.S.C. §§ 331, 342.

110. Marden, *supra* note 23, at 746. The FFDCA defines "food additive" as a substance, the use of which "may reasonably be expected to result, directly or indirectly, in its becoming a component or otherwise affecting the characteristics of any food." 21 U.S.C. § 321(s).

111. Marden, *supra* note 23, at 746.

certainty that no harm will result from the intended use of the additive."[112]

However, an additive may avoid the approval process if the additive is generally recognized as safe ("GRAS").[113] Additives are deemed GRAS if they are generally recognized by scientific experts in the appropriate field as safe.[114] Also, food additives used prior to 1958 may be deemed GRAS based on experience with their common use in food.[115] Thus, GM foods either undergo extensive premarket, scientific approval or are deemed safe based on already established scientific acceptance or experience with commonly used food additives.

3. The Food Label. The FFDCA prohibits the misbranding of food or the introduction of misbranded food into interstate commerce.[116] Foods are misbranded if their labels are false or misleading.[117] In general, under section 403(i) of the FFDCA, Congress authorizes the FDA to require a manufacturer to describe a food product by its common or usual name[118] or, in the absence of a common or usual name, by an appropriately descriptive term.[119] Furthermore, under section 201(n), the manufacturer must reveal all "material" facts in light of (1) any representations made or suggested by the manufacturer's label or (2) any consequences that may result from use of the product.[120] Thus, an appropriate label must be changed if a manufacturer represents something about its product but fails to provide all "material" information, if a food "differs from its traditional counterpart such that the common or usual name no longer applies to the new food, or if a safety or usage issue exists to which consumers must be alerted."[121] This does not mean, however, that any and all information is subject to mandatory

112. 1992 Statement of Policy, *supra* note 3, at 22,989 (citing 21 C.F.R. § 170.3(i)); *see also* Marden, *supra* note 23, at 746 (noting that the additive approval process requires "extensive toxicity and feeding studies").

113. *See* 21 U.S.C. § 321(s) (stating that the term "food additive" does not apply to substances that are "generally recognized, among experts . . . as having been adequately shown through scientific procedures . . . to be safe under the conditions of [their] intended use"); Marden, *supra* note 23, at 746.

114. 21 U.S.C. § 321(s); *see also* Marden, *supra* note 23, at 746.

115. Uchtmann, *supra* note 61, at 172 (describing GRAS status).

116. 21 U.S.C. § 331(a)–(b).

117. 21 U.S.C. § 343(a).

118. 21 U.S.C. § 343(i) (FFDCA § 403(i)).

119. 1992 Statement of Policy, *supra* note 3, at 22,991.

120. 21 U.S.C. §§ 343(a), 321(n) (FFDCA § 201(n)); *see* Fred H. Degnan, *Biotechnology and the Food Label: A Legal Perspective*, 55 FOOD & DRUG L.J. 301, 303–04 (2000) (describing the prongs of section 201(n)).

121. 1992 Statement of Policy, *supra* note 3, at 22,991.

disclosure; the FDA can only compel disclosure of information deemed so essential and material that omission would make the label misleading.[122]

A brief history of food label regulation will help to clarify this fundamental premise to which Congress and the FDA abide. Under section 403 of the FFDCA, Congress expressly empowered the FDA to require

> the identification of the ingredients used to fabricate the food; the prominent, clear declaration of the net weight of the contents of the food; the name and address of the manufacturer or responsible party involved in the marketing of the food; and a precise statement of the identity (the name) of the food.[123]

In requiring only this information, Congress deliberately limited "the amount of information that could be compelled to appear on the food label."[124] Then, with the enactment of the Nutrition Labeling and Education Act (NLEA) of 1990,[125] Congress amended section 403 to add "complete nutrition labeling"[126] to the basic foundational requirements of the food label.[127]

Consistent with the FFDCA's fundamental premise, Congress did not design the NLEA to compel the disclosure of routine information on labels; rather, the NLEA requires disclosure of only essential information that will enable consumers to make prudent choices concerning food.[128] An NLEA-

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122. *See* 21 U.S.C. § 343(a); *see also* Degnan, *supra* note 120, at 302–04 (emphasizing Congress's critical focus on essential and material information). For example, the FDA requires disclosure of the ingredient gluten derived from corn or wheat in order to protect those who suffer serious allergic reactions when exposed to wheat gluten, as that information is material to their safety. *See* 21 C.F.R. §§ 184.1321–.1322 (2004); Frederick H. Degnan, *The Food Label and the Right-to-Know*, 52 FOOD & DRUG L.J. 49, 53 & n.31 (1997) [hereinafter Degnan, *Food Label*].

123. Degnan, *supra* note 120, at 302 (citing 21 U.S.C. § 343(e), (g), (i) and referring to the initial requirements established under the 1938 enactment of the FFDCA).

124. *Id.* (asserting that the main goal of the labeling provisions is "to enable consumers to choose foods wisely by using the label as a vehicle for communicating essential information").

125. Pub. L. No. 101-535, § 2, 104 Stat. 2353, 2353 (codified at 21 U.S.C. § 343(q)(1) (2000)).

126. Degnan, *supra* note 120, at 302.

127. The NLEA applies "only where a manufacturer wishes to make nutrition-related claims about its product." *Id.* at 302–03; Pub. L. No. 101-535, § 3, 104 Stat. at 2357 (codified at 21 U.S.C. § 343(r)(1)).

128. Degnan, *supra* note 120, at 303. In recognizing the food label's limited educational potential, Congress enacted the NLEA with the goal of conveying meaningful information in a simple and clear format. *See id.* at 302–03. Thus, the nutrition label only contains essential information about the identity and nutritional quality of food in a fashion that consumers can use. *Id.* at 303.

governed food manufacturer must label its food with information concerning the nutrients specified in the Act, but section 403(q)(2)(B) gives the FDA authority to exclude any nutrient from mandatory labeling if the FDA finds the information "not necessary to assist consumers in maintaining healthy dietary practices."[129] When adopting final NLEA rules, the FDA emphasized Congress's concern for essentiality in stating "not all information related to maintaining healthy dietary practices can be included on the food label. . . . Not only would space constraints not allow for this, but the large amount of information would interfere with consumers' abilities to use the information of the greatest public health significance."[130]

In sum, a label is misleading under the FFDCA if a manufacturer omits facts that are *material* in light of representations made about the food or with respect to consequences arising from use of the food.[131] If the FDA required labeling of nonmaterial information or warnings for ingredients with little or no health risk, then information overload could result, whereby the more important information, and the intended impact of such, would be lost within the crowded label.[132] In order to convey information that reasonably can be understood and used by consumers, essentiality and materiality continue as the fundamental premises limiting the scope and amount of information subject to mandatory disclosure.[133]

4. Applying FDA Regulation to GM Foods. In response to inquiries and concerns from the GM food industry, government agencies, academia, and the public over the method of regulation under the FFDCA, the FDA issued its "Statement of Policy: Foods Derived from New Plant Varieties" ("1992 Statement of Policy").[134] Consistent with the Coordinated Framework's science-based risk assessment, the FDA established its view that, as a class, GM foods and the risks associated with them are no different from traditionally produced foods.[135]

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129. *Id.* (quoting H.R. REP. NO. 101-538, at 18 (1990)).

130. Food Labeling: Mandatory Status of Nutrition Labeling and Nutrient Content Revision, Format for Nutrition Label, 58 Fed. Reg. 2079, 2107 (Jan. 6, 1993) (codified at 21 C.F.R. pts. 1, 101).

131. *See supra* notes 120–22 and accompanying text.

132. *See* Degnan, *supra* note 120, at 306 (drawing upon the potential effects of overexposing consumers to unnecessary information).

133. *See id.* at 302–04.

134. 1992 Statement of Policy, *supra* note 3, at 22,984.

135. *Id.* at 22,990.

The FDA held fast to the FFDCA's regulatory scheme governing adulterated foods and food additives, finding it to be "fully adequate to ensure the safety of new food ingredients and foods derived from new varieties of plants, regardless of the process by which such foods and ingredients are produced."[136] The agency concluded that it would presume GM foods to be GRAS unless they contain substances that are allergens or change the character of the food.[137] Nonetheless, the FDA did recommend scientific guidelines and a voluntary, premarket consultation process for the GM-food industry to follow in dealing with safety issues.[138] In addition, the FDA reserved the right to regulate on a case-by-case basis any particular food produced by GM techniques that it deemed unsafe, just as it would do with traditionally produced unsafe foods.[139] This reservation of power ensures that GM products found harmful to humans do not reach consumers.

In 2001, the FDA proposed to replace the voluntary consultation process with a mandatory consultation process requiring manufacturers to submit information about "plant-derived bioengineered foods" or "animal feeds" at least 120 days prior to commercial distribution.[140] With this proposed rule, the FDA sought to increase premarket review of GM foods and to improve protection against erroneous GRAS presumptions. However, unchanged by this recent scientific review by the FDA is the general policy concerning GM foods: they are not inherently dangerous and do not present any greater risk to human health than non-GM foods.[141] This assertion also is evident in the established labeling policy.

In the context of labeling, the FDA emphasized reliance on the "misleading" and "materiality" standards defined in section 403 of the FFDCA, acknowledging that consumers must be

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136. *Id.* at 22,989.

137. *Id.* at 22,990. The statement reiterated that the food producer remains legally responsible for the safety of the GM-food product under the "adulterated food" provisions of section 402(a) and that the FDA expected that most genetic material inserted into existing plants and the products resulting from this technique would be considered GRAS under section 409. *Id.*

138. *Id.* at 22,990. To find the extensive guidelines, see Part VII of the 1992 Statement of Policy, *supra* note 3, at 22,991.

139. *Id.* at 22,990.

140. Premarket Notice Concerning Bioengineered Foods, 66 Fed. Reg. 4706, 4707 (Jan. 18, 2001) (to be codified at 21 C.F.R. pts. 192, 592) [hereinafter Premarket Notice] (illustrating the FDA's awareness of evolving rDNA technology and its inability to anticipate all novel scientific and regulatory issues concerning new GM products).

141. *See id.* at 4709 (reiterating the view that GM foods are presumed to be GRAS and unlikely to present a safety issue).

informed by appropriate labeling if a GM food differs from its traditional counterpart so that its common or usual name no longer applies or if there exists a safety or usage issue to which consumers must be alerted.[142] The FDA emphasized that without these material changes, the fact that a food was developed using new genetic modification techniques is not material information (as defined by section 201(n)) requiring disclosure of that fact on a label.[143] Under these standards, the agency proclaimed that the

> FDA believes that the new techniques are extensions at the molecular level of traditional methods and will be used to the same goals as pursued with traditional plant breeding. The agency is not aware of any information showing that foods derived by these new methods differ from other foods in any meaningful or uniform way, or that, as a class, foods developed by the new techniques present any different or greater safety concern than foods developed by traditional plant breeding.[144]

This is the essence of current GM-food labeling policy; to date there is simply no evidence of consumer risk sufficient to require special, mandatory labeling of every GM food under the essentiality and materiality standards of the FFDCA.[145]

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142. 1992 Statement of Policy, *supra* note 3, at 22,991. The FDA explained its position by example:

> [I]f a tomato has had a peanut protein introduced into it and there is insufficient information to demonstrate that the introduced protein could not cause an allergic reaction in a susceptible population, a label declaration would be required to alert consumers who are allergic to peanuts so they could avoid that tomato, even if its basic taste and texture remained unchanged. Such information would be a material fact whose omission may make the label of the tomato misleading under section 403(a) . . . .

Id.

143. *Id.* Support for the FDA's contention that the condition or method of food development is not material information stems from the Supreme Court's holding in *United States v. Ninety-Five Barrels, More or Less, Alleged Apple Cider Vinegar*, 265 U.S. 438 (1924). There the Court stated that "[w]hen considered independently of the product, the method of manufacture is not material. The act requires no disclosure concerning it." *Id.* at 445 (interpreting the Food and Drug Act of 1906, Pub. L. No. 59-384, 34 Stat. 768, precursor to the FFDCA). Thus, in reviewing safety concerns, the FDA focuses on the characteristics of the finished product, rather than the methods of production. *See* 1992 Statement of Policy, *supra* note 3, at 22,984–22,985.

144. 1992 Statement of Policy, *supra* note 3, at 22,991. The American Medical Association supports the FDA's position and has recognized the continuing validity of the scientific review used by the FDA and concluded that "[t]here is no scientific justification for special labeling of genetically modified foods, as a class, and voluntary labeling is without value unless it is accompanied by focused consumer education." Council on Scientific Affairs Report 10, Genetically Modified Crops and Foods, *at* http://www.ama-assn.org/ama/pub/category/13595.html (Dec. 2000).

145. *See infra* Part IV.B (analyzing judicial decisions that explain that without materiality there is no authority to mandate labeling, especially when consumer demand is the only justification).

5. Allowing Voluntary Labeling. The FDA has responded to consumer demand in the best way possible under its statutory authority. Instead of mandating labeling, the agency allows voluntary GM food labeling, but it does so with guidance to protect against the fact that a label implying that a food is better than another because it was, or was not, genetically modified is inappropriately "misleading" under the FFDCA.[146] In light of this concern, the FDA adopted voluntary labeling guidelines in 2001 to assist the biotech industry in providing statements that are truthful and not misleading.[147] The guidelines were published after the FDA reviewed information received from comments responding to the 1992 Statement of Policy, information contained in the FDA's 1993 information requests,[148] and information obtained from three public meetings held in 1999 on the topic of GM food labeling.[149] From this information, the FDA concluded,

> We are still not aware of any data or other information that would form a basis for concluding that the fact that a food or its ingredients was produced using bioengineering is a material fact that must be disclosed . . . . We are, therefore, reaffirming our decision to not require special labeling of all bioengineered foods.
>
> We are providing guidance to assist manufacturers who wish to label their foods voluntarily as being made with or without the use of bioengineered ingredients. While the use of bioengineering is not a material fact, many consumers are interested in the information, and some manufacturers may want to respond to this consumer desire.[150]

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146. *See* Degnan, *supra* note 120, at 308–09 (suggesting the potential of voluntary labels to mislead).

147. Draft Guidance for Industry: Voluntary Labeling Indicating Whether Foods Have or Have Not Been Developed Using Bioengineering; Availability, 66 Fed. Reg. 4839, 4839–4842 (Jan. 18, 2001) [hereinafter Draft Guidance].

148. In 1993, the FDA requested data and information on certain labeling issues that arose out of the labeling guidance given in the 1992 Statement of Policy. *See* Food Labeling; Foods Derived from New Plant Varieties, 58 Fed. Reg. 25,837 (Apr. 28, 1993) (publicizing the information requests).

149. In 1999, the FDA held three public meetings with the purpose of sharing the FDA's then-current approach to and experience over the preceding five years with GM foods, soliciting comments on whether the approach should be modified, and gathering information to be used in determining the best means of informing the public about GM foods. *See* Biotechnology in the Year 2000 and Beyond; Public Meetings, 64 Fed. Reg. 57,470 (Oct. 25, 1999); *see also* Draft Guidance, *supra* note 147, at 4839–4840 (establishing the background and evidentiary basis for the voluntary-labeling guidance document).

150. Draft Guidance, *supra* note 147, at 4840.

The FDA further advised that terms such as "GM free" and "biotech free" should either not be used in GM-food-label statements or should be used in a context that ensures that the labels are not misleading, for a claim implying that "zero" GM material exists in a product would be "very difficult to substantiate" given the prevalence of GM material in most food products.[151]

With or without evidence of risk, the above described Coordinated Framework is sufficient to protect consumers from whatever scientifically identified adverse effects GM foods may pose; when risk necessitates it, the scheme provides for scientific premarket review, requires appropriate labeling, or prevents a product from entering the market. Furthermore, the scheme allows manufacturers to provide voluntary, nonmisleading label statements to those consumers who desire such information.[152] But how does this regulatory scheme fare under judicial challenge, and do consumers have a fundamental right that supports their argument for mandatory labeling regardless of evidence of human harm?

IV. CONSTITUTIONAL (AND OTHER) HURDLES FACING GM-FOOD LABELS

The right-to-know battle involves allowing consumers to make informed decisions between GM and non-GM foods. Unfortunately for right-to-know activists, the FFDCA purposefully does not authorize the FDA to require food labels bearing whatever information consumers desire.[153] In attacking FDA policy, public interest groups have mounted legal challenges and legislatures have attempted to enact laws mandating GM-food labels. This Part of this Comment highlights the limited extent of an individual consumer's right to know, examines the unsuccessful legal challenges to current FDA policy, and exposes hurdles facing mandatory GM-food-labeling laws.

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151. *Id.* The actual guidance document released to the industry for comment provided an example of a likely nonmisleading statement that manufacturers could use when choosing to label a product containing GM material: "'Genetically engineered' or 'This product contains cornmeal that was produced using biotechnology.'" Guidance for Industry: Voluntary Labeling Indicating Whether Foods Have or Have Not Been Developed Using Bioengineering; Draft Guidance (Jan. 2001), *available at* http://www.cfsan.fda.gov/~dms/biolabgu.html.

152. *See infra* Part V.B (justifying voluntary labeling).

153. Degnan, *Food Label*, *supra* note 122, at 50–53, 56 (explaining that Congress "carefully assembled" the FFDCA to limit the amount of information the FDA could require to appear on a food label).

A. What Right to Know?

At the core of the GM-food-labeling debate is the consumer's right to know what is in the food he or she eats. What is detrimental to the GM-food critic's argument is that there is no fundamental right-to-know found within the U.S. Constitution.[154] Rather, the debate confirms that consumers' rights are limited and that a balance must be struck between the rights of all parties involved, particularly between food consumers and food suppliers.[155]

For instance, the consumer's right to safe foods,[156] the consumer's right to make informed food decisions,[157] and the consumer's right to freedom of religion[158] must be balanced against the food supplier's right to freedom of commercial speech and free interstate trade.[159] In performing this balance it becomes clear why courts have justified the FDA's decision not to require GM-food labels; consumers' limited rights to know are insufficient either to invalidate the current labeling approach or to validate a special mandatory labeling law.

B. Judicially Challenging FDA Policy

Despite the lack of a constitutionally protected right to know, the FDA's GM-food policy has not gone without judicial challenge. In 1998, in *Alliance for Bio-Integrity v. Shalala*, a

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154. One author stretches the right to know into a fundamental liberty interest based on the right to refuse unwanted medical treatment established in *Cruzan v. Director, Missouri Department of Health*, 497 U.S. 261 (1990). *See* Cynthia D. Fisher, Comment, *The Genie Is out of the Bottle: Consumers Demand Mandatory Labeling on Genetically Engineered Foods*, 4 J. LEGAL ADVOC. & PRAC. 88, 117–18 (2002). Summarily, Fisher argues that the Supreme Court held in *Cruzan* that a competent person has a constitutionally protected liberty interest in refusing unwanted medical treatment, which, based on the facts of the case, means a personal autonomy right to refuse nutritional life support. *Id.* at 117. From this, Fisher argues that there also should exist a right to accept nutrition, and that this right entails an individual's right to know what components make up her food so that she can make informed decisions concerning nourishment. *Id.* at 118. But to date there is no case holding or implying in dicta such a right.

155. *See* Kelly A. Leggio, Comment, *Limitations on the Consumer's Right to Know: Settling the Debate over Labeling of Genetically Modified Foods in the United States*, 38 SAN DIEGO L. REV. 893, 917–18 (2001) (suggesting this balancing approach).

156. *See supra* Parts III.B–C (discussing the EPA's and FDA's responsibility to ensure food safety under the FFDCA).

157. *See supra* Part III.C.3 (discussing FDA responsibility under the FFDCA to compel disclosure by manufacturers of essential and material information to consumers so that they can make informed food decisions).

158. *See* Leggio, *supra* note 155, at 923–24 (detailing how the consumer's right to freedom of religion impacts the food labeling debate).

159. *See infra* Part IV.C (elaborating on food suppliers' rights to freedom of commercial speech and interstate trade).

coalition of consumer groups and individuals, including scientists and religious leaders, challenged the 1992 Statement of Policy on six different grounds.[160] Ultimately, the court rejected all six claims and granted summary judgment for the FDA.[161]

First, plaintiffs argued that the policy statement was not an interpretive rule as the FDA claimed, but a substantive rule improperly exempted from the formal notice-and-comment process that the Administrative Procedures Act (APA) requires before application of a substantive rule.[162] The court rejected this argument, explaining that a substantive rule implements a statute and has the "'force and effect of law,'" whereas policy statements are "'statements issued by an agency to advise the public prospectively of the manner in which the agency proposes to exercise a discretionary power.'"[163] The court further clarified that rebuttable presumptions may properly be announced in policy statements because they leave an agency "free to exercise its discretion."[164] Under this standard, the FDA's GRAS presumption for GM foods was declared rebuttable because the FDA still "require[s] food additive petitions in cases where safety questions exist sufficient to warrant formal premarket review by FDA to ensure public health protection."[165] Thus, the court found no APA violation and concluded that "the plain language of the Statement clearly indicates that it is a policy statement" merely announcing a GRAS *presumption*, which does not bind FDA discretion.[166]

On their second ground, plaintiffs contended that in issuing its statement, the FDA did not comply with the National Environmental Protection Act (NEPA) of 1969, which requires federal agencies to include an environmental impact statement in every major federal action significantly affecting the quality of the human environment.[167] The FDA determined that its statement was not a major action under NEPA, so it did not issue

160. 116 F. Supp. 2d 166, 166, 170 (D.D.C. 2000). The concerns that led to the suit included some plaintiffs' fear that new GM foods could contain unexpected allergens or toxins and other plaintiffs' belief that their religion forbade consuming foods produced through rDNA techniques. *Id.*

161. *Id.* at 181.

162. *Id.* at 172 (citing 5 U.S.C. § 553 (1994)).

163. *Id.* (quoting Chrysler Corp. v. Brown, 441 U.S. 281, 302 n.31 (1979)).

164. *Id.* at 172–73 (citing various cases).

165. *Id.* at 172 (quoting 1992 Statement of Policy, *supra* note 3, at 22,990).

166. *Id.* at 173 (declaring, essentially, that the 1992 Statement of Policy was merely an interpretive rule).

167. *Id.* at 173–74 (citing 42 U.S.C. § 4332(2)(c)(i)).

an accompanying environmental impact statement.[168] Because the 1992 Statement of Policy is "reversible, maintains the substantive status quo, and takes no overt action," the court concluded that the FDA's determination was not arbitrary and capricious; thus, the statement was not a major federal action and did not require an impact statement under NEPA.[169]

On their third ground, plaintiffs argued that the FDA's presumption that GM foods are GRAS violates section 409 of the FFDCA and that it is therefore arbitrary and capricious.[170] To support their argument, plaintiffs pointed to comments made by lower level FDA officials, which were intended to reveal a lack of general recognition of safety among qualified experts.[171] But the court found these comments insufficient evidence in light of the entire administrative record, and in deferring to the FDA's scientific interpretation of the FFDCA, the court concluded that it "cannot say that the FDA's decision to accord [GM] foods a presumption of GRAS status is arbitrary and capricious."[172]

The *Alliance for Bio-Integrity* court was similarly deferential to the FDA's judgment concerning labeling. On ground four, plaintiffs argued that the FDA failed to require special labeling for GM foods in accordance with § 321(n).[173] Plaintiffs claimed that the agency should have considered as "material" under the statute the "widespread consumer interest" and "the special concerns of religious groups and persons with allergies" in having GM foods labeled.[174] But the court, finding the language of the statute unclear with respect to whether materiality pertains to both safety concerns and consumer interest, deferred to the FDA's reasonable interpretation that consumer interest is not "material" and that, absent unique risks to consumer health, § 321(n) does not authorize mandatory GM-food labeling.[175]

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168. 1992 Statement of Policy, *supra* note 3, at 23,005.

169. *Alliance for Bio-Integrity*, 116 F. Supp. 2d at 174–75 ("While declaring a rebuttable presumption that foods produced through rDNA technology are GRAS, the FDA has neither made a final determination that any particular food will be allowed into the environment, nor taken any particular regulatory actions that could affect the environment.").

170. *Id.* at 175 (referring to 21 U.S.C § 321(s)); *see supra* Part III.C.2.

171. *Alliance for Bio-Integrity*, 116 F. Supp. 2d at 177.

172. *Id.* at 177–78.

173. *Id.* at 178; *see supra* Part III.C.3 (analyzing the labeling provisions within the FFDCA).

174. *Alliance for Bio-Integrity*, 116 F. Supp. 2d at 178.

175. *Id.* at 178–79. The court went further in noting that it was "doubtful" the FDA would even have the power under the FFDCA to require GM-food labeling based solely on consumer demand. *Id.* at 179 (referring to *Stauber v. Shalala*, 895 F. Supp. 1178, 1193 (W.D. Wis. 1995), in which it was determined that the FFDCA would be violated if the

Plaintiffs also claimed that the genetic modification process itself was a material fact under § 321(n) and that the FDA's position that rDNA techniques pose no greater safety risks than traditional techniques was arbitrary and capricious.[176] But the court found no basis for this argument, concluding that the FDA's interpretation was rational and entitled to deference.[177]

On grounds five and six, plaintiffs argued that the FDA's decision not to regulate or require labeling for GM foods violated their constitutional right to free exercise of religion under the First Amendment and burdened their religion in violation of the Religious Freedom Restoration Act (RFRA) of 1993.[178] The court held that the free-exercise claim could not stand because it was undisputed that the FDA's policy statement was neutral and generally applicable.[179] As for the RFRA claim, the court acknowledged that the lack of labeling might inconvenience those plaintiffs whose religious beliefs required certain dietary restrictions concerning GM foods, but in denying relief the court held that the FDA statement "does not place 'substantial pressure' on any of the Plaintiffs, nor does it force them to abandon their religious beliefs or practices."[180]

Ultimately, *Alliance for Bio-Integrity* makes clear that courts will show extreme deference to the FDA's judgment and that GM-food critics have little legal ground upon which to stand when attempting to compel GM-food labeling—a consumer's limited right to know is insufficient. Nonetheless, this holding has not prevented legislative attempts to mandate labeling, and these attempts have their own hurdles to clear, as discussed in the next subpart.

FDA mandated labeling of rBST-treated dairy products based on consumer demand alone and without evidence of material difference between milk derived from rBST-treated cows and milk derived from non-rBST-treated cows). The *Alliance for Bio-Integrity* court posited that "without a determination that, *as a class*, rDNA derived food pose inherent risks or safety consequences to consumers, or differ in some material way from their traditional counterparts, the FDA is without authority to mandate labeling." *Id.* at 178 n.8.

176. *Id.* at 179.

177. *Id.*; *see also id.* at 179 n.10 (referring to the Supreme Court's interpretation in *United States v. Ninety-Five Barrels, More or Less, Alleged Apple Cider Vinegar*, 265 U.S. 438, 445 (1924) that the method of food production is not material information).

178. *Id.* at 179–80 (citing 42 U.S.C. §§ 2000bb–2000bb-4 (1994)).

179. *Id.* (dismissing the free exercise claim).

180. *Id.* at 180–81 (citations omitted).

C. Legislative Failure: Constitutionally Protected Rights and Federal Preemption

There have been both state and federal legislative attempts to enact statutory requirements for labeling GM foods and food additives. As of this writing, fifteen states have proposed such legislation.[181] For example, in the November 5, 2002 General Election in Oregon, voters considered and rejected a ballot measure requiring GM-product labels.[182] At the federal level, bills proposing to amend the FFDCA to address GM-food safety and labeling have been introduced in both houses of Congress, but with no success.[183] These bills continue to be reintroduced, and in the 108th congressional session, six bills pertaining to GM products were proposed to the House of Representatives under the sponsorship of Congressman Dennis Kucinich (D-Ohio).[184] Pertinent to this discussion are the Genetically Engineered Food Right to Know Act (GEFRKA) and the Genetically Engineered Food Safety Act (GEFSA).

Beginning with the latter bill, GEFSA proposes to amend the FFDCA to include GM products expressly in the definition of "food additive," thereby removing the FDA's GRAS presumption and requiring premarket review of all GM products.[185] This amendment would be unnecessary and inconsistent in light of already existing and well-established food regulations.[186]

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181. *See* Pew Initiative on Food and Biotechnology, Legislation Tracker 2003, *at* http://pewagbiotech.org/resources/factsheets/legislation/ (last visited Mar. 4, 2005) (listing California, Colorado, Connecticut, Florida, Hawaii, Iowa, Maine, Massachusetts, Michigan, New Hampshire, New York, Oregon, Rhode Island, Vermont, and Washington).

182. James Mayer & Michelle Cole, *Measures Labeling Altered Food Contents, Health Care Fail to Get Support*, OREGONIAN, Nov. 6, 2002, at A1. Measure 27 would have required a "Genetically Engineered" label to be placed on the surface or outside packaging of all foods or beverages sold or distributed in or from Oregon that are derived from genetically engineered materials. *See* Secretary of State, State of Oregon, Ballot Measure Statement, Measure 27 (Sept. 5, 2002).

183. *See, e.g.*, Genetically Engineered Food Right to Know Act, H.R. 3377, 106th Cong. (1999); S. 2080, 106th Cong. (2000).

184. The bills included the following: Genetically Engineered Food Right to Know Act, H.R. 2916, 108th Cong. (2003); Genetically Engineered Food Safety Act, H.R. 2917, 108th Cong. (2003); Genetically Engineered Crop and Animal Farmer Protection Act of 2003, H.R. 2918, 108th Cong. (2003); Genetically Engineered Organism Liability Act of 2003, H.R. 2919, 108th Cong. (2003); Real Solutions to World Hunger Act of 2003, H.R. 2920, 108th Cong. (2003); Genetically Engineered Pharmaceutical and Industrial Crop Safety Act of 2003, H.R. 2921, 108th Cong. (2003).

185. H.R. 2917 § 3(a).

186. *See generally* Karen A. Goldman, *Bioengineered Food—Safety and Labeling*, 290 SCIENCE 457 (2000) (advocating the current laws). See also *supra* Part III for a review of the applicable regulations.

As the FDA has determined, GM food components are "ubiquitous" in living organisms and no different from components in foods already on the market, which means they are presumed GRAS.[187] The key to this approach is the word "presumed." Just because the FDA presumes GM food components to be GRAS does not mean the agency will not require premarket review of GM components as GEFSA hopes to accomplish; in fact, the FDA expressly indicates that it will require a premarket review if there is sufficient evidence of human health risk.[188] Furthermore, GEFSA is unnecessary in light of the protection the EPA affords consumers under FIFRA. Because most GM foods carry pesticide components that trigger FIFRA, the EPA performs careful review of GM food components to ensure human and environmental safety under standards similar to those that would be required under GEFSA's food additive amendment.[189] Not only do current regulations undermine the need for GEFSA, they also should lessen consumer concern over the lack of labeling, which GEFRKA intends to change.

GEFRKA proposes to amend the FFDCA to require food that "contains a genetically engineered material, or [that is] produced with a genetically engineered material," to be labeled with a statement to that exact effect.[190] But, without superfluously repeating previous discussion, this bill also would be unnecessary and inconsistent with labeling laws in light of FIFRA's premarket review, the FFDCA's materiality standard, the FDA's interpretation of the FFDCA under which there is no material risk to human health, and the court holdings justifying the FDA's interpretation.[191] Not superfluous to this discussion, however, are the other hurdles that this legislative attempt at labeling—and similar state attempts like the attempt in Oregon—will face: commercial free speech under the First Amendment and, particular to state attempts, free interstate trade under the

187. 1992 Statement of Policy, *supra* note 3, at 22,990; Goldman, *supra* note 186, at 457 (using the term "ubiquitous"); *see also* Alliance for Bio-Integrity v. Shalala, 116 F. Supp. 2d. 166, 178 (D.D.C. 2000) (upholding the FDA's GRAS presumption).

188. 1992 Statement of Policy, *supra* note 3, at 22,990.

189. Goldman, *supra* note 186, at 457; *see supra* note 94 and accompanying text (analyzing the EPA's review of pesticide-type GM products, which includes consideration of allergenicity and toxicity to humans prior to entry into the commercial market).

190. Genetically Engineered Food Right to Know Act, H.R. 2916, 108th Cong. § 3(a) (2003).

191. *See supra* Parts III.C.2–4, IV.A–B (justifying current FDA policy and explaining Congress's intent under the FFDCA to require labeling only of essential and material information).

Commerce Clause. These hurdles represent the rights of the other parties involved in the labeling debate—the food suppliers.

1. Commercial Free Speech. The First Amendment protects the right to speak freely and the right not to be compelled to speak against one's will.[192] In the context of GM foods, when a state or federal law requires a manufacturer to label its products involuntarily whenever offered for sale in commerce, that law compels the manufacturer to speak commercially against its will.[193] The right not to speak is constitutionally protected even in the commercial context, although under a less demanding test.[194] This less demanding test was established in *Central Hudson Gas & Electric Corp. v. Public Service Commission*, in which the Supreme Court articulated that regulation of commercial speech is permitted when (1) a substantial government interest is identifiable; (2) the regulation "directly advances" the asserted government interest; and (3) the regulation is no more extensive than necessary to serve that interest.[195] However, this test only becomes relevant when the commercial speech in question concerns lawful activity and is not misleading; the government is always free to regulate speech that is "more likely to deceive the public than to inform it."[196]

In 1996, the *Central Hudson* test was employed when a group of dairy manufacturers challenged a Vermont law requiring the labeling of milk products derived from dairy cows that were administered a synthetic growth hormone that increases milk production.[197] The dairy manufacturers argued that the statute violated their right of commercial free speech protected by the First Amendment because it compelled them to speak against their will through mandatory labeling.[198] The U.S. Court of Appeals for the Second Circuit found that Vermont had

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192. U.S. CONST. amend. I; Int'l Dairy Foods Ass'n v. Amestoy, 92 F.3d 67, 71 (2d Cir. 1996) (citing Wooley v. Maynard, 430 U.S. 705, 714 (1977)).

193. *See Amestoy*, 92 F.3d at 71.

194. *Id.* (citing Cent. Hudson Gas & Elec. Corp. v. Pub. Serv. Comm'n, 447 U.S. 557, 562–63 (1980)).

195. *Cent. Hudson Gas*, 447 U.S. at 566.

196. *Id.* at 563, 566.

197. *Amestoy*, 92 F.3d at 69. The synthetic growth hormone was rBST. *Id.* While Vermont's law did not mandate labeling of GM foods as defined in this Comment, but rather food produced by animals that were administered GM components, the case at least establishes persuasive precedent for courts reviewing an analogous GM-food-labeling law.

198. *Id.* at 69–70. The dairy manufacturers also alleged a violation of the Commerce Clause, U.S. CONST. art. I, § 8, cl. 3, but the court did not reach this claim, as it found the Vermont law unconstitutional on commercial speech grounds. *Amestoy*, 92 F.3d at 70.

failed to establish the second part of the *Central Hudson* test—that the state's interest was substantial.[199] The court's reasoning stemmed from the fact that Vermont had enacted the labeling law based merely on consumer interest and the public's right to know; indeed, Vermont could not present any evidence that the synthetic hormone had negatively impacted public health, much less the dairy products themselves.[200] Holding that consumer curiosity alone is not a strong enough state interest to compel "even an accurate, factual statement," the court commented,

> Although the Court is sympathetic to the Vermont consumers who wish to know which products may derive from rBST-treated herds, their desire is insufficient to permit the State of Vermont to compel the dairy manufacturers to speak against their will. Were consumer interest alone sufficient, there is no end to the information that states could require manufacturers to disclose about their production methods.[201]

This holding further supports the FDA's general policy not to mandate labeling of GM foods because it establishes that the policy is consistent with commercial speech guidelines. In fact, the court in *International Dairy Foods Ass'n v. Amestoy* specifically emphasized the FDA's safety conclusions regarding the approved use of rBST in dairy cows by stating that it "easily understood" why Vermont similarly could not justify mandatory labeling "on the basis of 'real' harms."[202]

Thus, *Amestoy* stands for the proposition that consumer curiosity alone is an insufficient governmental objective to compel truthful speech.[203] By analogy, this proposition applies to

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199. *Amestoy*, 92 F.3d at 72–73 (applying the *Central Hudson Gas* test after concluding that the dairy manufacturers "amply demonstrated that the First Amendment is sufficiently implicated to cause irreparable harm").

200. *Id.* at 73 (emphasizing the state's burden of establishing "real" harms, not merely speculative or conjectural harms).

201. *Id.* at 74.

202. *Id.* at 73. In 1993, the FDA determined after extensive studies that dairy products derived from rBST-treated herds are indistinguishable from products derived from untreated herds and that therefore, no special label was required. 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, 6279–6280 (Feb. 10, 1994) (referencing Animal Drugs, Feeds, and Related Products; Sometribove Zinc Suspension, 58 Fed. Reg. 59,946–59,947 (Nov. 12, 1993)). Consistent with the 1992 Statement of Policy concerning GM foods, the FDA determined that absent a material difference between the products, the FFDCA provides no basis under which to require stricter labels indicating rBST treatment. *See id.* at 6280.

203. *See* LAWRENCE O. GOSTIN, PUBLIC HEALTH LAW AND ETHICS 375 (Lawrence O. Gostin ed., 2002) (proposing that only a strong public health interest can enable government to compel truthful speech in a constitutionally permissible manner).

any GM food labeling situation: if there is no evidence that the GM food poses a legitimate public health risk, the government has no authority to require a manufacturer to label its product as "genetically modified."[204] To date, such a risk has not been established. Unless such a risk is established, the commercial free speech hurdle likely will not be overcome.

2. Free Interstate Trade. The Commerce Clause of the U.S. Constitution imposes limitations on state action discriminating against trade among the states.[205] State actions "must yield to the principle that 'one state in its dealings with another may not place itself in a position of economic isolation.'"[206] Of further importance in the GM-food context, states cannot burden interstate commerce by adopting a regulation not essential for the protection of public health.[207]

A state law that mandates labeling of GM foods sold or distributed in that state (e.g., Oregon) would inhibit the ability of GM food manufacturers and distributors in other nonlabeling states to trade freely within the labeling state.[208] Absent a valid state interest in protecting public health, this inhibition is a violation of food suppliers' right to free interstate trade.[209] Given the fact that neither the FDA nor the federal courts have found evidence to suggest that GM foods present a significant health risk to humans, finding evidence to support the claim that a mandatory labeling law is essential to protect public health will be difficult.[210] Like the commercial free speech hurdle, consumer curiosity and the limited right to know will likely be insufficient to withstand constitutional attack under the Commerce Clause.

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204. *See generally Amestoy*, 92 F.3d at 67–81 (enjoining the enforcement of a Vermont labeling statute because the state interest was not substantial).

205. *See* U.S. CONST. art. I, § 8, cl. 3 (reserving this power to the U.S. Congress); *see also* Dean Milk Co. v. City of Madison, 340 U.S. 349, 351, 354 (1951) (holding unconstitutional two Madison, Wisconsin ordinances that prohibited the sale or importation of milk from sources not approved by city inspectors).

206. *Dean Milk*, 340 U.S. at 356 (quoting Baldwin v. G.A.F. Seelig, Inc., 294 U.S. 511, 527 (1935)).

207. *Id.* at 356 ("To permit Madison to adopt a regulation not essential for the protection of local health interests and placing a discriminatory burden on interstate commerce would invite a multiplication of preferential trade areas destructive of the very purpose of the Commerce Clause.").

208. *See supra* note 182 and accompanying text (summarizing the rejected Oregon law that would have required such labeling).

209. *See Dean Milk*, 340 U.S. at 356.

210. *See* Int'l Dairy Foods Ass'n v. Amestoy, 92 F.3d 67, 73 (2d Cir. 1996) (rationalizing that it is understandable that Vermont was unable to establish a sufficient health risk in light of the FDA's similar inability).

3. Federal Preemption. Another state-specific hurdle is federal preemption. To make pesticide product labels uniform throughout the United States, FIFRA expressly prohibits states from imposing or continuing in effect any requirements for labeling or packaging in addition to or different from EPA requirements, and any claim relating to inadequate labeling is preempted by FIFRA as long as the label was approved by the EPA.[211] Thus, any state law enacted to require labeling of a GM product must be limited in its application or risk invalidation under FIFRA.[212]

The preemption hurdle may also crop up under the FFDCA. Although there is no litigation interpreting the issue, it is possible that § 343-1, enacted by the 1990 NLEA amendments governing nutrition labeling, would have a preemptive effect on a mandatory GM food-labeling law.[213] The NLEA's express preemption language generally prevents a state from enacting laws that regulate food labeling concerning an established standard identity; sale under a common name; imitation foods; misleading containers; package forms; representations of definition, quality, and dietary use; artificial flavoring; nutritional information; and nutrition levels and health-related claims.[214]

Even if § 343-1 is deemed not to preempt state laws expressly outside the nutrition labeling context, a federal law still may preempt a state law that diverges from the comparable federal law's objective or purpose or where Congress has intended to occupy the area.[215] Particularly important then is the

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211. *See* 7 U.S.C. § 136v(b) (2000); *see also In re* StarLink Corn Prods. Liab. Litig., 212 F. Supp. 2d 828, 836 (N.D. Ill. 2002) (referring to the Supreme Court's interpretation of the Public Health Cigarette Smoking Act of 1969, 15 U.S.C. §§ 1331–1340 (2000) in *Cipollone v. Liggett Group, Inc.*, 505 U.S. 504 (1992), which established governing precedent for federal statutes with expressly preemptive language akin to FIFRA).

212. *See, e.g.*, *StarLink*, 212 F. Supp. 2d at 836 (explaining the effect of FIFRA's express preemption clause).

213. *See* 21 U.S.C. § 343-1(a) (providing an express preemption clause for unifying the format of nutritional labeling in the United States).

214. *Id.* (delineating the application of § 343-1 to the subsections listed under that section).

215. 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, 166 (2003) (canvassing the potential for a state law to be preempted when it conflicts with an area Congress intended to govern); *see also* Grocery Mfrs. of Am., Inc. v. Gerace, 755 F.2d 993, 999–1001 (2d Cir. 1985) (interpreting the NLEA's preemption clause in the context of imitation foods). In *Grocery Manufacturers*, the court held that the FFDCA preempted a New York law that required the labeling of a particular cheese as an "imitation." *Id.* at 1002–03. The court reasoned that complying with the law created a "misbranded" product that directly violated the FFDCA. *Id.* at 1001.

prohibition in § 343-1 against state-enacted laws that require labeling "not identical" to the standard of identity established by the FDA.[216] Given that the FDA does not consider GM foods, as a class, dangerous to public health and safety, a state labeling law that identifies GM foods any differently arguably conflicts with this standard, and therefore, the FFDCA.[217] GM food suppliers could argue that § 343-1 preempts such a law.[218]

With these hurdles, it seems that legislative attempts at mandatory GM food labeling or any other form of stricter GM food governance will fail.[219] The ultimate reality is that the FDA, Congress, and the federal courts have not found sufficient scientific evidence of a valid government interest in protecting consumers from a real harm. Thus, the balance between the consumer's right to know and the food supplier's rights under the Constitution tilts in favor of the latter.

V. CONCLUSIONS AND SUGGESTIONS

This Comment has endeavored to elucidate the safety protections afforded by current federal regulation of GM foods in an attempt to ease consumers' fear and reduce the call for mandatory labeling. Part V summarizes those protections and introduces other protective options available to consumers. It also suggests that the federal government should do more to ease consumer fears in light of these protections and alternatives.

A. Existing Protections Revisited

Current regulation of GM foods is sufficient to protect consumers from adverse risks that GM foods may create. The Coordinated Framework provides consumer protection through science-based risk assessment.[220] Consumers can be confident that U.S. regulatory agencies administer their policies using the most current and sound scientific data available.[221]

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216. 21 U.S.C. § 343-1(a)(1).

217. *See* 1992 Statement of Policy, *supra* note 3, at 22,990 (establishing the standard that GM foods pose no greater health risks than their traditional counterparts).

218. *Cf.* Robertson, *supra* note 215, at 166–67 (examining the competing arguments that the NLEA may or may not preempt state law).

219. *But see id.* at 170–84 (proposing a model State Consumer Right-to-Know Act intended to overcome these hurdles).

220. *See supra* notes 77–79 and accompanying text (sketching the Coordinated Framework's scientific approach).

221. *See supra* note 144 (noting the American Medical Association's approval of the FDA's scientific review).

Under the Plant Protection Act, the USDA requires field testing or prerelease notification and review to determine whether any adverse impact exists to prevent a GM crop's entrance into the commercial market.[222]

Under the FFDCA, the EPA establishes tolerance levels for pesticide-type GM products to ensure a reasonable certainty that no harm will result from dietary or other exposure.[223] Through FIFRA, the EPA requires registration and field testing of GM products, which allows for the collection of data on human and environmental effects and the establishment of proper product labeling.[224] Furthermore, when manufacturer negligence creates a breakdown in FIFRA protection, tort law and the threat of settlement seem to provide a means of governing manufacturer behavior even when consumers lack adequate legal standing.[225]

In accordance with the FFDCA, the FDA mandates food manufacturer compliance with the safety standards implicit in the definition of adulterated foods.[226] FDA regulations require that a GM food or ingredient either maintain GRAS presumption based on established scientific acceptance or undergo extensive premarket approval as a food additive if the GM product contains substances that are allergens or that change the character of the food.[227] To protect against erroneous GRAS presumptions, a mandatory premarket consultation process has been proposed.[228] Although the presence of genetic modification is not material information sufficient to authorize mandatory labeling under the FFDCA,[229] and although the FDA has found no scientific evidence suggesting that GM foods pose any greater safety concerns than their traditional counterparts,[230] the FDA will mandate appropriate labeling to reveal facts that are *material* in light of representations made in a label or in light of consequences posing a safety or usage issue to which consumers must be alerted.[231]

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222. *See supra* notes 80–84 and accompanying text (describing the USDA's GM-food regulation).

223. *See supra* notes 90–91 and accompanying text (analyzing these tolerance levels).

224. *See supra* notes 94–96 and accompanying text (discussing GM product registration).

225. *See supra* notes 97–100 and accompanying text (relating the adequacy of the legal system).

226. *See supra* Part III.C.1 (discussing the FDA's regulation of adulterated foods).

227. *See supra* Part III.C.2 (analyzing the FDA's regulation of food additives).

228. *See supra* note 140 and accompanying text (noting the FDA proposal).

229. *See supra* note 143 and accompanying text (explaining this conclusion in the 1992 Statement of Policy).

230. *See supra* note 144 and accompanying text (recounting the agency's declaration).

231. *See supra* note 142 and accompanying text (outlining the FDA's objective to inform customers).

Still, the FDA does allow voluntary, nonmisleading statements to appear on GM foods should manufacturers choose to respond to consumer demand.[232]

B. Justifying Voluntary Labeling

Without a scientific basis for distinguishing between products, voluntary labeling is the most appropriate regulatory policy in light of consumer purchasing power, labeling costs, statutory and constitutional implications, and the rights of all parties involved in the GM-food-labeling debate.[233]

Voluntary labeling allows "nonmaterial, but nevertheless desired, information" to appear on a food label.[234] While the FDA lacks statutory authority to require nonmaterial information to appear on a label, it does have statutory authority to allow this information to appear on a label at the manufacturer's discretion—as long as the voluntary statement is not false or misleading.[235] A voluntary approach neither compels speech nor inhibits commerce, therefore avoiding the constitutional and preemption hurdles that preclude a mandatory approach.[236] In this way, the FDA has responded to consumer demand in the hope of expanding consumers' options without imposing unnecessary or illegal burdens on other parties.[237]

The premise behind voluntary labeling rests with the GM food industry's response to consumer demand. If consumers value the difference in a product despite any scientific basis for such a difference, the market will provide products and information accordingly.[238] Appropriately, consumers who value this information will pay the costs associated with obtaining that information when they buy the product, and individuals who do not desire the information will not be burdened.[239]

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232. *See* Draft Guidance, *supra* note 147, at 4839–42; *see also supra* Part III.C.5 (discussing voluntary labels and guidelines).

233. *See supra* Part IV (asserting the improbability of a mandatory GM-food-labeling law in light of the hurdles such a law must overcome).

234. Degnan, *supra* note 120, at 310.

235. *See* Draft Guidance, *supra* note 147, at 4840.

236. *See supra* Part IV.C.1–2 (explaining these hurdles).

237. *See supra* Part IV.C.1.

238. J. Howard Beales III, *Modification and Consumer Information: Modern Biotechnology and the Regulation of Information*, 55 FOOD & DRUG L.J. 105, 112–13 (2000) (arguing that voluntary labeling is the best policy in the case of GM foods and noting the efficiency of voluntary labeling in other contexts, such as the sale of free range chickens, kosher products, and organic foods).

239. *Id.* As an example, costs associated with producing, labeling, and separating organic foods are passed on to the consumers who choose to utilize the benefits of organic certification. *Id.* at 113.

The higher economic costs associated with GM-food labeling stem from separating and tracking GM ingredients in the food supply.[240] In order to label GM foods appropriately, either as "non-GM" or as "GM," the foods and ingredients must be identified and separated from their traditional counterparts from the time the seed is created to the time the product is packaged; this process could be very costly considering the prevalence of GM crops and the current grain handling system.[241] But if sufficient consumer demand exists for a GM-labeled product and manufacturers voluntarily label the product appropriately, then consumers will have what they demand at their own cost.

Mandatory labeling of scientifically indistinguishable products also breeds information costs. Label size and consumer ability to absorb information limit what can be communicated to consumers in a label.[242] Requiring the nonmaterial fact of genetic modification to appear on a food label would make it more difficult for consumers to locate essential health information.[243] Furthermore, special GM food statements would complicate the food label: consumers may not understand what exactly a GM label means and they may needlessly avoid a perfectly healthy product.[244] Voluntary labeling limits the number of food products that will have a GM label to only those demanded by consumers, thus either reducing information costs or attributing the costs only to those consumers who demand the information.[245]

In sum, the costs associated with mandatory GM food labeling suggest that the current voluntary labeling approach is the most appropriate, absent sufficient evidence of material risk to consumers. Voluntary labeling avoids the hurdles that mandatory labeling laws face, but at the same time allows for a response to consumer demand. Consumers can be comforted by the fact that non-GM products will exist in the competitive market as long as there is a demand for the products. Even without a voluntarily labeled GM-food option, consumers can rely on the most glaring non-GM alternative: certified organic foods.[246]

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240. *Id.* at 115.

241. *Id.*; *see also supra* notes 6–7 and accompanying text (exposing the prevalence of GM foods in the U.S. market).

242. Beales, *supra* note 238, at 116.

243. *Id.*

244. *Id.* (illustrating a confusing GM label: "cheese manufactured using rennet from genetically modified mircroorganisms").

245. *See id.* at 116–17; *see also supra* notes 124–30 and accompanying text (revealing Congress's concern for information costs).

246. *See generally* Organic Foods Production Act of 1990, Pub. L. No. 101-624, 104 Stat. 3935 (codified as amended at 7 U.S.C. §§ 6501–6523 (2000 & Supp. II 2002))

C. Mandating Premarket Notification

Aside from voluntary labeling, there is another option that could allow the FDA to improve protection against the uncertain risks posed by GM foods without violating the agency's labeling authority—it could promulgate a final rule mandating premarket consultation.[247] As previously mentioned, in 2001 the FDA proposed a requirement that would have mandated the submission of data and information regarding bioengineered foods produced for consumption by humans or animals.[248] This rule would have required the food industry to submit information regarding GM foods at least 120 days prior to the foods' commercial distribution.[249] Promulgating a final rule with regard to mandatory premarket consultation would increase protection against erroneous GRAS presumptions, provide information for ongoing evaluation of new bioengineered foods, and "permit the agency to assess . . . whether plant-derived bioengineered foods comply with the standards of the [FFDCA]."[250] However, the recent Pew Initiative Report questions the FDA's authority to enforce mandatory premarket consultation under the current legislative scheme because most GM foods are presumed GRAS.[251] The FDA cannot require premarket approval of substances in foods that are not food additives.[252] While the Pew Initiative provides some viable options for achieving mandatory premarket consultation under the current scheme, it also elaborates on an option that would require the grant of new statutory authority by Congress.[253] Notably, new statutory authority would strive to avoid unnecessary labeling, but at the same time increase

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(governing organic statements). Certified organic foods provide a viable alternative to GM foods because in order for organic foods to obtain certification they cannot be chemically treated or genetically engineered. Andrew J. Nicholas, Comment, *As the Organic Food Industry Gets Its House in Order, the Time Has Come for National Standards for Genetically Modified Foods*, 15 LOY. CONSUMER L. REV. 277, 285–86 (2003) (providing the organic requirements and a thorough review of organic food regulation).

247. In April 2004, the Pew Initiative on Food and Biotechnology made this exact recommendation, among many others, after a thorough reassessment of the United States' regulatory framework governing agricultural biotechnology. *See* PEW INITIATIVE ON FOOD & BIOTECHNOLOGY, ISSUES IN THE REGULATION OF GENETICALLY ENGINEERED PLANTS AND ANIMALS 87 (Apr. 2004), *available at* http://pewagbiotech.org/research/regulation/ (last visited Mar. 4, 2005).

248. Premarket Notice, *supra* note 140, at 4706; *see supra* notes 140–44 and accompanying text (chronicling this proposal).

249. Premarket Notice, *supra* note 140, at 4706.

250. *Id.*

251. PEW INITIATIVE ON FOOD & BIOTECHNOLOGY, *supra* note 247, at 79.

252. *Id.*

253. *Id.* at 87–100.

consumer confidence in the FDA's ability to protect the public from the potential risks of GM foods.[254]

D. Government and Industry Must Do More to Ease Consumer Fears

While one might argue that Thomas Jefferson's advice to inform the discretion of the people supports providing the people with the personal autonomy provided by a GM-food label, this Comment concludes that the people already have this autonomy; they only need to be informed of it.[255] Autonomy exists in the consumer's ability to demand *voluntary* GM-food labels and his ability to choose certified organic foods.[256] The federal government and the GM-food industry must do more to educate consumers about their options and to support publicly current policies and existing protections. Advertising and marketing similar to that provided by the public interest groups critical of GM foods will do much to ease consumer fears.[257] Without an aggressive attempt to change public sentiment, the GM food-labeling debate is certain to continue.

Empowering individuals to make informed decisions concerning the foods they consume is an emotionally charged and attractive pro-labeling position, but mandatory GM food labeling is not a viable option to date. A proposal to change current labeling policy would require a substantial shift in a deeply rooted and adequately protective regulatory scheme. Such a proposal will neither pass constitutional muster nor overcome federal preemption without sufficient evidence of risk to human health. Although mandatory labeling might provide consumers with the ability to choose whether to consume, support, or boycott certain GM foods, such a shift in policy is not possible nor even necessary to meet these demands. Instead, there are other means of empowering the discretion of the people—consumers must be informed that they are sufficiently protected and that they have viable alternatives.

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254. *Id.* at 87 (finding that the achievement of mandatory premarket notification authority would "increase the credibility of the regulatory system").

255. *See supra* note 1 and accompanying text.

256. *See supra* Part V.B.

257. *See supra* notes 23–32 and accompanying text (exposing the one-sided effect of public interest group marketing).