University of Maryland Francis King Carey School of Law
DigitalCommons@UM Carey Law

The Appendix

2011

Buyer Beware: An Exploration of Health Risks and Legal Policies in Favor of a Labeling Requirement for Genetically Modified Organisms

Rebecca Jesada

Follow this and additional works at: http://digitalcommons.law.umaryland.edu/appendix

Part of the Environmental Law Commons, and the Health Law Commons

Recommended Citation

Rebecca Jesada, *Buyer Beware: An Exploration of Health Risks and Legal Policies in Favor of a Labeling Requirement for Genetically Modified Organisms* , 14 J. Health Care L. & Pol'y S30 (2011),
Available at: http://digitalcommons.law.umaryland.edu/appendix/3

This Article is brought to you for free and open access by DigitalCommons@UM Carey Law. It has been accepted for inclusion in The Appendix by an authorized administrator of DigitalCommons@UM Carey Law. For more information, please contact smccarty@law.umaryland.edu.

BUYER BEWARE: AN EXPLORATION OF HEALTH RISKS AND LEGAL POLICIES IN FAVOR OF A LABELING REQUIREMENT FOR GENETICALLY MODIFIED ORGANISMS

REBECCA JESADA*

INTRODUCTION

Genetically modified (GM) plants—also known as genetically modified organisms (GMOs), transgenic crops, or the product of recombinant DNA (rDNA) technology—were introduced in the commercial marketplace in 1996.[1] Since then, the global surface area planted in such crops has been increasing annually at a growth rate of more than ten percent.[2] Twenty-five countries planted GM crops in 2008, a significant increase from the six countries that started out in 1996.[3] This rapid growth shows no sign of slowing down.[4] The total accumulated global area covered by biotechnology (biotech) crops between 1996 and 2008 has now surpassed two billion acres, and while it took ten years to reach the first

Copyright © 2011 by Rebecca Jesada

∗ Rebecca Jesada is a 2010 graduate of the University of Maryland School of Law and a health law certificate recipient. The author gratefully acknowledges the editorial staff of the *Journal of Health Care Law & Policy* for their help with this Comment, as well as her family for their support throughout her academic career.

1. Yong Gao, *Biosafety Issues, Assessment, and Regulation of Genetically Modified Food Plants*, *in* THE GMO HANDBOOK 297, 298 (Sarad R. Parekh ed., 2004).

2. *Id.*

3. International Service for the Acquisition of Agri-Biotech Applications, ISAAA Brief 39-2008 Executive Summary, http://www.isaaa.org/Resources/Publications/briefs/39/executivesummary/default.html (last visited Apr. 19, 2011).

4. *See id.* (providing compiled statistics on the growth of commercial biotechnology crops and farmers around the world from 1996 to 2008).

billion acre milestone,[5] it took only three years to hit the second billion.[6] Amidst this global surge, the U.S. is by far the leading grower of GM crops.[7] Herbicide-tolerant soybean and insect-resistant corn are two of the most common GM crops in the U.S.[8] These products are now ubiquitous in the American food supply: as much as eighty-five percent of corn and ninety-one percent of soybeans in this country may be genetically engineered (GE).[9] Up to seventy percent of processed foods found in the grocery store contain such ingredients.[10] Because the existing regulatory framework does not require manufacturers to disclose these components on their labels,[11] these foods are making their way to the American dinner table without the knowledge of consumers. Though GM products have been available for thirteen years, and though they fall under the purview of three different federal agencies (the United States Department of Agriculture (USDA), the Environmental Protection Agency (EPA), and the Food and Drug Administration (FDA)),[12] the policy debate surrounding appropriate regulatory measures is ongoing.[13]

A. Defining GMOs and the Stakeholders

Biotechnology has been defined as the application of "scientific principles to living organisms and their components to produce new inventions or processes."[14] More specifically, GM crops result from the use of rDNA technology enabling the insertion of genes from one species into another in order to produce desirable traits, such as pesticide resistance.[15] These combinations could not occur under traditional breeding procedures.[16] Due to the genetic engineering process, it is thought that GM

5. *Id.*

6. *Id.*

7. *Id.*

8. Gao, *supra* note 1, at 298.

9. CTR. FOR FOOD SAFETY, GE FOOD, http://truefoodnow.org/campaigns/genetically-engineered-foods/ (last visited Apr. 19, 2011).

10. *Id.*

11. *See infra*, Part I.B.1.

12. *See infra*, Part I.A.1.

13. Matthew Rich, *The Debate Over Genetically Modified Crops in the United States: Reassessment of Notions of Harm, Difference, and Choice*, 54 CASE W. RES. L. REV. 889, 889 (2004).

14. W. Christopher Matton & F. Scott Thomas, *The Continuing Balance: Federal Regulation of Biotechnology*, 44 JURIMETRICS 283, 284 (2004).

15. Doug Farquhar & Liz Meyer, *State Authority to Regulate Biotechnology Under the Federal Coordinated Framework*, 12 DRAKE J. AGRIC. L. 439, 441 (2007).

16. *Id.*

foods could pose unique health, environmental, agricultural,[17] and economic consequences.[18] Thus, the stakeholders in this debate tend to be consumer advocacy groups, health-related entities, and environmental and organic farming organizations on the one hand, versus the powerful biotechnology industry and government regulators on the other.[19] This Comment will focus primarily on the human health perspective rather than environmental and agricultural risks.[20] Cloned meat sources and other forms of GM crops, such as those developed for pharmaceutical purposes, are beyond the scope of this analysis.

B. Biotechnology Policy Principles: Regulating out Vs. Regulating in

An overarching theme throughout any discussion of biotechnology is whether it is more appropriate to assume that a new development is safe or unsafe until proven otherwise. The approach of the European Union (EU) has been consistent with the latter[21] and in general, the Precautionary Principle.[22] This concept holds that government has a duty to intervene or regulate where there is even a *possibility* of harm to the public health or the environment.[23] The United States takes the opposite perspective, that "GMOs should be permitted to flourish in the absence of proven hazards."[24]

17. *See generally* Rich, *supra* note 13, at 895–900 (describing the effects of GMO use on the environment and agriculture, such as a potential decrease in biodiversity).

18. *See* Jim Chen, Lecture, *Beyond Food and Evil*, 56 DUKE L.J. 1581, 1582 (2007) (noting the risk that economic pressure to produce GMOs could put farmers who are already under financial strain out of business).

19. *See, e.g.*, Michael Jacobson, Opinion-Editorial, *The Genetically Modified Food Fight*, 172 W. J. MED. 220, 220 (2000) (arguing on behalf of the Center for Science in the Public Interest that additional testing and regulation of GMOs is needed). *See also* Gregory N. Mandel, *Technology Wars: The Failure of Democratic Discourse*, 11 MICH. TELECOMM. & TECH. L. REV. 117, 134 (2005) (pointing out that in the debate over biotechnology, "polarization and deadlock lead each group to focus on opposition and preventing the other side from achieving its goals, rather than searching for and pursuing mutually beneficial outcomes" and noting that mutually beneficial solutions tend to "receive minimal attention from interest groups, the media, and the public").

20. *See infra*, Part II.

21. Thomas J. Moyer & Stephen P. Anway, *Biotechnology and the Bar: A Response to the Growing Divide Between Science and the Legal Environment*, 22 BERKELEY TECH. L.J. 671, 695 (2007).

22. Rich, *supra* note 13, at 901.

23. *Id.*

24. Moyer & Anway, *supra* note 21, at 695. At the same time, some scholars believe it is an oversimplification to state that the EU follows the precautionary principle, while the U.S. rejects it. *See, e.g.*, John D. Graham, *The Perils of the Precautionary Principle: Lessons from the American and European Experience*, HERITAGE LECTURES (Jan. 15, 2004), *available at* http://www.heritage.org/Research/Lecture/The-Perils-of-the-Precautionary-Principle-Lessons-from-the-American-and-European-Experience (arguing that it is a "fallacy" to categorize the EU as precautionary and the U.S. as the opposite because there is no unified concept behind the "precautionary principle" and both countries utilize precautionary stances toward regulation in different ways).

The precautionary principle derives originally from German environmental policy in the 1970's, and has since come to inform many international treaties and protocols, such as the United Nations Cartagena Protocol on Biosafety.[25] The Protocol authorized member states to apply the precautionary principle by regulating or banning GMOs where there is scientific uncertainty about their risks.[26] The EU has viewed GMOs with an inherent distrust, imposing a strict regulatory scheme beginning in 1998,[27] which effectively banned products containing GMOs by refusing to approve them for sale.[28] The resulting moratorium on the import of American agricultural products created with genetic engineering, particularly corn, has been a source of dispute between the U.S. and the EU ever since and has cost the U.S. at least three hundred million dollars according to some estimates.[29] In 2003, the U.S., Argentina, and Canada filed a complaint against the EU with the World Trade Organization (WTO), arguing that the de facto ban violated international trade rules.[30] The EU ended the moratorium to some extent the following year by approving an American variety of GE corn, but only after member states were unable to reach a decision for or against approval.[31] In May 2006, the WTO issued a final ruling that found the EU ban to be in violation of several trade

25. Michael Pollan, *The Year in Ideas: A to Z; Precautionary Principle*, N.Y. TIMES, Dec. 9, 2001, at 92.

26. Debra M. Strauss, *Feast or Famine: The Impact of the WTO Decision Favoring the U.S. Biotechnology Industry in the EU Ban of Genetically Modified Foods*, 45 AMER. BUS. L.J. 775, 815 (2008). The Director of the Trade and Agriculture Project at the Institute for Agriculture and Trade Policy has described the impact of the Cartagena Protocol as follows:

> There is already a broad international consensus on how to handle GE crops at the international level established at the Cartagena Protocol. This consensus acknowledges that each country has the right to regulate GE crops based on precautionary principles, to require labeling of GE crops, and to protect farmers and others from unfair liability arising from the release of GE crops into the environment and food distribution system.

Press Release, Inst. for Agric. & Trade Policy, WTO Ruling on Genetically Engineered Crops Would Override International, National, and Local Protections (Feb. 7, 2006), http://www.iatp.org/iatp/library/admin/uploadedfiles/WTO_Ruling_on_Genetically_Engineered_Crops_Wou.pdf.

27. Strauss, *supra* note 26, at 780 ("U.S. consumers appear to be less aware of the potential risks and more trusting of their regulatory agencies; Europeans are more risk averse to the human health and safety issues associated with GM food products.").

28. Justin Gillis & Paul Blustein, *WTO Ruling Backs Biotech Crops; European Ban, Challenged by U.S. and Allies, Violates Trade Regulations, Panel Says*, WASH. POST, Feb. 8, 2006, at D01 (noting that the ban occurred from 1998 until 2004).

29. Strauss, *supra* note 26, at 781–82 (citing RAYMOND J. AHEARN, CONGRESSIONAL RESEARCH SERVICE, TRADE CONFLICT AND THE U.S.-EUROPEAN UNION ECONOMIC RELATIONSHIP 19 (2007), *available at* http://www.nationalaglawcenter.org/assets/crs/RL30732.pdf).

30. *Id.* at 775.

31. *Id.* at 808.

regulations.[32] How to correctly interpret this complex decision has been a source of ongoing controversy since then, and its impact remains unclear.[33] Biotechnology companies would like the world to view the ruling as "an unequivocal endorsement of GM foods,"[34] while others note the continued resistance among European consumers[35] and the fact that few GM products have actually been approved by the EU since the moratorium was lifted in 2004.[36]

Amidst this international landscape of uncertainty, it becomes more urgent to ask whether the U.S. is taking the appropriate approach to regulating GMOs within its borders. This Comment will explore the risks that flow from rejecting the Precautionary Principle, beginning with an examination of the existing regulatory framework for GMO labeling within the U.S. and the rationale for current FDA policy.[37] Not only are the long-term health risks of GMOs unknown,[38] but there are many known, potential consequences associated with their integration into the food supply, such as increased allergenicity,[39] toxicity,[40] and antibiotic resistance.[41] The debate surrounding labeling of GMOs has often resulted in polarized arguments, with GMO proponents arguing against a labeling requirement on one end, and GMO opponents arguing for a total ban on the other.[42] The implementation of a mandatory labeling requirement is a moderate solution to bridge this gap; without banning GMOs altogether, such a requirement would at least enable consumer awareness and choice and encourage the pursuit of additional research.[43] After addressing the legal insufficiency of a

32. *Id.* at 776.

33. For a detailed discussion of the ruling, see *id.* at 785-806.

34. *Id.* at 806-07.

35. *Id.* at 807.

36. Foreign Agricultural Service: U.S. Mission to the European Union, Biotechnology, http://www.fas.usda.gov/posthome/useu/GMOs.html (last visited Apr. 25, 2011). According to the Foreign Agricultural Service U.S. Mission to the European Union, just nine products resulting from biotechnology have been approved for marketing in the EU since May 2004. *Id. See also* Strauss, *supra* note 26, at 808 (noting that of the more than forty-seven biotechnology products awaiting EU approval since the lifting of the moratorium, several have been delayed in the review process for over six years, in stark contrast to the typical six to nine month process in the U.S., Canada, and Japan).

37. *See infra*, Part I.A.1.

38. *See infra*, Part II.A.4.

39. *See infra*, Part II.A.1.

40. *See infra*, Part II.A.2.

41. *See infra*, Part II.A.3.

42. Press Release, GE Labeling Debate Continues in the U.S., Jun. 27, 2002, http://www.organicconsumers.org/gefood/uslabels070302.cfm.

43. *See infra*, Part II.B.

state law solution, this Comment concludes that a labeling requirement should fall under federal law.[44]

I. THE ROLE OF LAW FROM FIELD TO TABLE

A. Introduction to Existing Regulatory Structure

1. Coordinated Framework for Regulation of Biotechnology

In 1986, the White House created a committee within the Office of Science and Technology Policy (OSTP) to explore options for regulating GMOs, then in their infancy.[45] The resulting publication, the Coordinated Framework for Regulation of Biotechnology (Coordinated Framework),[46] announced several opinions and decisions that would become foundational principles, informing federal policy over the next several years.[47] Most important was the decision to utilize existing federal oversight agencies and legal authorities rather than creating new ones for the specific purpose of regulating GMOs.[48] The Coordinated Framework took the approach that the *products* of biotechnology should be regulated rather than the *process* itself.[49] It also laid the groundwork for the relationship between the USDA, EPA, and FDA.[50] USDA was tasked to focus on the potential threat to existing agriculture, EPA on the environmental consequences of pesticides, and FDA on the human health impacts.[51] Using existing agencies for oversight had the advantage of cost efficiency while also avoiding "dilution of relevant expertise and resources caused by the redistribution of those resources across different departments."[52] The disadvantages of using older laws, which were written before the wide-ranging implications of newly emerging biotechnology techniques could be anticipated,[53] are explored in the remainder of this Comment. As critics of the Coordinated Framework

44. *See infra*, Part II.C.

45. Alan McHughen & Stuart Smyth, *US Regulatory System for Genetically Modified [Genetically Modified Organism (GMO), rDNA or transgenic] Crop Cultivars*, 6 PLANT BIOTECH. J. 2, 4 (2007).

46. Coordinated Framework for Regulation of Biotechnology, 51 Fed. Reg. 23,302 (Jun. 26, 1986).

47. Farquhar & Meyer, *supra* note 15, at 441–42.

48. Lauren Zeichner, *Product vs. Process: Two Labeling Regimes for Genetically Engineered Foods and How They Relate to Consumer Preference*, 27 ENVIRONS ENVTL. L. & POL'Y J. 467, 477 (2004).

49. Coordinated Framework for Regulation of Biotechnology, 51 Fed. Reg. 23,302–303 (Jun. 26, 1986).

50. *Id.* at 23,303.

51. McHughen & Smyth, *supra* note 45, at 4.

52. *Id.*

53. Farquhar & Meyer, *supra* note 15, at 457.

have expressed, "Congress wrote many of the laws used to govern biotechnology before scientists even knew that rDNA modifications were possible, and the laws are not keeping pace with new technological developments."[54]

2. USDA and EPA Authority

The Animal and Plant Health Inspection Service (APHIS) of USDA regulates GM plants under authority granted by the Plant Protection Act of 2000.[55] Its primary concern is the protection of agriculture from pests.[56] According to a 2008 article, USDA has authorized over twelve thousand field trials since the relevant regulation was first published in 1987.[57] The majority of common GM plants are approved for field trials, import, or transportation between states under a simple notification procedure.[58] This process requires a letter to the agency demonstrating that the plant meets particular threshold standards,[59] such as not originating from a noxious weed species.[60] For proposed plants that do not meet such standards, there is a permit process involving heightened scrutiny.[61] In 1993, the USDA implemented new regulations enabling GM plant producers to seek non-regulated status for certain plants considered safe based on prior review by the agency.[62] Obtaining non-regulated status involves an assessment of potential environmental impacts of releasing the proposed plant and additional requirements[63] in order to comply with the Plant Protection Act[64] and National Environmental Policy Act (NEPA).[65]

The EPA, on the other hand, regulates proposed GM plants under authority of the Federal Insecticide, Fungicide and Rodenticide Act (FIFRA), first enacted in 1947.[66] According to the agency, it regulates pesticidal *characteristics* rather than the plants themselves.[67] As a result,

54. *Id.*

55. Plant Protection Act, 7 U.S.C §§ 7701–7786 (2006 & Supp. 2009).

56. McHughen & Smyth, *supra* note 45, at 4–5.

57. *Id.* at 5.

58. *Id.*

59. *Id.*

60. *Id.*

61. *See id.* at 5–6 (describing the permitting process, which involves higher scrutiny than the notification process and applies to genetically modified plants that don't meet the requirements for notification).

62. *Id.* at 6.

63. *Id.*

64. Plant Protection Act, 7 U.S.C. §§ 7701–7786 (2006 & Supp. 2009).

65. National Environmental Policy Act, 42 U.S.C. §§ 4321–4370f (2006).

66. Federal Insecticide, Fungicide, and Rodenticide Act, 7 U.S.C. §§ 136–136y (2006).

67. McHughen & Smyth, *supra* note 45, at 9.

proposed GM plants with pesticide or virus resistance (regardless of the mechanism creating the resistance) have fallen under EPA review since 1995, when the agency started enforcing its initial regulations.[68] In 2001, the EPA began exempting certain categories of GM plants from its oversight.[69] EPA approval involves review of specified data ranging from product characterization to toxicity in non-target species and soil, and assessment of risks associated with gene escape.[70]

B. Regulating for Human Health and Safety: The Role of the FDA

1. The Federal Food, Drug, and Cosmetic Act

The FDA is primarily responsible for regulating the safety of food products in the American marketplace.[71] Under the Food, Drug, and Cosmetic Act (FDCA),[72] which was initially passed in 1938, the agency has authority to take legal action against producers of adulterated or misbranded foods or impose labeling requirements.[73] Adulterated food contains "any poisonous or deleterious substance which may render it injurious to health."[74] Misbranding, on the other hand, means advertising or labeling that it is false or misleading.[75] A misleading label fails to reveal facts that are "material" with respect to the representations made on the label or the consequences that may result from using the product.[76] Whether or not genetic modification is a material fact under this rubric is the critical inquiry.[77] The FDA provided its response to this question in a pivotal 1992

68. *Id.*

69. *Id.*

70. *See id.* at 9–11 (explaining the various categories of data required for submission as part of the approval process and the concerns the EPA seeks to address by analyzing each type of data).

71. Farquhar & Meyer, *supra* note 15, at 450; Zeichner, *supra* note 48, at 480.

72. Federal Food, Drug & Cosmetic Act, 24 U.S.C. §§ 301–399 (2006 & Supp. 2009).

73. Zeichner, *supra* note 48, at 480–81. *See also* CTR. FOR FOOD SAFETY & APPLIED NUTRITION, U.S. FOOD & DRUG ADMIN., GUIDANCE FOR INDUSTRY: VOLUNTARY LABELING INDICATING WHETHER FOODS HAVE OR HAVE NOT BEEN DEVELOPED USING BIOENGINEERING (draft) (2001), http://www.fda.gov/Food/GuidanceComplianceRegulatoryInformation/GuidanceDocuments/FoodLabelingNutrition/ucm059098.htm (last visited Apr. 19, 2011) (explaining that the FDA has authority to impose labeling requirements under the Food, Drug and Cosmetic Act when the label for an existing food product fails to provide certain "material" information and describing situations where specific labeling has typically been required, such as when the absence of the information could pose a particular health risk).

74. 21 U.S.C. § 342 (a)(1) (2006).

75. *Id.* § 343(a)(1).

76. *Id.* § 321(n).

77. 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, 159 (2003).

policy statement, which announced that the agency did not consider the *process* to be material.[78] Rather, the FDA would regulate bioengineered foods based on the end *product*, a policy consistent with the Coordinated Framework's approach.[79] The statement also clarified that labeling of GM ingredients would not be required because they are considered "generally regarded as safe" (GRAS) and laid the groundwork for evaluating the safety of proposed GM foods under the FDCA.[80]

Under these standards, adulterated foods, meaning "foods containing unexpected or novel substances, or usual substances falling outside normal ranges for that kind of food,"[81] trigger FDA review, while unadulterated foods do not, regardless of the process used to create them.[82] GM foods that have an identical or nearly identical composition as their traditional counterparts (meaning "composed of the same substances and in the same amounts and relative proportions"[83]) are considered unadulterated and therefore do not require regulatory review.[84] This criteria set is also known as the substantial equivalence doctrine.[85] Because most GM food products qualify as unadulterated,[86] they are subject to no more than the same labeling requirements imposed on regular foods.[87] Only when a proposed GM product contains an additive that is neither GRAS nor a known allergen will additional scrutiny— and labeling of the allergen under the FDCA or a change of the product name to reflect its actual substance— be required.[88]

2. Voluntary FDA Consultation

Though there is no mandatory assessment process for unadulterated foods, the FDA does offer consultations to evaluate the safety of new

78. Zeichner, *supra* note 48, at 482.

79. *See infra*, Part II.A.1.

80. Foods Derived From New Plant Varieties, 57 Fed. Reg. 22,984, 22,990–991 (May 29, 1992).

81. McHughen & Smyth, *supra* note 45, at 7.

82. *Id.*

83. *Id.*

84. *Id*. *See also* Farquhar & Meyer, *supra* note 15, at 450 ("In this context, 'equivalent' means that there is no meaningful change in nutritional value or composition of the good and that the new variety is as safe as the existing varieties already in commerce.").

85. Zeichner, *supra* note 48, at 481–82.

86. *Id*. at 482.

87. Robertson, *supra* note 77, at 160; Farquhar & Meyer, *supra* note 15, at 452 ("If the nutritional content or potential allergens are the same, FDA will not require a label.").

88. *See* Robertson, *supra* note 77, at 160 (explaining the four limited circumstances under which GMO labeling could be required according to current FDA policy); Farquhar & Meyer, *supra* note 15, at 451 (noting that pre-market FDA approval is required for new genetically modified plant varieties if the new product contains a food additive that has not been deemed GRAS or if the plant "contains a known allergen that it previously did not contain").

foods.[89] Unlike the reviews required by the USDA and EPA, this process is informal and voluntary.[90] It involves submission of data by the developer of the proposed product to the FDA, which evaluates the product's nutritional composition in comparison to its non-GM counterpart and whether it contains any new toxins or allergens.[91] In 1997, the FDA provided procedural guidelines for compiling the relevant data.[92] At the end of the consultation, the agency does not approve or reject the product based on its evaluation; instead, it develops a memo describing the product and potentially relevant safety considerations.[93] Some articles suggest that all GM food products currently available to the public have been submitted for such a consultation.[94] There is no reliable way of verifying whether such claims are accurate, however, because the consultation process is voluntary. As a result, the FDA only has information on the products for which manufacturers sought consultation, but there may be countless other products on the market containing GMOs. Moreover, even if all products have been subjected to consultation, the process does not impose stringent requirements, nor does it prove that a new product is safe.[95] In actuality, the FDA memo represents nothing more than a conclusion that the product is "as safe as its non-modified counterparts," and this conclusion is based only on the evidence reviewed, which is provided by the developer.[96] It is also noteworthy that under these voluntary consultation procedures, the FDA has never rejected a proposed product or refused to allow its development.[97]

3. Case Law Upholding FDA Policy

The FDA's rejection of mandatory labeling for GMOs was upheld by a federal district court in 2000.[98] In *Alliance for Bio-Integrity v. Shalala*,[99] a

89. McHughen & Smyth, *supra* note 45, at 8.

90. *Id.*

91. *Id.*

92. U.S. Food & Drug Admin., Consultation Procedures Under FDA's 1992 Statement of Policy: Foods Derived from New Plant Varieties, http://www.fda.gov/Food/GuidanceComplianceRegulatoryInformation/GuidanceDocuments/Biotechnology/ucm096126.htm (last visited Apr. 19, 2011).

93. McHughen & Smyth, *supra* note 45, at 9.

94. *See, e.g.*, Jacobson, *supra* note 19, at 220 (noting in 2000 that all companies marketing new GM foods had undergone voluntary consultation with the FDA).

95. McHughen and Smyth, *supra* note 45, at 9.

96. *Id.* ("It is worth noting that the FDA does not formally 'approve' an application, or even pass judgment on the safety or efficacy of the new product. Instead, the FDA issues a 'memo' summarizing the features and how they may affect safety concerns. . . . The FDA does not conclude that: 'This new food/feed is safe.' Instead, it concludes, based on the evidence reviewed, that: 'This new food/feed is as safe as its non-modified counterparts.'").

97. Rich, *supra* note 13, at 902 (noting in 2004 that the FDA had not refused to permit development of a single GM product in the last ten years).

98. Alliance for Bio-Integrity v. Shalala, 116 F. Supp. 2d 166, 179 (D.D.C. 2000).

group of consumer advocacy and public interest organizations, along with religious leaders, researchers, and other individuals, challenged the FDA's policy of presuming GM food products to be GRAS under the FDCA.[100] Legal grounds for their claims ranged from violation of the Administrative Procedure Act (the 1992 policy statement did not undergo notice-and-comment)[101] to violation of the First Amendment (based on the impossibility of avoiding certain food products, if unlabeled, due to religious objections)[102] and a claim that the GRAS presumption was arbitrary and capricious.[103] The plaintiffs argued that the FDA had a duty to consider consumer interest in labeling based on the FDCA and the special requirements of people with allergies and religious limitations.[104] The Court found, however, that the FDA's scientific and technological expertise was entitled to deference,[105] in particular the agency's conclusion that genetic engineering as a process does not constitute a material change to food products.[106] As the Court summarized,

> Plaintiffs . . . fail to recognize that the determination that a product differs materially from the type of product it purports to be is a factual predicate to the requirement of labeling. Only once materiality has been established may the FDA consider consumer opinion to determine whether a label is required to disclose a material fact.[107]

The Court also rejected the plaintiffs' constitutional and administrative law arguments and ultimately awarded summary judgment to the FDA.[108]

The *Alliance* Court's holding has been interpreted as establishing that the FDA's authority to mandate labeling of GM foods under current law is extremely limited.[109] Whether the Court's legal analysis is correct is a matter of debate, and there are no other cases directly addressing the

99. *Id.* at 166.

100. *Id.* at 170.

101. *Id.*

102. *Id.*

103. *Id.*

104. *Id.* at 178.

105. *Id*. at 179 ("The FDA has already determined that, in general, rDNA modification does not 'materially' alter foods, and . . . this determination is entitled to deference.").

106. *Id.*

107. *Id.*

108. *Id.* at 181.

109. Zeichner, *supra* note 48, at 483. *See also* Emily Marden, *Risk and Regulation: U.S. Regulatory Policy on Genetically Modified Food and Agriculture*, 44 B.C. L. REV. 733, 756 (2003) ("Ultimately, this decision made clear that critics of FDA's policy had very little legal ground on which to stand. The case, however, did heighten public awareness of GM foods and added to the perception that the government was not regulating these products.").

issue.[110] If this narrow interpretation of the FDA's statutory authority is appropriate, then the only circumstances under which the agency could properly require GMO labeling would be in the face of a known health or safety risk.[111] Yet there are many potential, unknown health risks posed by GMOs that concern consumers and remain entirely unaddressed by the FDA's policy of regulating the product only.[112] Section II of this Comment argues that such risks constitute sufficient justification for a labeling requirement.[113] In order to reach this end in light of the *Alliance* Court's analysis and the FDA's current position, new federal statutory authority will be necessary (or, in the absence of an overhaul to existing FDA policies like substantial equivalence, amendments to the FDCA to create a pre-market approval requirement that captures GM foods deemed "unadulterated" are needed).

II. MANDATORY LABELING OF FOOD PRODUCTS CONTAINING GMOS SHOULD BE REQUIRED UNDER FEDERAL LAW

A. Mandatory Labeling Would Enable Consumers to Make Informed Decisions in Light of the Known and Unknown Health Risks Associated with GMOs

1. Allergens

One of the most serious health concerns associated with GMOs is the possibility of introducing a food allergen that consumers would be unable to anticipate in a particular product.[114] There are multiple ways in which rDNA technology creates this possibility, because it enables scientists to transfer genes between unrelated plants[115] and even kingdoms (e.g., the

110. *See* Moyer & Anway, *supra* note 21, at 701 ("Alliance for Bio-Integrity remains one of the few reported judicial opinions to directly address the growing safety concerns associated with GMOs.").

111. Zeichner, *supra* note 48, at 483.

112. *Id.* at 487 ("Consumers are concerned that the process of genetic engineering may create unknown product characteristics that could pose risks in the long-term….Therefore consumer concerns are not completely addressed in the case of GE foods, by informing them solely of product-based risks."); Rich, *supra* note 13, at 904 ("Until new legislation aimed directly at the regulation of genetically modified products is put into place, the FDA's choices are determining the government's approach to the new technology, and may not reflect the concerns of the people as represented by their legislators.").

113. *See infra*, Part II.B.

114. Premarket Notice Concerning Bioengineered Foods, 66 Fed. Reg. 4706, 4709 (Jan. 18, 2001); Jacobson, *supra* note 19, at 220; McHughen & Smyth, *supra* note 45, at 8; Gao, *supra* note 1, at 304.

115. *See* Gao, *supra* note 1, at 297.

insertion of an animal gene into a plant).[116] First, the direct expression of transferred allergenic proteins may occur, in which case the source of the inserted gene is determinative of allergenicity.[117] Because genetic engineering increases the variety of proteins that can be used beyond those available with traditional breeding, it increases the possibility of inserting a protein that is an allergen.[118] Second, the transfer could cause an indirect effect by activating or de-activating genes adjacent to the insertion site and thereby altering the existing allergenic proteins in the host plant.[119] Notably, this kind of effect is also possible under traditional breeding techniques.[120] Third, because rDNA technology enables the expression of proteins at higher concentrations than would normally be possible, "these higher concentrations may increase the potential for such proteins to be allergenic."[121]

Under any of these mechanisms, *known* allergens do not pose a significant threat because they can be identified, and they must be labeled under the FDCA.[122] It is the possibility of introducing an *unknown* allergen (i.e., a protein that has not previously been identified as a common allergen) that presents a serious health risk under a regulatory scheme that fails to require testing for allergenic properties or labeling of GM ingredients, which would at least alert consumers to the possibility of an unidentified allergen's presence.[123] As one author has stated, "successful testing ordinarily requires human volunteers, which is expensive. Although the likelihood that any particular protein in a genetically modified food is an allergen is relatively small, it is also unlikely that such an allergy would be discovered without extensive testing."[124] In a 2001 policy statement, the FDA commented that it would most likely consider food containing an unexpected allergen to be adulterated, and therefore the agency "should be made aware of the modification and have an opportunity to assess whether

116. Margaret Gilhooley, *Reexamining the Labeling for Biotechnology in Foods: The Species Connection*, 82 NEB. L. REV. 1088, 1111 (2004).

117. Gao, *supra* note 1, at 304.

118. Premarket Notice Concerning Bioengineered Foods, 66 Fed. Reg. at 4709.

119. Gao, *supra* note 1, at 304 ("As a result of transformation, neighboring genes at the site of integration of the insert DNA may be turned off or turned on, resulting in changes in existing proteins. Consequently, the possibility exists that the content of existing allergens of the plant could be elevated or reduced.").

120. *Id.*

121. Premarket Notice Concerning Bioengineered Foods, 66 Fed. Reg. at 4709.

122. *See* 21 U.S.C. § 343(w) (2006) (describing food labeling requirements for known allergens).

123. Rich, *supra* note 13, at 894; *see also* Jacobson, *supra* note 19, at 220 ("An allergen newly introduced into the food supply (say, from a bacterium) would be difficult to identify.").

124. Rich, *supra* note 13, at 894.

and how the food could legally be marketed."[125] The statement was part of a proposed notice requirement, however, and the FDA never issued a final ruling.[126]

One example of the allergy risks associated with genetic engineering occurred when a U.S. company developed a nutritionally enhanced soybean containing a protein from the Brazil nut.[127] Scientists were aware that the Brazil nut was allergenic to some individuals, but did not know which specific protein caused the allergy.[128] Initial research involving human testing determined that the GM soybean expressed the allergenic protein; therefore, the product was destroyed and never reached the commercial marketplace.[129] Though in this case, the allergen was caught prior to causing any detrimental or potentially fatal consequences,[130] the situation serves as an example that the introduction of new allergens into the food supply is more than a theoretical possibility. Had the producer of the proposed product not discovered the problem, it would have been left to the company's discretion whether or not to seek review by the FDA.[131] Without a mandatory review and labeling requirement, there remains a strong possibility that unknown allergens will be introduced into the food supply in the future.

2. Toxins

Genetic engineering also presents a risk of creating new toxins or altering levels of existing ones.[132] As with allergens, the effect may be direct or indirect.[133] A common example of the direct effect is *Bacillus thuringiensis* (Bt) plants, an early commercial product of rDNA technology that introduced genes from soil bacterium into host crops like corn in order to give them insecticidal properties.[134] There is no definitive research proving that the consumption of such plants is safe or unsafe.[135] Though studies thus far have not demonstrated any short-term risks,[136] the products have not been on the market long enough to make an analysis of their long-

125. Premarket Notice Concerning Bioengineered Foods, 66 Fed. Reg. at 4710.

126. Gilhooly, *supra* note 116, at 1097–98.

127. Gao, *supra* note 1, at 304.

128. *Id.*

129. *See id* (noting that all field testing was stopped and all plant material destroyed).

130. *See id* (noting that the product never moved beyond field testing).

131. *See supra*, Part I.B.2.

132. Gao, *supra* note 1, at 299–300.

133. *Id.*

134. *Id.* at 301. More specifically, the transferred gene causes the host plant to express particular endotoxins that repel common insects. *Id.*

135. Rich, *supra* note 13, at 894–95.

136. *Id.*

term effects feasible.[137] The widespread use of Bt crops has caused some in the scientific community to hypothesize about the potential dangers associated with higher exposure levels, particularly for immuno-compromised individuals.[138] Genetic engineering may also produce an indirect effect on levels of plant toxins because "the introduction of new genes may increase or decrease the expression of the existing proteins or enzymes, which in turn results in the change of other substances in plants."[139] Finally, the process itself can have the indirect effect of increasing (or decreasing) the amount of toxins produced by a plant, if, for instance, a transgene is inserted into a host gene that plays a role in regulating toxin levels.[140] Because the most common scientific methods used for genetic modification involve random insertion, there is a distinct possibility of this occurrence.[141]

In 1990, a genetically engineered version of the supplement tryptophan was taken off the market after scientists discovered that it was responsible for producing deadly contaminants.[142] The mistake cost at least thirty-six Americans their lives, and caused 1500 people to develop a permanently disabling blood disorder known as eosinophilia-myalgia syndrome (EMS).[143] The *New York Times* reported that the Japanese chemical company responsible for marketing the supplement has paid billions in damages to victims of the incident.[144] Although the genetic modification

137. *Id.* at 895.

138. *Id.*

139. Gao, *supra* note 1, at 299–300. *See also* Jacobson, *supra* note 19, at 220 ("Levels of naturally occurring toxins, such as solanine, might accidentally be increased in genetically modified plants.").

140. Gao, *supra* note 1, at 300. *See also* JEFFREY M. SMITH, GENETIC ROULETTE: THE DOCUMENTED HEALTH RISKS OF GENETICALLY ENGINEERED FOODS 84–6 (2007) (discussing the alteration in levels of plant metabolites that results from gene insertion and providing examples of studies demonstrating increased toxin production by genetically engineered tobacco, yeast, potatoes, and wheat).

141. Gao, *supra* note 1, at 300; Robertson, *supra* note 77, at 168 ("Techniques, such as directly inserting genes using a 'gene gun' or transferring DNA through bacteria, do not provide great control over where the genetic material is inserted."). For further discussion of the disruptive effect of randomly inserting transgenes into host plant DNA, see Smith, *supra* note 140, at 64–5.

142. Denise Grady, *Dietary Supplement Found to Be Contaminated*, N.Y. TIMES, Sep. 1, 1998, at F8. *See also* THE CAMPAIGN TO LABEL GENETICALLY ENGINEERED FOODS, GENETICALLY ENGINEERED FOODS AND YOUR HEALTH (2003) (on file with author) (describing the dietary supplement as "mutated tryptophan" and asserting that it "wreaked havoc" in the form of death and disability before the FDA recalled it).

143. *See, e.g.*, Genetically-Modified Foods: The Silent Killer, GM Tryptophan-EMS-Killed 37 and Permanently Disabled 1500 People, http://todayyesterdayandtomorrow.wordpress.com/2007/06/09/gm-tryptophan-ems-killed-37-and-permanently-disabled-1500-people/ (last visited Apr. 19, 2011). The disorder is known as EMS because it causes elevated counts of eosinophils, a type of white blood cell. Grady, *supra* note 142.

144. Grady, *supra* note 142.

process was never definitively proven to be the source of the toxin production, substantial evidence indicates that it likely was.[145] Most notably, some experts have blamed the lack of a labeling requirement—which made it impossible to discern whether consumers had ingested a conventional or GE version of the supplement— for the months-long delay in discovering the source of the toxins.[146] Had there been a labeling requirement, the FDA would arguably have been able to isolate the source of the contaminant more quickly and save lives or prevent disability as a result.

3. Antibiotic Resistance

The third known health risk that may be associated with genetic engineering is antibiotic resistance.[147] It is common practice to use antibiotic-resistant marker genes as part of the procedure so scientists can determine whether they have successfully inserted the target gene.[148] As one author has summarized, "Some scientists fear that the quality [of antibiotic resistance] could be transferred either to humans who consume the plant, or to naturally occurring pathogenic bacteria, thus reducing the therapeutic effects of antibiotics taken for medical reasons."[149] The serious consequences of antibiotic resistance have been well documented in recent years, due to the media spotlight on so-called superbugs, such as Extensively-Drug-Resistant Tuberculosis (XDR TB) and Methicillin-resistant Staphylococcus Aureus (MRSA).[150] Whether or not genetic

145. *See* JEFFREY M. SMITH, SEEDS OF DECEPTION 107–25 (2003) (describing the available evidence, scientific and media coverage surrounding the incident, and the FDA's resistance to experts' efforts to link the genetic engineering process with the fatal toxins).

146. John B. Fagan, Physicians & Scientists for Responsible Application of Science & Technology, Tryptophan Summary (Nov. 1997), http://www.psrast.org/jftrypt.htm.

147. Rich, *supra* note 13, at 895. Antibiotic resistance has become a serious public health threat in recent decades. CTRS. FOR DISEASE CONTROL & PREVENTION, FAST FACTS: FACTS ABOUT ANTIBIOTIC RESISTANCE, http://www.cdc.gov/getsmart/antibiotic-use/fast-facts.html (last visited Apr. 19, 2011). It is thought to result from the misuse and overuse of antibiotics to combat common bacterial infections in human and veterinary medicine. *Id.* As a result of this growing phenomenon, bacterial illnesses are posing more serious health consequences as the underlying bacteria that cause them become resistant to the frontline antibiotics previously used for treatment. *Id.*

148. Rich, *supra* note 13, at 895.

149. *Id. See also* THE CAMPAIGN TO LABEL GENETICALLY ENGINEERED FOODS, *supra* note 142 (describing the use of antibiotics as markers in genetic engineering and the risk that these markers may increase antibiotic resistance).

150. TASK GROUP ON PUBLIC PERCEPTIONS OF BIOTECHNOLOGY, EUROPEAN FEDERATION OF BIOTECHNOLOGY, ANTIBIOTIC RESISTANCE MARKERS IN GENETICALLY MODIFIED (GM) CROPS 2 (2001), *available at* http://www.efb-central.org/images/uploads/AntibioticRM_English.pdf ("Today resistance to antibiotics is so widespread that some of the first generation of antibiotics are of no use anymore. Multiple antibiotic resistance in pathogenic strains of *Staphylococcus* and

engineering practices contribute substantially to antibiotic resistance is not entirely resolved and merits focused scientific study.[151] In the meantime, the possibility is sufficient to support a labeling requirement, so consumers who wish to avoid GM products due to this uncertainty are afforded the opportunity to do so.

4. Unknown Long-Term Health Risks

Uncertainty is the bottom line for many consumers. There is no determinative research on the long-term effects of eating genetically engineered foods.[152] They have not been on the market long enough for scientists to conduct longitudinal studies or even studies that take into account one human lifespan.[153] Additionally, because labeling has not been required to date, future researchers face the potentially insurmountable task of creating control groups that have never been exposed to GM products—an element that is, at best, difficult to determine when consumers cannot distinguish between conventional and GM foods.[154] As one author framed

Mycobacterium tuberculosis, especially in hospitals, is of particular concern to the medical community.").

151. *See id.* at 4 (acknowledging that antibiotic resistant markers have not necessarily been proven safe and noting that alternative markers are under investigation but will require additional safety studies prior to commercialization).

152. Rich, *supra* note 13, at 901 ("To some extent, the question of how safe or dangerous genetically modified crops are is still unanswerable, due to a lack of studies on the long-term effects of GMOs on both human health and the environment."); *id.* at 900 ("At the very least, the cumulative force of the research is indeterminate of the risk posed by GMOs to human health.").

153. *See id.* at 900 (indicating that there is existing research concluding GMOs are safe for human health, but only in the "short term," and characterizing research suggestive of health risks as "speculative"). GM plants first became available on the commercial market in 1996. Gao, *supra* note 1, at 298. Therefore an individual who has been consuming GMOs since 1996 has been exposed to them for only fifteen years, whereas the average life expectancy in the U.S. is about 78. Melonie Heron et al., *Deaths: Final Data for 2006*, 57 NAT'L VITAL STAT. REP. 1 (2009), *available at* http://www.cdc.gov/nchs/data/nvsr/nvsr57/nvsr57_14.pdf. Furthermore, there has been an observed tendency for the biotechnology industry to produce studies concluding that GM products are safe, "while most of the risk-finding studies are conducted by private researchers." Rich, *supra* note 13, at 900.

154. There is no surefire way to ensure that a study participant has entirely avoided foods containing GM ingredients, but participants who claim to exclusively consume certified organic foods would be a starting point, since foods that are certified and labeled as organic cannot contain GM ingredients. *See* Zeichner, *supra* note 48, at 488 ("The USDA organic label was created in accordance with organic principles that promote awareness of the impacts that production of food has on the environment, the animal world and society as a whole. After much consideration, the USDA decided that genetic engineering was not consistent with these ideals and concluded that the organic label should not be used on foods that have gone through GE processes."). On the other hand, this exclusion applies only to the *process* of genetic engineering. Therefore under USDA policy, "the unintended presence of [GM] products does not affect the status of an organic product or operations." Rich, *supra* note 13, at 911 (citing National Organic Program, 7 C.F.R. § 205 (2003)). In other words, a food that is certified organic may unintentionally contain GMOs

the issue: "The introduction of GMO products into the United States food supply serves as an experiment, albeit performed on unwilling subjects and without following scientific method."[155] An FDA report in 2000 revealed that consumers are concerned about "the potential for unknown long-term effects of the technology, in particular health effects."[156] This attitude, also known as the hazard model, is informed by comparisons to other agricultural technologies (e.g., growth hormones) and the belief that the government does not adequately consider consumer interests.[157]

One example of an unknown but potentially long-term health risk is the possibility that genetic modification could somehow alter the level of existing nutrients in the host plant or their ability to be absorbed by the human body.[158] This prospect, like producing new allergens or toxins, arises as a result of the random insertion of the transgene.[159] Though an alteration in the level of most nutrients would not typically have fatal consequences, it could nonetheless be seriously injurious to health in situations where certain populations rely on a particular GM food as their main source of a specific nutrient.[160] Assume, for example, that a particular neighborhood with a large Latino population is a major consumer of corn and depends on this dietary staple as its primary source of Vitamin B1 (thiamin). Because there is no labeling requirement, this group has no way of determining whether it is consuming conventional or GM corn. If the GM corn contains lowered values of vitamin B1, and this population is consuming mostly GM corn, then negative health consequences may ensue. Memory loss and Alzheimer's disease are associated with a lack of acetylcholine,[161] and the synthesis of this neurotransmitter requires sufficient amounts of Vitamin B1.[162] What's more, the affected individuals would not be aware of the source of the problem and, therefore, would not be empowered to make adjustments in their purchasing and eating habits to account for this potential impact.

due to pollen drift. *Id*. This situation aggravates the difficulty of identifying a group of individuals for research purposes who have never consumed GMOs.

155. Rich, *supra* note 13, at 901.

156. Zeichner, *supra* note 48, at 485 (citing ALAN S. LEVY & BRENDA M. DERBY, U.S. FOOD & DRUG ADMIN., REPORT ON CONSUMER FOCUS GROUPS ON BIOTECHNOLOGY (2000)).

157. *Id* at 486 (citing ALAN S. LEVY & BRENDA M. DERBY, U.S. FOOD & DRUG ADMIN., REPORT ON CONSUMER FOCUS GROUPS ON BIOTECHNOLOGY (2000)).

158. Rich, *supra* note 13, at 895.

159. *See supra* note 141 and accompanying text. For further discussion, see Gao, *supra* note 1, at 306 (describing the four ways in which an alteration of nutrient levels could potentially occur).

160. Gao, *supra* note 1, at 306.

161. The World's Healthiest Foods, Corn, http://www.whfoods.com/genpage.php?tname=foodspice&dbid=90 (last visited Apr. 19, 2011).

162. *Id.*

Opponents of GMO labeling point out that the same problem can occur using conventional breeding techniques and that the issue is addressed by the nutritional analysis GM foods undergo.[163] This FDA consultation is entirely voluntary, however,[164] so there is no way of ensuring that a significant change in the nutritional profile of a GM plant would be identified. The fact that genetic engineering can now be used to improve the nutritional profile of certain foods[165] increases the odds that a particular population will rely solely on a GM food for a particular nutrient.[166] For instance, a variety of rice with enhanced levels of Vitamin A (also known as Golden Rice) is currently under development,[167] with the goal of distributing it to developing countries where large numbers of people suffer from the debilitating effects of Vitamin A deficiency, such as blindness.[168] Only if the developer of Golden Rice chooses to undergo voluntary consultation with the FDA will an independent compositional analysis be performed to evaluate the nutrients contained in the new product. Otherwise, it is entirely possible that a critical nutrient in the rice, other than Vitamin A, could potentially be lowered as a result of the genetic modification process; thus, a population that mainly eats rice would suffer any health consequences associated with a reduction of that nutrient.

B. Policy Arguments Support a Mandatory Labeling Requirement for GMOs

As an initial premise, expecting the developers of GM foods to self-police when they stand to benefit significantly from the commercial availability of these products creates a conflict of interest.[169] Not only is future profit at stake, but the biotechnology industry has also invested billions of dollars in research and development,[170] and therefore, has an obvious interest in promoting the widespread use of GMOs whether or not

163. Gao, *supra* note 1, at 306 ("The potential alteration in nutrient composition of new GM varieties is addressed through characterization of the inserted gene and compositional analysis of the GM foods.").

164. *See supra*, Part I.B.2.

165. Gao, *supra* note 1, at 306.

166. *See id.* (noting that the greatest incidence of Vitamin A deficiency is found in South and Southeast Asia because rice is the primary food in these regions, and it does not produce Vitamin A).

167. *Id.* at 306–07.

168. Gregory Jaffe, *The Next Generation*, 26 ENV. FORUM 38, 40 (2009); Baris Karapinar & Michelangelo Temmerman, *Benefiting from Biotechnology: Pro-Poor Intellectual Property Rights and Public-Private Partnerships*, 27 BIOTECH. L. REP. 189, 191 (2008).

169. THE CAMPAIGN TO LABEL GENETICALLY ENGINEERED FOODS, *supra* note 142.

170. Rich, *supra* note 13, at 909 ("The biotech food industry has not only spent billions of dollars on research and development, but has also spent millions in fighting labeling initiatives.").

they are safe.[171] A labeling requirement would level this uneven playing field by putting the burden of proving the safety of GMOs on those in a position to gain from them.[172] Such a requirement would "encourage biotech companies to 'sell' the consumers on their products, rather than slipping the products into the market without notice to consumers."[173] Otherwise, American consumers bear the potential risks and costs associated with this technology.[174]

In a similar vein, a labeling requirement would increase consumer awareness of the issue and promote public debate.[175] It would also highlight the need for and encourage additional research on the safety of GM foods.[176] Considering the deadly tryptophan incident in 1990, for example, begs the question whether a labeling requirement would have inspired the manufacturer to conduct more extensive testing of its product prior to marketing. Labeling would enable consumers to correlate GM products with their corporate manufacturers;[177] thus, it would encourage FDA consultation and additional research because the reputation of a company's name brand would be on the line.

The American public overwhelmingly supports mandated labeling.[178] In 2000, the FDA convened consumer focus groups on the topic of GMO labeling in four states selected to reflect cultural and geographic diversity.[179] The study found that almost all participants favored a labeling requirement,[180] and, additionally, that they expressed shock and "outrage" upon learning that GMOs were already available to the public.[181] An ABC poll the following year concluded that ninety-three percent of respondents believed there should be a federal labeling requirement for all GE foods.[182] Also in 2001, the Center for Science in the Public Interest found that about

171. *Id.* ("It would seem that [the biotech industry has] bet the proverbial bank on the success of their products, and thus [has] more than just a glancing interest in the widespread public acceptance of genetically modified foods.").

172. THE CAMPAIGN TO LABEL GENETICALLY ENGINEERED FOODS, *supra* note 142.

173. Rich, *supra* note 13, at 915.

174. *Id.* at 909.

175. THE CAMPAIGN TO LABEL GENETICALLY ENGINEERED FOODS, *supra* note 142.

176. *Id.*

177. *Id.*

178. *See infra*, notes 180–87 and accompanying text.

179. *See* Megan Carter Judge, Consumers and Benefits of Genetically Modified Vegetables 30 (Mar. 2010) (unpublished M.S. dissertation, California Polytechnic State University) (on file with author) (reporting the details of the FDA focus group study, which is no longer available from FDA).

180. *See id.* at 32 ("Participants were in agreement on the value of a 'mere disclosure' labeling.").

181. *Id.* at 33.

182. Gary Langer, *Behind the Label: Many Skeptical of Bio-Engineered Food*, ABCNEWS.COM (2001), http://abcnews.go.com/sections/scitech/DailyNews/poll010619.html.

two-thirds of its survey participants wanted GMO labeling.[183] Additional studies by the Pew Initiative and Novartis, a major producer of GM foods, reported that seventy-five percent and ninety-three percent of respondents, respectively, supported a labeling requirement.[184] Consumer support for stricter regulations is not just a thing of the past; more recently, there was a strong backlash against President Bush's proposals to loosen regulation of GM crops.[185] In March 2009, a group of eighty-two public interest, environmental advocacy, and farming organizations[186] sent a letter to the Secretary of the USDA demanding that the agency provide stricter oversight with more public input and freeze approvals of GM crops pending such changes.[187] While the attitude of the public may not be based on scientific knowledge, its buying power keeps the biotechnology industry in business; to overlook public outcry is overly paternalistic from a policy standpoint and undermines the principles of democratic government, particularly in light of the industry's unmatched lobbying power.[188]

Not only does the public *want* to know what it is eating,[189] but there is also a substantial movement arguing that the public has a *right* to know.[190] Consumers may wish to avoid GMOs for many reasons, whether due to concern over potential health risks, dietary limitations, or religious or

183. Gregory A. Jaffe, Center for Science in the Public Interest, Labeling Genetically Modified Foods: Communicating or Creating Confusion? (Jun. 27, 2002), http:www.cspinet.org/biotech/pew-forum.html.

184. Zeichner, *supra* note 48, at 485 (citing *Compilation and Analysis of Public Opinion Polls on Genetically Engineered Foods*, CTR. FOR FOOD SAFETY, http://www.centerforfoodsafety.org/facts&issues/polls.html (Feb. 1, 2000)).

185. *See* Press Release, Ctr. for Food Safety, Diverse Farmer and Public Interest Groups Urge USDA to Freeze Approvals of Genetically Engineered Crops (Mar. 20, 2009), http://www.centerforfoodsafety.org/2009/03/20/diverse-farmer-and-public-interest-groups-urge-usda-to-freeze-approvals-of-genetically-engineered-crops.

186. Signatories to the letter included groups as diverse as the California Farm Stewardship Association, Farm Aid, Health Care Without Harm, the National Cooperative Grocers Association, the Rodale Institute, the Sierra Club, the Union of Concerned Scientists, and small seed companies and family farms, among others. Letter from Eighty-Two Public Interest Groups to Tom Vilsack, Secretary, U.S. Dep't of Agric. (Mar. 20, 2009), *available at* http://www.centerforfoodsafety.org/pubs/Final_APHIS-2008-2003%20Supplemental%20Comments.pdf.

187. *Id.*

188. Rich, *supra* note 13, at 906 ("To ignore mass public concern is irresponsible, and denotes a paternalistic approach to public policy. . . . The public's 'right to know' might better be thought of as a 'right to be heard.' And listened to. This is the essence of a representative government, a fact not lost to the biotech industry, which has taken full advantage of their lobbying power to ensure technology-friendly regulations.").

189. *See supra*, notes 180–87 and accompanying text.

190. *See* Rich, *supra* note 13, at 904–09 (describing the consumer right-to-know argument within the context of consumer choice and the biotech industry's desire to avoid a labeling requirement).

moral restrictions.[191] Vegetarians, for instance, "may find unacceptable the presence of a non-vegetable constituent even in the form of a gene, which only expresses agronomic characteristics useful for growth."[192] Because GMOs are found in a vast majority of grocery store products,[193] it would be difficult, if not impossible, for such consumers to avoid them altogether.[194] Without labeling, their only choice is to grow their own food or purchase only certified organic food, options that would not be feasible for many Americans based on the land and other resources required for the former and the higher cost and limited availability of the latter.[195] From a policy perspective, these options are so unrealistic that people are essentially not afforded a choice at all.

What's more, individuals cannot identify food products containing GM ingredients and are therefore excluded not only from taking personal responsibility for their health in this regard, but also from expressing a preference that should be reflected in the marketplace.[196] As many experts have pointed out, the industry's argument is contrary to the very concept of consumer choice: "Without labeling, no choice can be made, and thus no preference can be conveyed to the manufacturers. The fear of the biotech industry may not be that irrational choices will be made by consumers, but that consumers will legitimately reject their products."[197] Some ardent proponents of this approach go so far as to argue that the lack of a labeling requirement constitutes consumer deception in cases where a GM food is so different from its conventional counterpart that it cannot be understood to be the same product.[198]

C. The Solution Should Come Under Federal Rather than State Law to Achieve Uniformity and Circumvent Legal Challenges that Would Most Likely Make State Legislative Responses Ineffective

A mandatory labeling scheme should be implemented under federal law in order to avoid the constitutional problems that have plagued state efforts to enact such laws thus far. State responses to biotechnology issues

191. Robertson, *supra* note 77, at 170; Gilhooley, *supra* note 116, at 1112.

192. Gilhooley, *supra* note 116, at 1112.

193. *See supra* note 10 and accompanying text.

194. Rich, *supra* note 13, at 907.

195. *Id.*

196. *Id.* at 908.

197. *Id.*

198. Gilhooley, *supra* note 116, at 1103–04 ("The important question is whether the consumer would understand a food to be different, and not what they thought it to be, if the food incorporated a gene from a different plant without a disclosure.").

have varied widely: a 2007 article reported that nine states[199] at that time had labeling laws (mandatory or voluntary), while twenty-two[200] gave tax breaks or other funding to attract biotech producers.[201] At the other end of the spectrum, dozens of bills have been introduced at the state level proposing to ban particular biotech products or requiring a permit to import or commercially release them within the state.[202] Where states have passed mandatory GMO labeling requirements, the courts have not upheld them.[203] A frequently cited example, which presents similar concerns though it is not precisely parallel, is Vermont's mandatory labeling of milk products containing the growth hormone rBST.[204] In 1995, the Court of Appeals for the Second Circuit granted an injunction to the dairy industry against enforcement of the statute.[205] The dairy producers successfully argued that it violated the First Amendment.[206]

Preemption by federal food labeling laws may also pose an insurmountable challenge. It is important to distinguish labeling from food safety, which the Supreme Court considers to be a local issue.[207] States are free (to some extent) to impose more rigorous restrictions on food safety than the FDCA does,[208] and courts typically set the threshold at explicit

199. Farquhar & Meyer, *supra* note 15, at 459 (citing National Conference of State Legislatures, Biotechnology Statutes Chart, Jul. 7, 2007, http://www.ncsl.org/programs/agri/biotchlg.htm). The nine states with labeling laws are: Alaska, Maine, Michigan, Minnesota, Mississippi, Pennsylvania, Vermont, Virginia and Wisconsin. *Id.*

200. The states with financial breaks for biotechnology producers include: Arizona, Arkansas, California, Colorado, Connecticut, Delaware, Hawaii, Illinois, Iowa, Kansas, Louisiana, Maine, Massachusetts, Maryland, Michigan, Minnesota, New Hampshire, New Jersey, New Mexico, North Carolina, Oklahoma, and Texas. Farquhar & Meyer, *supra* note 15, at 459 (citing National Conference of State Legislatures, Biotechnology Statutes Chart, http://www.ncsl.org/programs/agri/biotchlg.htm).

201. *Id*.

202. *Id.* (citing National Conference of State Legislatures, Biotechnology Statutes Chart, http://www.ncsl.org/programs/agri/biotchlg.htm) ("California is the only state to have an outright ban on a biotechnology product, but twenty-nine bills have been introduced seeking to ban some aspect of biotechnology, and nine states require a permit either for the importation or release of genetically-modified products.").

203. *See* Robertson, *supra* note 77, at 163–65 (describing successful constitutional challenges to state statutes mandating labeling of GMOs, based on Commerce Clause and First Amendment claims).

204. *Id.* at 163–64.

205. Int'l Dairy Foods Ass'n v. Amestoy, 92 F.3d 67, 69 (2d Cir. 1996).

206. *Id.* at 72–73. The dairy manufacturers also made an argument based on Commerce Clause grounds, but the Court did not reach this claim because it found that they were entitled to an injunction based on the First Amendment claim. *Id.* at 70.

207. Farquhar & Meyer, *supra* note 15, at 468.

208. *Id*. at 469 ("The definition of adulterated food in the FDCA is considered a floor for food safety regulations, not a ceiling. Therefore, under the FDCA, states may place additional restrictions on food production produced using biotechnology. . . . Short of a ban, states may

preemption or conflict preemption as a requirement for blocking state action in this area.[209] For food labeling, however, there is clear evidence of Congressional intent to preempt state regulation.[210] The Nutrition Labeling and Education Act (NLEA)[211] is the impetus behind the common nutrition facts panel found on grocery store shelves around the country.[212] This information is required under the first section of the NLEA.[213] The second section of the statute involves voluntary claims that expressly or implicitly relate to any of the nutrients on the requisite nutrition facts (e.g., "high in fiber").[214]

The NLEA addresses preemption explicitly.[215] First, states may not impose food labeling requirements that are not identical to those under the first section of the NLEA.[216] An exception to this provision leaves states free to regulate nutrient labels for food sold in restaurants rather than retail locations like grocery stores.[217] Second, states are prohibited from regulating the voluntary health claims falling under the second section of the statute, even when they are made on food sold by restaurants.[218] The FDA posits that information on biotechnology procedures used to create a food product does not constitute nutritional information that meets disclosure requirements; therefore, "it is unlikely it will find that the general public of a state has a particular need for the information; and thus, it is unlikely that the FDA will grant an exemption for mandatory labeling."[219] Even if an exemption were granted, Constitutional objections—namely the

regulate food safety so long as those regulations do not contradict federal regulations, and food producers can comply with both sets of rules.").

209. *Id.* at 468 ("Because food safety is generally a local concern, courts require either explicit preemption or conflict preemption in order to preempt a state or local regulation.") (citing Fla. Lime & Avocado Growers, Inc. v. Paul, 373 U.S. 132, 144 (1963)).

210. *Id.*

211. 21 U.S.C. §§ 343(q)-(r) (2006 & Supp. 2009).

212. *Id.* § 343(q)(1).

213. *Id.*

214. *Id.* § 343(r)(1)(A); *id.* § 343(r)(1)(B).

215. *Id.* § 343-1(a)(4); *id.* § 343-1(a)(5).

216. *Id.* 343-1(a)(4).

217. N.Y. State Rest. Ass'n v. N.Y. City Bd. Of Health, 509 F. Supp 2d 351, 357 (S.D.N.Y. 2007).

218. *Id.* at 358.

219. Farquhar & Meyer, *supra* note 15, at 469–70 (citing CTR. FOR FOOD SAFETY & APPLIED NUTRITION, U.S. FOOD & DRUG ADMIN., GUIDANCE FOR INDUSTRY: VOLUNTARY LABELING INDICATING WHETHER FOODS HAVE OR HAVE NOT BEEN DEVELOPED USING BIOENGINEERING (draft) (2001), http://www.fda.gov/Food/GuidanceComplianceRegulatoryInformation/GuidanceDocuments/FoodLabelingNutrition/ucm059098.htm (last visited Apr. 19, 2011).

commercial free speech rights of GMO producers under the First Amendment—are likely to impede state litigation.[220]

Even without the constitutional obstacles facing state legislatures in this arena, state legislation would not be the appropriate forum for imposing a labeling regime.[221] States lack the resources to conduct adequate research on the human health impacts of GM products, and as a consequence, state officials feel this responsibility should fall on the shoulders of the federal government.[222] A 2004 survey by the Pew Foundation suggested that states operate under conflicting influences when it comes to biotechnology: if their regulations are too strict, they could drive biotech dollars to other states, but if they are not strict enough, the health and safety of their residents could be at risk.[223] The Pew survey also revealed that state officials are primarily concerned with the local impacts of biotechnology, such as economic issues facing local farmers.[224] Considering these challenges to state labeling legislation in the aggregate, as one author has concluded, "If Congress wishes to treat biotechnology differently from conventional crops, and either grant states greater or lesser power to regulate the field, it must act and specify that desire. Until then, courts will likely view the inaction as satisfaction with the currently [sic] regulatory scheme, including that scheme's preemption."[225]

D. Voluntary Labeling Is Not a Viable Alternative and Would Most Likely Violate FDA Policy

One option for food producers is voluntary labeling to express the absence of GMOs (e.g., "GMO free") or indicate that biotechnology has not

220. For further discussion, see *id.* at 470. For additional discussion of preemption by the NLEA, see Robertson, *supra* note 77, at 165–68.

221. *See infra* notes 222–25 and accompanying text.

222. Farquhar & Meyer, *supra* note 15, at 458 (citing MICHAEL R. TAYLOR ET AL., RESOURCES FOR THE FUTURE, TENDING THE FIELDS: STATE & FEDERAL ROLES IN THE OVERSIGHT OF GENETICALLY MODIFIED CROPS 22 (2004), *available at* http://www.pewtrusts.org/uploadedFiles/wwwpewtrustsorg/Reports/Food_and_Biotechnology/Tending_Fields_Biotech1204.pdf).

223. *Id.* (citing MICHAEL R. TAYLOR ET AL., RESOURCES FOR THE FUTURE, TENDING THE FIELDS: STATE & FEDERAL ROLES IN THE OVERSIGHT OF GENETICALLY MODIFIED CROPS 26 (2004), *available at* http://www.pewtrusts.org/uploadedFiles/wwwpewtrustsorg/Reports/Food_and_Biotechnology/Tending_Fields_Biotech1204.pdf).

224. *Id.* (citing MICHAEL R. TAYLOR ET AL., RESOURCES FOR THE FUTURE, TENDING THE FIELDS: STATE & FEDERAL ROLES IN THE OVERSIGHT OF GENETICALLY MODIFIED CROPS 22 (2004), *available at* http://www.pewtrusts.org/uploadedFiles/wwwpewtrustsorg/Reports/Food_and_Biotechnology/Tending_Fields_Biotech1204.pdf).

225. *Id.* at 474.

been used in the development of a particular food product.[226] There are two reasons that voluntary labeling is problematic and does not offer a sufficient solution for notifying consumers about GM ingredients. First, there is a likelihood that many voluntary labels violate FDA regulations,[227] although the FDA has not expressly prohibited them.[228] The agency issued a policy statement in 2001 indicating that claims like "GMO free" may be misleading, and therefore barred under the FDCA,[229] because a threshold level of GM components in food items has not been established, and such a label may imply that foods containing GMOs are inferior.[230] Additional guidance from the FDA provided examples of acceptable claims that would "avoid or minimize" an implication of inferiority, such as "we do not use ingredients that were produced using biotechnology."[231] On the other hand, it described in detail the many ways in which a claim could be misleading.[232] For instance, even when it is true that a particular ingredient was not genetically modified, such a statement would be misleading "if consumers believe that the entire product or a larger portion of it than is actually the case is free of bioengineered material."[233] Another example of a potentially misleading statement is a claim that an item or ingredient is not genetically modified, when there has never been a GM version of that item or ingredient available on the market.[234] This guidance is likely to be confusing to food manufacturers and therefore overly burdensome to interpret and implement,[235] especially considering the potential costs and legal exposure that result from violating the FDCA.[236]

226. *Id.* at 452.

227. Robertson, *supra* note 77, at 161.

228. *Id.* ("Even voluntary disclosure of the presence or absence of GMOs on labels may violate FDA regulations."); *see also* Chen, *supra* note 18, at 1583 (describing in detail the conflict between voluntary labeling and the FDCA).

229. Voluntary Labeling Indicating Whether Foods Have or Have Not Been Developed Using Bioengineering, 66 Fed. Reg. 4839, 4840 (Jan. 18, 2001).

230. *Id*.

231. CTR. FOR FOOD SAFETY & APPLIED NUTRITION, U.S. FOOD & DRUG ADMIN., GUIDANCE FOR INDUSTRY: VOLUNTARY LABELING INDICATING WHETHER FOODS HAVE OR HAVE NOT BEEN DEVELOPED USING BIOENGINEERING (draft) (2001), http://www.fda.gov/Food/GuidanceComplianceRegulatoryInformation/GuidanceDocuments/FoodLabelingNutrition/ucm059098.htm (last visited Apr. 19, 2011).

232. *Id.*

233. *Id*.

234. *Id.*

235. Robertson, *supra* note 77, at 161 ("The FDA has given confusing signals regarding whether producers can voluntarily and legally use labels specifically noting that they do not use GMO ingredients."); *id.* at 163 ("Until this issue is litigated, non-GMO food producers will increase their exposure to law suits by continuing to market products with labels referring to health or environmental issues and the absence of GMO ingredients.").

236. *See* 21 U.S.C. § 333(a) (2006) (describing the criminal penalties for violating the FDCA); *id.* § 335b(a) (describing civil penalties for violating the FDCA).

The second obvious problem is that this type of labeling is purely voluntary,[237] so it remains difficult or impossible to distinguish most GM products from their unlabeled, non-GM counterparts. In light of the strong possibility that many voluntary labels (even those considered appropriate by the FDA) will be misleading or confusing to the public, they may even undermine the goal of empowering consumers with accurate information.[238] Such a system leaves consumers vulnerable to exaggerated labeling claims that play into popular suspicions of biotechnology.[239] From another perspective, a voluntary labeling scheme may also be unfair in that it places the costs associated with labeling on the producers of non-GMO foods, whereas the producers of GMOs are the ones introducing a new technology that deviates from the established status quo.[240] Some states have successfully steered clear of this issue by integrating biotechnology considerations into their organic labeling regulations, such as requiring that certified organic foods be produced with little or no genetic modification.[241]

CONCLUSION

At the heart of the controversy surrounding GMOs is this question: is it appropriate for the government to presume GM foods are safe and allow the biotechnology industry to market them until proven otherwise, or should the onus of demonstrating their safety be on the companies who stand to profit from them?[242] Though no studies definitively prove that GMOs are harmful, no studies prove that they are safe either.[243] Considering the possibility of serious health and safety risks,[244] we should err on the side of adopting an overly cautious approach to regulation. As history has demonstrated, if any of the potential risks actualize, the result could be

237. *See supra* notes 86–88 and accompanying text.

238. Jaffe, *supra* note 183 ("Much of the information provided in a voluntary system will take advantage of consumers' concerns and lack of knowledge about biotechnology, instead of providing accurate and non-disparaging information.").

239. *Id*; s*ee also* Chen, *supra* note 18, at 1585–86 ("Fear about food is one of the most deeply seated forms of behavioral protection against the natural world. . . . It is precisely here, where food comes into contact with notions of good and evil, that the classic regulatory state must take its stand.").

240. Rich, *supra* note 13, at 909 ("While it may be in the industry's best interest to not label, the alternative is that those who do not want to eat genetically modified foods will bear the cost. Whether or not such an expectation is fair to the concerned consumer remains in doubt.").

241. Farquhar & Meyer, *supra* note 15, at 471.

242. *See supra*, Part B.

243. Rich, *supra* note 13, at 906 ("The studies done on genetically modified crops are at the very least inconclusive in terms of impact upon human health and the environment. Enough doubt remains to substantiate legitimate concern.").

244. *See supra*, Part II.A.

irrevocable damage.[245] American consumers should not have to shoulder this burden. In the absence of mandatory FDA review, a federal labeling requirement would provide an appropriate middle ground by enabling consumers to make their own choices based on the information available.[246]

245. Robertson, *supra* note 77, at 170.

246. *See supra*, Part II.B.