Limitations on the Consumer's Right to Know: Settling the Debate Over Labeling of Genetically Modified Foods in the United States*

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I. INTRODUCTION

Confusion concerning genetically modified (GM) foods has grown over the past few years into a debate whether GM foods should be labeled as such for the benefit of the consumer. The public has been confronted with conflicting accounts of safety hazards from the scientific community[1] and consumer advocate groups[2] that have resulted

1. Recently released studies by the National Academy of Sciences, the Organization for Economic Cooperation and Development, and the Subcommittee on Basic Research of the U.S. House of Representatives Committee on Science claim GM foods are safe. *See The Weight of the Evidence: Assessing the Safety of Biotech Foods*, FOOD INSIGHT (May–June 2000), *available at* http://ificinfo.health.org/insight/ MayJune 00/weight.htm. Rejecting mandatory labeling for GM foods in May 2000, the Food and Drug Administration stated: "scientific review continues to show that all bioengineered foods sold here in the United States today are as safe as their non-bioengineered counterparts." Press Release, Food and Drug Administration, FDA to Strengthen Pre-Market Review of Bioengineered Foods, *at* http://www.fda.gov/bbs/ topics/NEWS/ NEW00726.html (May 3, 2000). In December 2000, the American Medical Association recognized the continuing validity of such studies, encouraged further studies, and

in a fear of biotechnology that must be addressed.[3] Consumer advocate groups have focused on mandatory labeling of GM foods as a solution to calm consumer fears and protect mankind from potential safety risks.[4] The scientific community and the regulatory authorities responsible for maintaining food-labeling guidelines, however, have found that GM foods pose no additional safety risk to consumers[5] and have therefore sought other solutions to manage public fears.

In May 2000, the debate reached a new height when the Food and Drug Administration (FDA) announced that mandatory labeling is not an appropriate way to deal with GM foods.[6] The FDA has chosen instead to establish a set of guidelines for voluntary labeling.[7] In addition, the FDA has decided to mandate that food producers and manufacturers

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concluded that "[t]here is no scientific justification for special labeling of genetically modified foods, as a class, and [that] voluntary labeling is without value unless it is accompanied by focused consumer education." *Genetically Modified Crops and Foods, at* http://www.ama-assn.org/ama/pub/article/2036-3604.html (Dec. 14, 2000).

2. Activists including Greenpeace, the Sierra Club, the Organic Consumers Association, the International Center for Technology Assessment, and others have performed demonstrations to stop the use of GM crops for fear that there has not been enough research to demonstrate safety at this time. *See* Lisa M. Krieger, *Activists Pressure Federal Officials to Label Genetically-Altered Foods*, SAN JOSE MERCURY NEWS, Dec. 14, 1999, 1999 WL 28717179. The International Center for Technology Assessment filed suit against the FDA in February 1999 to contest the FDA's position supporting the safety of GM foods. *Id.*; *see also* Alliance for Bio-Integrity v. Shalala, 116 F. Supp. 2d 166 (D.D.C. 2000), discussed *infra* Parts III.B, IV.A.3.

3. For a general discussion of the debate, see Mark Mansour & Jennifer B. Bennett, *Dispute Over Modified Food Hits U.S.*, NAT'L L.J., Nov. 29, 1999, at B11. For a pro-GM view, see Elizabeth Whelan, *The Case for Genetically Modified Food, at* http://www.nutrinews.com/public/home/index.cfm (last visited July 28, 2001). For an opposing view see Claire Robinson, *The Case Against Genetically Engineered Food, at* http://www.nutrinews.com/public/home/index.cfm (last visited July 28, 2001).

4. *See* Mansour & Bennett, *supra* note 3, at B11.

5. *See supra* text accompanying note 1.

6. FDA announced a plan rejecting mandatory labeling, but requiring "developers of bioengineered foods and animal feeds [to] notify the agency when they intend to market such products." *See* Press Release, FDA to Strengthen Pre-Market Review of Bioengineered Foods, *at* http://www.fda.gov/bbs/topics/NEWS/NEW00726.html (May 3, 2000). The proposed solution requires notification at least 120 days prior to marketing. *Id.* The FDA will review information submitted and release this information to consumers via its Web site. *Id.* The FDA released a detailed report of its new year-2000 GM food policy and proposed regulations in January 2001. *See* Premarket Notice Concerning Bioengineered Foods, 66 Fed. Reg. 4706 (proposed Jan. 18, 2001) (to be codified at 21 C.F.R. pts. 192 & 592). The FDA also released guidelines for voluntary labeling of GM foods. *See* Draft Guidance for Industry: Voluntary Labeling Indicating Whether Foods Have or Have Not Been Developed Using Bioengineering; Availability, 66 Fed. Reg. 4839 (Jan. 18, 2001).

7. *See supra* text accompanying note 6.

consult with the FDA concerning new GM foods before introducing them to the market.[8] This decision to require mandatory safety testing and approval of GM foods instead of mandatory labeling, while one of the first resolutions in the debate over GM foods, will not be the final word.

Consumer advocacy groups will, no doubt, fight the decision made by the FDA not to mandate labeling of GM foods. The focus of these efforts will be on rising consumer fears and the consumer's right to know.[9] The first lawsuit challenging the FDA's decision not to mandate labeling was recently dismissed.[10] Congress has yet to address several bills that would require, for example, mandatory labeling of GM foods[11] or mandatory testing and product consultation procedures[12] due to the recent FDA action. More important, and more likely to extend the debate, are several state bills proposed to mandate labeling[13] or take alternate action against GM food products on the state level.[14]

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8. *Id.* Prior to this decision, the FDA reviewed new GM foods through a voluntary consultation process. *See* Statement of Policy: Foods Derived from New Plant Varieties, 57 Fed. Reg. 22,984, 22,988–89 (May 29, 1992). The FDA relied on the legal duty of food producers to ensure product safety established under the FDA guidelines for adulterated foods (foods that contain added poisonous substances). *Id.* at 22,988.

9. In response to the FDA's announcement of a voluntary, as opposed to a mandatory labeling policy, proponents of mandatory labeling openly denounced the decision saying that "voluntary labeling means no labeling at all," and that the FDA has turned the United States into a country of "guinea pigs." Mike Pezzella, *GM Food Regulations Aim to Avoid Euro-Style Frankenfood Panic*, BIOTECHNOLOGY NEWSWATCH, May 15, 2000, at 1, 2000 WL 7388302; *see also* Anita Manning, *FDA Plans to Serve Data Before Biotech Food, but Critics Say Labeling Is Needed*, USA TODAY, May 4, 2000, at 11D, 2000 WL 5777274. The reaction was the same in January 2001 when the FDA released its updated GM food policy rejecting mandatory labeling. *See* Marc Kaufman, *FDA Issues Biotech Food Rules: Proposals Address Labeling, Advance Notice of New Products*, WASH. POST, Jan. 18, 2001, at E3 (noting that opponents of GM have called the recent FDA policy "misguided").

10. *See* Alliance for Bio-Integrity v. Shalala, 116 F. Supp. 2d 166 (D.D.C. 2000) (discussed *infra* Parts III.B, IV.A.3).

11. *See* H.R. 3377, 106th Cong. (1999), WL 1999 CONG US HR 3377. Several other GM related bills introduced in 2000 and 2001 will also be reviewed. *See* S. 2080, 106th Cong. (2000); S. 2315, 106th Cong. (2000); H.R. 115, 107th Cong. (2001); H.R. 2343, 107th Cong. (2001); H.R. 713, 107th Cong. (2001).

12. *See* S. 3184, 106th Cong. (2000), WL 1999 CONG US S 3184.

13. *See* H.R. 5395, 90th Leg. (Mich. 2000), WL 1999 MI H.B. 5395; H. 5399, 90th Leg. (Mich. 2000), WL 1999 MI H.B. 5399; H.R. 3973, 81st Sess. (Minn. 2000), WL 1999 MN H.F. 3973; H.R. 453, 184th Gen. Assemb. (Pa. 2000), WL 1999 PA H.R. 453; S. 1513, 1999–2000 Reg. Sess. (Cal. 2000); H.R. 794, 1999–2000 Sess. (Vt. 2000), WL 1999 VT H.B. 794; S. 295, 1999–2000 Sess. (Vt. 2000), 1999 VT S.B. 295.

14. California has reviewed legislative guidelines designed to protect the "parents' right-to-know" whether their children eat GM products in public schools. S. 1514, 1999–2000 Reg. Sess. (Cal. 2000). California also recently passed a bill establishing a rice certification program designed to monitor "characteristics of commercial impact" which include those characteristics that cannot be identified without special testing in order to avoid commingling of rice varieties. CAL. FOOD & AGRIC. CODE §§ 55000–108

Another important focus of the debate has centered around foreign policies that mandate labeling of certain GM foods and the potential interference such policies will pose on world trade due to the United States' decision not to follow suit.[15] While many attempts have been made to develop a uniform international policy, little progress has occurred in this area.[16] With the recent stance taken by the FDA, the United States government is likely to continue to advocate against foreign anti-GM policies on the ground that they are not based on sound scientific principles but rather on exaggerated consumer fears.

The GM food labeling debate must be settled soon. For the consumer to reap the benefits of the powerful new genetic technologies designed specifically to enhance food safety, nutrition, and supply, scientific progress must no longer be obstructed or overrun by unfounded fears. The labeling debate has already caused a few leading food suppliers to publicly shy away from using genetically modified foods to avoid public

(Deering 1997 & Supp. 2001). New York is considering a "moratorium on the planting and growing" of GM crops for 5 years. Assemb. 9871, 223d sess. (N.Y. 2000), WL 1999 NY A.B. 9871. Nebraska has before it bills that would create a state grain certification program to verify that grain has not been genetically modified, and make food suppliers liable if their GM crops "cross-pollinat[e]" neighboring non-GM crops. Leg. 959, 96th Leg., 2d Reg. Sess. (Neb. 2000), WL 1999 NE L.B. 959. West Virginia is considering a bill that would restrict GM food sales in public schools. S. 605, 75th Leg. (W. Va. 2000), WL 2000 WV S.B. 605. Iowa will review two bills, one of which prohibits those that sell GM products from passing any charges associated with genetic modifications along to the consumer. S. 2189, 78th Gen. Assemb., 2d Sess. (Iowa 2000), WL 1999 IA S.F. 2189.

15. *See* Frederick H. Degnan, *The Food Label and the Right-to-Know*, 52 FOOD & DRUG L.J. 49, 56 (1997); 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); John Stephen Fredland, Note, *Unlabel Their Frankenstein Foods!: Evaluating a U.S. Challenge to the European Commission's Labeling Requirements for Food Products Containing Genetically-Modified Organisms*, 33 VAND. J. TRANSNAT'L L. 183 (2000); Terence P. Stewart & David S. Johanson, *Policy in Flux: The European Union's Laws on Agricultural Biotechnology and Their Effects on International Trade*, 4 DRAKE J. AGRIC. L. 243 (1999); Dennis T. Avery, *Scrap Cap: EU Food Standards Are a Global Health Hazard*, WALL ST. J. EUR., July 5, 2000, at 6, 2000 WL-WSJE 21065536.

16. After several years of debate, the Codex Alimentarius Commission, a United Nations group representing 167 countries, in attempting to settle the international debate over labeling of GM foods, again postponed a decision on the matter in May 2000, pending further study. *See UN Group Stuck on Labeling of Genetically-Modified Foods*, DOW JONES INT'L NEWS, May 10, 2000, WL, All News Plus Wires. For a general overview of the Codex Alimentarius and its focus in regard to GM food labeling, see H. Michael Wehr, *Update on Issues Before the Codex Alimentarius*, 52 FOOD & DRUG L.J. 531 (1997).

scrutiny.[17] Even more importantly, due to the great difficulty and high cost associated with developing new labeling procedures, the debate has generated serious alarm for food suppliers, thereby causing technological delays in certain areas.[18] Faced with the nearly impossible task of developing new procedures to establish whether GM foods are used in its products, food producers have become weary of using GM technologies in general.[19] Because GM foods are designed to avoid the use of harmful chemical pesticides, to improve nutritional value,[20] and to reduce world food supply shortages,[21] settlement of the labeling issue

17. Frito-Lay, Gerber Products, and McDonalds have publicly announced efforts to ban certain uses of GM food products. *See* David Barboza, *Modified Foods Put Companies in a Quandary*, N.Y. TIMES, June 4, 2000, at A1. *But see* David Koenig, *PepsiCo Shareholders Reject Proposal to Stop Using Genetically Engineered Crops*, ASSOCIATED PRESS NEWSWIRES, May 3, 2000, WL 5/3/00 APWIRES 19:39:00.

18. Mandatory labeling initiatives tend to raise costs for manufacturers in several areas. For instance, mandatory labeling would add costs to test products in order to segregate those products that need labeling from those that do not. Also, such labeling initiatives would require new labels to be designed and printed, new packaging for products to be developed, and the establishment of new distribution chains. Total cost increases due to mandatory labeling requirements could be as high as 1.4% of the national cost of that product. W. KIP VISCUSI, PRODUCT-RISK LABELING: A FEDERAL RESPONSIBILITY 9 (1993). Food costs alone, if one out of every fourteen products required new labeling in a sampling of five states, could reach as high as fifty million dollars a year. *Id.* While costs are a large source of alarm for food suppliers, the biggest concern over mandatory labeling of GM foods centers around the "impossib[ility] to track the origin of ingredients in many food products" making it tremendously difficult to determine which products would need to be labeled. Kim Severson, *Food in the News: California Says No to Biotech Food Labels*, S.F. CHRON., May 10, 2000, Food (Zone 6), at 7. Food suppliers are also worried that mandatory labeling will only give consumers reason for unnecessary concern and result in decreases in product sales as well. *See* Barboza, *supra* note 17, at A1. Requiring mandatory nutritional product labeling in the early 1990s was estimated to cost over 100 million dollars. Food Labeling; Declaration of Ingredients, 56 Fed. Reg. 28,592, 28,616 (June 21, 1991).

19. *See supra* note 18 and accompanying text.

20. Biotechnology has already been used to modify foods to provide disease resistance, reduce the need for harmful pesticides, enhance the nutritional value of foods, speed the growth process in several important crops, provide herbicide tolerance, and improve general taste and quality of foods. For example, the following GM foods can be found on the market today: corn, soybeans, and potatoes that do not require high doses of herbicide or pesticide treatments; tomatoes and peppers with better flavor; soybeans with lower saturated fat contents; and papayas that are resistant to threatening viruses. *See* International Food Information Council Foundation, *Background on Food Biotechnology*, *at* http://ific.org/food/biotechnology.vtml (last visited July 27, 2001). *See generally* MARTINA MCGLOUGHLIN, WHY SAFE AND EFFECTIVE FOOD BIOTECHNOLOGY IS IN THE PUBLIC INTEREST (Wash. Legal Found, Critical Legal Issues Working Paper Series 99), *at* http://www.wlf.org (Nov. 2000); Elizabeth Whelan, *The Case for Genetically Modified Food*, *at* http://www.nutrinews.com/public/index.cfm (last visited July 28, 2001).

21. In a report released in the summer of 2000 by the World Academy of Sciences, GM foods have been deemed "crucial to overcoming hunger for 800 million food-short residents of poor countries and preventing the deaths of six million children under five who currently die each year from malnutrition." Dennis T. Avery, *Bountiful Harvest:*

must focus on fostering technological growth and not on increasing consumer fears.

Recent studies have demonstrated that these consumer fears are real. However, the studies have also demonstrated greater consumer support than fear for GM foods.[22] Statistics indicate that even the consumer himself does not necessarily believe that the "right to know" should be enforced through mandatory labeling and that the consumer is willing to trust the FDA to make these important decisions.[23] These findings, in combination with several recent scientific studies that find no safety risk inherent in GM foods in general,[24] demand a careful review of the opposition's scientifically unsound and arguably flawed position on the matter.

This Comment supports the FDA's recent stance rejecting mandatory labeling as a solution to accommodate consumer fears. While the consumer's right to know is an important right to protect, it is not an absolute right. The FDA has consistently recognized limitations on this right where no apparent safety risk exists.[25] For this reason, the FDA's decision is

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Biotech Can Feed the World, WALL ST. J. EUR, July 28, 2000, at 8, 2000 WL-WSJE 21067302. Golden rice, for example, is one of the first breakthroughs in biotechnology designed specifically to assist the poorest countries in the world. *See* J. Madeline Nash, *Grains of Hope*, TIME, July 31, 2000, at 38. The rice has been genetically designed to provide vitamin A, an essential nutrient not normally provided in rice, to benefit over one million children that die due to lack of the vitamin as well as more than 350,000 that go blind as a result of vitamin A deficiencies. *Id.* "Despite fears of genetically altered soybeans, corn and other crops, people will have to rely more and more on genetic engineering and other advances in science and technology to feed the world," according to U.S. Agriculture Secretary, Dan Glickman. David White, *Give Biotech a Chance to Feed World, Ag Chief Says*, BIRMINGHAM NEWS, Oct. 11, 2000, *available at* www.bhamnews.com/archive.html. World Hunger has been identified as a more serious concern than Global Warming or Pollution. *See Americans Say Hunger More Urgent World Problem Than Global Warming and Pollution; More than Two-Thirds Support the Use of Food and Agricultural Biotechnology as a Tool to Help Solve Problem, at* http://betterfoods. org/fft_10_00.htm (Oct. 12. 2000).

22. The International Food Information Counsel announced recent data on a multiyear study designed to weigh changes in consumer attitudes related to GM foods over time. *See U.S. Consumer Attitudes Toward Food Biotechnology, at* http:ificinfo. health. org/foodbiotech/survey.htm (last visited July 14, 2000).

23. *Id.* For instance, 54% of those surveyed in May 2000 said they would be likely to buy foods altered by biotechnology to "taste better and fresher" as compared to 43% that said they would not. *Id.* Likewise, 69% of those surveyed said they would purchase modified foods designed to require "fewer pesticide applications" as compared to only 28% that said they would not. *Id.* When asked whether they supported the FDA in its labeling decisions, 52% said they did compared to 43% that said they did not. *Id.*

24. *See supra* text accompanying note 1.

25. *See* Fred H. Degnan, *Biotechnology and the Food Label: A Legal Perspective,*

consistent with its own policies and legal precedent.

Following this introduction, Part II of this Comment begins by providing some background to the scientific and regulatory nature of the GM food debate.[26] Due to the dispute that is likely to center around the FDA's recent decision, Part III of this Comment addresses the precedent that supports the FDA's actions and demonstrates that the FDA has acted appropriately under the circumstances. Part IV adopts and applies a balancing approach designed to evaluate whether mandatory labeling initiatives are appropriate to protect the consumer's right to know. When weighing the rights of the food suppliers (i.e., those that would be burdened with the task of labeling GM food products) against the consumer's right to know, the FDA was warranted in finding mandatory labeling an inappropriate solution for GM foods in general.

Because many states have already started exploring alternative forms of legislation[27] to address consumer concerns, Part V focuses on the need for individual states to follow the guidelines established by the FDA and suggests that states apply the right to know balancing test when evaluating pending bills and other proposed initiatives in this area. Finally, Part VI establishes goals for addressing the GM food debate on the state level. In addition, several possible solutions are provided that focus on maintaining an appropriate balance between the supplier's commercial rights and the consumer's right to know.

II. BACKGROUND

Much of the confusion over GM foods derives from a lack of public education about the differences between traditional food processing methodologies and modern genetic technologies. Most consumers do

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55 FOOD & DRUG L.J. 301 (2000).

26. This Comment makes no attempt to settle all scientific disputes concerning GM technologies. Rather, it seeks only to introduce the reader to those factors that led the FDA to make its finding that GM food products in general do not pose particular risks of harm. The FDA spent more than ten years listening to debate from opposing points of view from the scientific community, consumer advocate organizations, industry officials, and environmentalists before announcing its new policy in January 2001. *See*, Statement of Policy: Foods Derived from New Plant Varieties, 57 Fed. Reg. 22,984, 22,984 (May 29, 1992); Press Release, Food and Drug Administration, FDA to Strengthen Pre-Market Review of Bioengineered Foods, *at* http://www.fda.gov/bbs/topics/NEWS/NEW00726.html (May 3, 2000); Premarket Notice Concerning Bioengineered Foods, 66 Fed. Reg. 4706, 4707–08 (proposed Jan. 18, 2001) (to be codified at 21 C.F.R. pts. 192 & 592); Draft Guidance for Industry: Voluntary Labeling Indicating Whether Foods Have or Have Not Been Developed Using Bioengineering; Availability, 66 Fed. Reg. 4839, 4839–40 (Jan. 18, 2001). For the purposes of this Comment, and the analysis that follows, the scientific conclusions of the FDA are crucial to the validation of the FDA's stance on the GM food labeling debate.

27. *See supra* notes 13–14.

not realize that a majority of foods currently on grocery store shelves were created using some form of genetic enhancement.[28] In fact, the food industry has utilized genetic modification as a standard tool for over one hundred years.[29] Modern technologies are actually considered safer and more efficient than the older methods employed[30] and should therefore give less reason for concern. Following is a brief discussion of the new technologies that are the source of consumer fear and how they relate to those that have been used to modify food products for many years. Also included is a discussion of the fears that GM opponents raise and the precautionary principle. Finally, a list of the relevant regulatory agencies involved in protecting consumer safety and the policies used to determine how labeling regulations are established is provided.

A. Genetics in the Food Industry

All foods contain genetic material,[31] whether derived from plants or animals. Inside every plant or animal cell lies its essential coding material, DNA.[32] Most people are familiar with the role of DNA in heredity and the reproduction of a species.[33] But, DNA also encodes for

28. *See infra* note 55.

29. According to FDA Commissioner, Jane E. Henney, M.D., "all crops have been genetically modified through traditional plant breeding for more than a hundred years." Larry Thompson, *Are Bioengineered Foods Safe?*, FDA CONSUMER (Jan.–Feb. 2000), *at* http://www.fda.gov/fdac/features/2000/100_bio.html.

30. Traditional plant breeding has been deemed safe and "biotechnology can make it safer." International Food Information Council Foundation, *Background on Food Biotechnology*, *at* http://ific.org/food/biotechnology.vtml (last visited July 27, 2001). Biotechnology offers more specificity in gene transfer by providing the technology to move single genes, as opposed to thousands of genes using traditional cross-breeding techniques, which will reduce the chance of transferring unwanted genes. *Id.*; *see also* 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, 668 (1999) (noting that "[g]enetic engineering allows plant breeders to get more precise results in a shorter amount of time").

31. "In fact we consume posting of DNA every time we eat anything, as it is present in all plant and animal material." Posting of Dr. Richard H. Phipps, *GM Crops: An Alternative View to Greenpeace*, FEED COMPOUNDER, June–July 2000, at 1, to Agbioview@listbot.com (Aug. 31, 2000) (on file with author).

32. DNA, an abbreviation for deoxyribonucleic acid, is located in the nucleus of all plant and animal cells. *See generally* LAURALEE SHERWOOD, FUNDAMENTALS OF PHYSIOLOGY: A HUMAN PERSPECTIVE B-1 to B-14 (2d ed. 1991). All plants and animals are "composed of cells" and thus filled with genetic material. WILLIAM K. PURVES ET AL., LIFE: THE SCIENCE OF BIOLOGY 60 (3d ed. 1992).

33. Human chromosomes which carry the traits for, among others, hair color, eye color, and height, that are unique to every individual, are comprised of stretches of DNA

the production of proteins[34] and thus plays an important role in establishing the primary structure and function of the plant or animal as a whole.[35]

A gene is a "stretch of DNA," which is responsible for encoding, or directing the production of, a particular protein.[36] Proteins are those chemical substances that dictate the ultimate traits of a plant or animal,[37] such as color, height, microbial resistance, and nutritional content. By a process of natural selection,[38] the plants and animals carrying the most successful DNA code, and thus the most suitable traits, will survive over those with less suitable traits for the environment in which the organism lives.[39] Thus, by a process of natural selection, the world has inherent in it an evolutionary method to weed out the less desirable traits of an organism in favor of more desirable traits.[40] Evolution, therefore, is a consistent process of genetic modification[41] that enables change and improvement within a species over time.

Like the process of natural selection, genetic technologies used in food development are designed to foster the survival of the most desirable

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material. A human child exhibits traits based on a combination of genetic material received from his or her mother and father. For an overview of patterns of inheritance and how traits are genetically determined, see PURVES ET AL., *supra* note 32, at 207–35. *See also* DANIEL L. HARTL, GENETICS 40–45 (3d ed. 1994).

34. SHERWOOD, *supra* note 32, at B-1.

35. *Id.*

36. *Id.*

37. *Id.*

38. Charles Darwin is responsible for developing the evolutionary theory of natural selection in 1858 as described in his famous book, The Origin of Species. *See* PURVES ET AL., *supra* note 32, at 15–16. The theory is based on the fact that no two individuals are exactly the same and that there is some genetic variation between two individuals (i.e., no two individuals carry exactly identical genetic codes) with the exception of identical twins. Darwin reasoned that the genetic variations affected the probability of survival of that particular individual, and thus a survival of the trait which enabled that individual to survive and not the other. Darwin "saw close parallels between artificial selection by breeders and selection in nature." *Id.* at 15.

One example of the natural selection theory was demonstrated by a study on finches in the Galapagos Islands. Due to an unusually long drought in 1977, it was determined that finches with larger bill sizes were better adapted to the environment and thus survived the drought whereas those with smaller bill sizes were unable to do so. *Id.* at 411. Due to the deaths of several smaller billed birds, natural selection resulted in a larger group of individuals carrying the trait for a larger bill and thus a higher probability that such a trait would be passed along to future generations. *Id.* For an overview of the development of the theory of evolution, which is based only in part on the theory of natural selection, see *id.* at 400–19.

39. *See id.* at 15–16.

40. *See id.*

41. One of the basic forms of genetic variation comes from genetic mutation, which is defined as any "heritable change in genetic material." HARTL, *supra* note 33, at 459. Mutation can occur spontaneously or due to exposure to a "mutation-causing agent." *Id.* at 460. Although cells are equipped with the ability to repair mutations in DNA, a mutation can occur in any cell and may be very difficult to detect. *Id.*

plant or animal species.[42] The use of genetic technology and cross-breeding of plant material for desired characteristics is not a new phenomenon[43] as some opponents of GM foods today might think. Traditional plant breeding techniques date at least as far back as the late 1800s, when Gregor Mendel applied a cross-breeding method using pea plants to study character trait inheritance.[44] Traditional cross-breeding techniques involve a selective mating between two like organisms (a fish with a fish or a pea plant with a pea plant) resulting in a genetically modified offspring that carries a combination of traits (encoded by the genes) from the original parents.[45] Using this method, scientists were eventually able to identify and select particular traits in order to generate organisms with more desirable characteristics. Scientists no longer had to wait for the long-term evolutionary genetic modification process to take effect.[46]

One of the main disadvantages of the traditional cross-breeding technique, however, is the time it takes for the mating of the genes to occur.[47] Because obtaining offspring with more desirable trait characteristics can take multiple crosses, and therefore multiple generations of offspring, the process can take many years.[48] Another major problem that hinders the use of the traditional method is that many genes are transferred when two organisms are crossed thereby making it harder to obtain the desired

42. The process of artificial selection, or generating an organism with particular desired characteristics, has been done through cross-breeding—the mating of two different plant strains—for many years. PURVES ET AL., *supra* note 32, at 324. In fact, cross-breeding was used in the 1930s to hybridize, (or generate) corn from two genetically dissimilar plant strains, and in the 1950s to enhance wheat and rice production. *Id.*

43. *See* Thompson, *supra* note 29, *at* http://www.fda.gov/fdac/features/2000/100_bio.html. For a general overview of traditional versus modern genetic enhancement techniques and how they have been used in plant modification, see Statement of Policy: Foods Derived from New Plant Varieties, 57 Fed. Reg. 22,984, 22,985–86 (May 29, 1992).

44. For a more detailed discussion of Mendel's famous experiments, see HARTL, *supra* note 33, at 2.

45. For a general overview of the use of "plant breeding [as] a form of genetic engineering," and its impact on the development of agriculture, see PURVES ET AL., *supra* note 32, at 324.

46. *Id.*

47. *See supra* text accompanying note 30.

48. Depending on the length of time for the species to reproduce, creating a new generation of organisms generally takes more than twelve years. *See* John Henkel, *Genetic Engineering Fast Forwarding To Future Foods*, *at* http://www.fda.gov/bbs/topics/CONSUMER/geneng.html (last modified Feb. 1998).

trait without the possibility of combining undesirable traits as well.[49]

Using the more advanced recombinant DNA technology,[50] scientists are able to select specific genes from one organism and insert them into the genome of another without actually breeding or mating the two.[51] This method greatly decreases the time necessary to create a modified organism and expands the possibilities of genetic engineering by providing scientists access to a much wider variety of genes from which to choose.[52] The new technology, then, applies a standard technique in a more efficient and specific manner.[53] This added efficiency and specificity should therefore serve to make genetically altered foods safer. Regardless, it is the possibility of taking a gene from one organism and inserting it into a different type of organism, one from a fish to a tomato for example, which has created enhanced health concerns and public fear that did not exist before.[54]

Many products on consumer shelves today were developed, at least in part, using genetic modification techniques.[55] Using the more traditional

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49. PURVES ET AL., *supra* note 32, at 324.

50. For a detailed discussion on the use of recombinant DNA technology, see HARTL, *supra* note 33, at 351–83; PURVES ET AL., *supra* note 32, at 306–27; *Methods for Genetically Engineering a Plant*, FDA CONSUMER (Jan.–Feb. 2000), *at* http://www.fda.gov/fdac/features/2000/biochart.html; *see also* Statement of Policy: Foods Derived from New Plant Varieties, 57 Fed. Reg. 22,984, 22,985–86 (May 29, 1992).

51. "Foreign DNA can be introduced into a cell" by using Recombinant DNA technology, also referred to as "'genetic engineering'" or "'cloning.'" PURVES ET AL., *supra* note 32, at 306. Unlike traditional cross-breeding techniques that required a mating between the foreign DNA donor and the recipient, recombinant DNA techniques can be conducted in the laboratory. *Id.* For a general overview of the technique, see *id.* at 306–27. The more traditional technique has been found significantly limited in comparison to recombinant DNA technology because it can only be used between organisms that can "interbreed with one another." *Id.* at 324. The cross-breeding technique is also less efficient because it involves a mating of two entire genomes and therefore can result in a combination of "unwanted genes" and desired genes. *Id.*

52. *See id.*; *supra* text accompanying note 30.

53. *See supra* text accompanying notes 30, 51.

54. *See supra* text accompanying notes 1–3. Opponents to GM foods are fearful, for example, of modified products like potato chips with chicken genes, apple juice containing silk moth genes, or corn tortilla chips with firefly genes. *See* Union of Concerned Scientists, *Transgenic Café*, *at* http://www.ucsusa.org/food/tcmenu.html (last visited July 15, 2001). In its recent proposal, the FDA agrees that this added efficiency gives rise to the need for a more careful review of GM foods before marketing. *See* Premarket Notice Concerning Bioengineered Foods, 66 Fed. Reg. 4706, 4709 (proposed Jan. 18, 2001) (to be codified at 21 C.F.R. pts. 192 & 592).

> Given the efficiencies of rDNA techniques, the advances in these techniques, and the rapidly expanding information related to genomes, FDA expects that these techniques are likely to be utilized to an increasingly greater extent . . . and that the products of this technology are likely in some cases to present more complex safety and regulatory issues than seen to date.

Id. However, the FDA continues to find that GM foods in general are safe, therefore requiring mandatory safety testing but not mandatory labeling. *Id.*

55. "More than fifty genetically engineered crops, including corn, squash, and

selective breeding technologies, for instance, European scientists created cabbage, brussels sprouts, broccoli and cauliflower by exploiting specific traits of the wild mustard seed.[56] In the year 2000, GM seeds were expected to supply 38% of the United States' corn crop, 57% of the soybean crop, and 70% of the canola crop.[57] It is estimated that more than fifty genetically engineered crops are currently on the market, including squash and the infamous "Flavr Savr" tomato.[58] Genetic technologies have likewise been employed in animals. Take the famous rbST cow,[59] for example, that through modern GM techniques was given the capability to produce more milk than other cows.[60]

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tomatoes, already have entered commercial production." Deborah Silver, *Gene Labeling Not a Must*, RESTAURANTS & INSTITUTIONS, June 15, 2000, at 86; *see also* International Food Information Council Foundation, *Background on Food Biotechnology*, *at* http://ific.org/food/biotechnology.vtml (last visited July 27, 2001). Approximately 70% of grocery store food may include genetically altered material. *See* Barboza, *supra* note 17, at A1. For a listing of approved GM food products see Union of Concerned Scientists, *Foods on the Market*, *at* http://www.ucsusa.org/agriculture/gen.market.html (last visited July 23, 2001); *Genetically Modified Crops Approved by the FDA*, *at* http://www.nutrinews.com/public/showArticle.cfm?objectID=63793F9C-86E2-4B15-B66A78C91EF9F943 (last visited Jan. 11, 2001).

56. PURVES ET AL., *supra* note 32, at 402; *see also* J. Howard Beales III, *Modification and Consumer Information: Modern Biotechnology and the Regulation of Information*, 55 FOOD & DRUG L.J. 105, 105 (2000).

57. Mark Albright, *Biotech Battle Becomes a Campaign of Words*, SAN DIEGO UNION-TRIB., May 11, 2000, at C2.

58. *See* Silver, *supra* note 55. The Flavr Savr tomato, genetically enhanced to stay firm for a longer period of time and therefore to taste better, was the first GM food to be approved for sale by the FDA and complete the FDA's voluntary consultation process. *See* Karen A. Goldman, *Labeling of Genetically Modified Foods: Legal and Scientific Issues*, 12 GEO INT'L ENVTL. L. REV. 717, 735–36 (2000). Like GM foods in general, the FDA found the Flavr Savr to be "as safe as tomatoes bred by conventional means." *Id.* at 736. After a review of the new product and a comparison to traditional varieties, the FDA determined that the Flavr Savr did not require "special labeling . . . based on its assessment that the Flavr Savr 'maintains the essential characteristics of traditionally developed tomatoes.'" *Id.*

59. *See* discussion *infra* Part V.A.1. In 1993, the FDA approved the use of rbST (recombinant bovine growth hormone) for injection into dairy cows to generate an increase in milk production. *See* Interim Guidance on the Voluntary Labeling of Milk and Milk Products from Cows that Have Not Been Treated with Recombinant Bovine Somatotropin, 59 Fed. Reg. 6279 (Feb. 10, 1994). Vermont attempted to require that such milk be labeled, but the law mandating labeling was challenged by dairy manufacturers in the Second Circuit and overturned. Int'l Dairy Foods Ass'n v. Amestoy, 92 F.3d 67, 73 (2d Cir. 1996). For additional background and discussion about rbST milk and the labeling debate, see Kathleen Lennon, *Government's Udder Disregard for a Consumer's Right to Information on RBST: Mandatory Labeling of Milk Products Should Be Allowed*, 22 VT. L. REV. 433 (1997).

60. *See supra* text accompanying note 59.

The food industry has applied modern GM techniques since the 1970s and not one report of harm due to the new modification process has yet been documented.[61] Additionally, the same genetic techniques have been used to generate GM drugs for at least twenty-five years with no evidence that the process itself is harmful.[62] The scientific community continues to advocate, based on the lack of demonstrated harm and the fact that foods have been genetically modified for hundreds of years, that modern GM technologies do not pose any additional risk of harm when compared to crops generated using traditional forms of genetic enhancement. GM opponents, on the other hand, argue that modern GM technologies are simply different and that a lack of evidence of harm should not amount to a presumption of safety.[63]

B. Opposition to GM Foods and the Precautionary Principle

What are the specific concerns that GM opponents raise? Although they identify a long list of *potential* risks that GM foods *may* pose, the answer is none that have shown any scientific validity.[64] In fact, after

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61. Elizabeth Whelan, *The Case for Genetically Modified Food*, *at* http://www.nutrinews.com/public/showArticle.cfm?objectID=7C4DBF9A-95FD-4939-BE591EBDD62B1157 (last visited July 23, 2001). Potential hazards have been identified, such as the potential introduction of new allergens to a food product; however, the hazards that arise are not unique to modern GM technologies. Such hazards arise due to the nature of the trait introduced, not the process of genetic modification. *Id.*

62. *See id.* It is interesting that GM drugs have not met the same resistance as GM foods since both are created using the same modern genetic technologies. It has been suggested that the clear benefits of pharmaceuticals leave consumers less concerned. *See infra* text accompanying note 310.

63. *See* Claire Robinson, *The Case Against Genetically Engineered Food*, *at* http://www.nutrinews.com/public/showArticle.cfm?objectID=15557691-BE38-4F4B-A29EE688ED9EB07D (last visited Feb. 26, 2001).

64. According to Dr. C. S. Prakash, Professor of Biotechnology and advocate for the scientific community, "[t]here is no scientific reason to believe that genetically-engineered foods are any less safe than the foods we've been eating for centuries." *What the Experts Say About Food Biotechnology*, *at* http://ificinfo.health.org/foodbiotech/whatexpertssay.htm (Feb. 2000). Although there have been no examples in commercial food products where the risk has proven to be real, opponents of GM foods claim that such foods may set off allergies, create new toxic compounds, or cause antibiotic resistance. *See What Are They Hiding*, *at* http://www.gefoodalert.org/html/hiding.htm (last visited Sept. 25, 2000). Opponents base the need for labeling on these concerns. *Id.*

However, under the mandatory consultation process conducted by the FDA (which requires that each of these concerns is evaluated to establish food safety before commercial release of the food), any identifiable changes in food content like added toxic compounds, allergens, or safety hazards would subject (and always have subjected) the product to rejection by the FDA (or mandatory labeling requirements as an alternative) where safety is at risk. *See generally* Statement of Policy: Foods Derived from New Plant Varieties, 57 Fed. Reg. 22,984 (May 29, 1992).

Opponents have also identified environmental risks such as increased weediness, gene transfer (by pollination for example) to wild relatives of the GM food, and the creation of

considering more than 50,000 written comments regarding the FDA's proposed 2000 labeling policy, the FDA determined that those "comments [from individuals requesting mandatory labeling] were mainly expressions of concern about the unknown."[65] GM opponents claim that GM foods *may* contain new allergens or toxins thereby creating enhanced safety risks, or that GM crops *might* cause environmental problems by contaminating non-GM crops.[66] Because it is possible that such hazards *could* result, just as it is also possible that these very same hazards may result with any new food product introduced to consumer shelves,[67] the FDA has, for many years, evaluated new food products for exactly the speculative risks that GM opponents identify[68] as sufficient to demand

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new plant viruses to be associated with GM technologies. *See* Union of Concerned Scientists, *Fact Sheet: Risks of Genetic Engineering*, *at* http://www.ucsusa.org/agriculture/gen.risks.html (last visited Sept. 25, 2000). The FDA is also required to take into consideration environmental impacts when making decisions to approve products for sale in the United States. *See* Statement of Policy: Foods Derived from New Plant Varieties, 57 Fed. Reg. at 23,004. Thus, the concerns raised by opponents to GM have been, and continue to be, addressed by the FDA through a consultation process with food manufacturers. Generally, if any of these risks proved true, the product would not likely make it to consumer shelves; if it did, it would be required to contain an appropriate label under the Federal Food, Drug and Cosmetic Act (FFDCA). *See id.* at 22,991.

65. Draft Guidance for Industry: Voluntary Labeling Indicating Whether Foods Have or Have Not Been Developed Using Bioengineering; Availability, 66 Fed. Reg. 4839, 4840 (Jan. 18, 2001).

66. *See supra* text accompanying note 64; *see also* L.L. Wolfenbarger & P.R. Phifer, *The Ecological Risks and Benefits of Genetically Engineered Plants*, 290 SCIENCE 2088 (Dec. 15, 2000); *GM Plants: Panacea or Plague: Fears & Facts About GM Plants*, *at* http://www.botany.about.com/science/botany/library/weekly/aa010301b.htm (last visited Feb. 26, 2001); Claire Robinson, *The Case Against Genetically Engineered Food*, *at* http://www.nutrinews.com/public/showarticle.cfm?ObjectID= 15557691-BE38-4F4B-A29EE688ED9EB07D (last visited Feb. 26, 2001); *Safer Food, Safer Farms Campaign —The Need for Labeling Genetically Engineered Foods*, *at* http://www.foe.org/safefood/factsheetge.html (last visited Feb. 26, 2001).

67. There are 10,000–20,000 new food products introduced to consumer product shelves every year. *See* John Henkel, *Genetic Engineering Fast Forwarding to Future Foods*, FDA CONSUMER, *available at* http://www.fda.gov (last modified Feb. 1998). Only a small handful of this batch of new food products, those with additives like artificial sweetener, require premarket approval by the FDA so long as the ingredients used are generally recognized to be safe. *Id.*

68. See *supra* text accompanying note 64 for a discussion of the factors that the FDA considers when consulting with food suppliers prior to allowing the product to be sold. *See also infra* text accompanying note 105. In fact, the FDA's new policy mandates that new GM products are tested for exactly the specified risks that GM opponents raise. *See* Premarket Notice Concerning Bioengineered Foods, 66 Fed. Reg. 4706, 4709–15, 4717 (proposed Jan. 18, 2001) (to be codified at 21 C.F.R. pts. 192 & 592) (requiring GM food suppliers to test and report to the FDA particular data and information on any new GM food, including the information needed to determine if the

mandatory labeling.

Those that oppose GM foods essentially argue that there are too many uncertainties with GM foods. Opponents to GM claim that not enough testing has been done to ensure that such products are one hundred percent safe for human consumption or that they do not pose a risk of harm to the environment.[69] As with any new technology, it is true that unforeseen risks may exist, and it is this fear of the unknown that truly drives the opposition to GM foods. Opponents worry that the introduction of GM foods could, like the introduction of certain other products in the past, result in some unforeseen disaster.[70]

Anti-GM advocates urge regulators to apply the "precautionary principle"[71] when demanding mandatory labeling or a halt to GM food production to avoid any possibility of future harm. The precautionary principle calls for "precautionary measures" to be taken whenever a threat to public safety or the environment arises from a particular activity regardless of whether it can be shown that the activity actually causes the identified risk.[72] It has been called the "better . . . safe than sorry" principle.[73]

If applied to GM foods, the precautionary principle would require the impossible: that scientists prove to a certainty that GM foods are absolutely safe. Like any new food product (or any new consumer product for that matter) it cannot be shown to a certainty that no risk exists. Applying the precautionary principle to GM technologies could, in fact, be more hazardous than any risk that may later surface because the principle does not take into account the potential risks that arise from banning, restricting, or overregulating the use of such a promising new technology.[74] In other words, applying the precautionary principle, as

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new food contains allergens, food additives, compositional differences, or is otherwise adulterated).

69. Julie Teel, *Regulating Genetically Modified Products and Processes: An Overview of Approaches*, 8 N.Y.U. ENVTL. L.J. 649, 650, 655–61 (2000).

70. *See* Claire Robinson, *The Case Against Genetically Engineered Food*, *at* http://www.nutrinews.com/public/showArticle.cfm?objectID=15557691-BE38-4F4B-A29EE688ED9EB07D (last visited Feb. 26, 2001). Opponents cite nuclear power, DDT and "mad cow" disease as examples where technology that was originally believed safe was later found to generate unforeseen risks. *Id.*

71. The precautionary principle is "the idea that new technologies and substances should be regulated before they can cause harm rather than after their harmful potential has been demonstrated." Jonathan H. Adler, *More Sorry than Safe: Assessing the Precautionary Principle and the Proposed International Biosafety Protocol*, 35 TEX. INT'L L.J. 173, 194 (2000).

72. INDUR M. GOKLANY, APPLYING THE PRECAUTIONARY PRINCIPLE TO GENETICALLY MODIFIED CROPS 2 (Aug. 2000), *available at* http://www.agbioworld.org/pdf/PP_and_GM_Crops_—_GOK/any1.pdf.

73. Adler, *supra* note 71, at 194.

74. A ban on GM foods, contrary to the claims of its proponents, would be imprudent rather than precautionary. The precautionary principle—properly applied, using a broader consideration of the public health and environmental

opponents suggest, ignores the potential hazards of NOT using GM techniques, i.e., the benefits of GM foods.[75] "The unfortunate reality is that efforts to regulate one risk can create other, often more dangerous risks."[76]

Pro-GM and anti-GM groups alike agree that additional testing is needed.[77] However, halting the use of GM technologies—directly in the form of a ban or indirectly by requiring labeling of GM products—due to a fear of the unknown is not a rational science-based solution to managing potential risks. In order to enjoy the benefits of a new technology, while at the same time protecting against real future risks, a cost-benefit analysis[78] must be employed on a case-by-case basis[79] instead

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consequences of a ban—argues instead for a sustained effort to research, develop, and commercialize GM crops, provided reasonable caution is exercised during testing and commercialization of these crops.

GOKLANY, *supra* note 72, at 25; *see also* Adler, *supra* note 71, at 195 (explaining that the real question that should be asked is whether the costs of the precautionary regulation exceed the benefit of the regulation); ExxonMobil Corp., *Unbalanced Caution*, N.Y. TIMES, Nov. 2, 2000, at A31 (expressing concern over abuse of the precautionary principle by ignoring scientific findings of safety in the pursuit of a nonexistent risk-free activity).

75. GOKLANY, *supra* note 72, at 25.

76. Adler, *supra* note 71, at 195. A good example of the potential pitfalls of resistance to biotechnology enhanced foods centers on the growing human population and the corresponding need to produce more food and other materials on a planet that is not increasing in size. Although it is true that feeding and clothing the growing world population can be done without GM, the choice to avoid GM results in the need for more land devoted to farming. Opponents claim that the use of GM could lead to insect resistance or create superweeds, thus changing environments in a negative way; however, not using GM and instead choosing to use more land to satisfy the demands of a growing world would obviously lead to great environmental damage as habitats are destroyed to be used for these purposes. *See id.* at 201. Loss of habitat has been attributed as the cause, for instance, of more than "one third of documented animal extinctions." *Id.* Thus, habitat destruction may be the greatest source of risk to biological diversity at this time. *Id.* There is a choice between sacrificing more land to meet growing demands or relying on GM or other technologies to increase yields without the need to destroy more land. The costs and benefits of each should be compared before determining which is really more environmentally healthy.

77. After a review of scientific literature available dealing with environmental risks and GM, it has been concluded that "[n]either the risks nor the benefits of [genetically engineered organisms] are certain or universal." Wolfenbarger & Phifer, *supra* note 66, at 2092. Further research and comparisons are called for with the recognition that it is not possible to accurately predict with certainty what the ecological consequences of introducing any new species would be. *See id.*

78. *See* Adler, *supra* note 71, at 205. "If the goal is to minimize risk, the focus should be on *which risk is greater*—the risk of a new technology, or the risk of doing without it." *Id.* "The presence of uncertainty about a technology, without more, cannot establish a presumption that more regulation is required." *Id.*

of the precautionary-only policy suggested by anti-GM advocates.

The bottom line in the debate today is that no valid scientifically based objection to modern genetic technologies currently exists. Rather, anti-GM groups have launched a successful lobbying campaign based only on speculation.[80] There is no reason to assume that new GM foods are any more of a hazard to human health than any other foods, or that the FDA's regulations are not adequate for addressing any safety risk that may arise. For precisely these reasons, the FDA has rightfully found that mandatory labeling is not the answer for dealing with unrealistic consumer fears. Further research and testing of GM products, not the consumer oriented food product label, will be the forum to address the concerns raised by opponents to GM.

C. GM Food-Labeling Regulation

Three main regulative bodies are responsible for monitoring food labeling in the United States: (1) the FDA, (2) the U.S. Department of Agriculture (USDA), and (3) the Environmental Protection Agency (EPA).[81] While the USDA and the EPA play important roles in the regulation of GM products, the majority of GM foods fall within the realm of the FDA's regulatory authority.[82] The FDA is primarily responsible for ensuring the safety of the public from harmful food products under the Federal Food, Drug and Cosmetic Act (FFDCA) of 1938.[83]

Pursuant to its duty to protect the public safety under the FFDCA, the FDA has spent several years reviewing scientific reports and public

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79. In fact the FDA's new policy is designed to "foster[] a case-by-case approach to address[] relevant scientific and regulatory issues rather than a single set of tests that likely would not be applicable in all circumstances." Premarket Notice Concerning Bioengineered Foods, 66 Fed. Reg. 4706, 4717 (proposed Jan. 18, 2001) (to be codified at 21 C.F.R. pts. 192 & 592).

80. *See supra* text accompanying note 64. Because none of the food products currently on consumer shelves exhibit safety risks, the risks identified are no more than mere speculation at this time. *See supra* text accompanying note 1; *infra* text accompanying note 105.

81. The FDA is primarily responsible for monitoring food safety and labeling involving foods derived from crops or biotech plants as well as the safety of animal feed products. The USDA is responsible for reviewing field-testing of GM plants and other environmental safety issues, while the EPA focuses its efforts on regulating pesticide use. *See* Thompson, *supra* note 29, *at* http://www.fda.gov/fdac/features/2000/100_ bio.html; *see also* Statement of Policy: Foods Derived from New Plant Varieties, 57 Fed. Reg. 22,984, 22,985 (May 29, 1992); Premarket Notice Concerning Bioengineered Foods, 66 Fed. Reg. at 4708. Food advertising issues are regulated by the U.S. Federal Trade Commission. *See Backgrounder—Food Labeling*, *at* http://ificinfo.health.org/ backgrnd/ bkgr5.htm (last visited July 14, 2000).

82. *See supra* text accompanying note 81.

83. 21 U.S.C. §§ 301–95 (1994).

comments concerning the use of GM technologies.[84] The FDA announced its first policy relating to GM food products in 1992. The 1992 policy, as it is now called, declared that GM plant products were no different from other traditional plant products and granted them "GRAS" (Generally Recognized As Safe) status.[85] In May 2000, after eight additional years of scientific review, the FDA announced similar findings as to the safety of GM foods.[86] However, unlike the 1992 policy, the FDA decided to adopt a mandatory consultation process, requiring a more strict review of GM products before they enter the market.[87] In both policies, the FDA determined that mandatory labeling of GM foods is not proper due to the lack of scientific evidence pointing to a risk of harm to the public.[88] The FDA's decision to focus on voluntary labeling guidelines and a mandatory consultation process is consistent with its obligations under the FFDCA and its prior treatment of similar food products.[89]

III. FDA'S VOLUNTARY LABELING PROGRAM AND MANDATORY CONSULTATION PROCESS IS CONSISTENT WITH FFDCA REQUIREMENTS AND LEGAL PRECEDENT

Although the debate continues in the public arena and in legislative forums,[90] the FDA decision not to mandate labeling for GM foods[91] where no general safety risk can be scientifically validated is an

84. *See* Statement of Policy: Foods Derived from New Plant Varieties, 57 Fed. Reg. 22,984, 22,984 (May 29, 1992).

85. *Id.* at 22,990. Because DNA exists in every food product and the use of GM techniques involves only a change in the method of production, the FDA found that transferred genetic material "do[es] not raise a safety concern as a component of food. In regulatory terms, such material is presumed to be GRAS." *Id.*

86. Press Release, Food and Drug Administration, FDA to Strengthen Pre-Market Review of Bioengineered Foods, *at* http://www.fda.gov/bbs/topics/NEWS/NEW0 0726.html (May 3, 2000).

87. *Id.*; *see infra* text accompanying note 105.

88. *See* Statement of Policy: Foods Derived from New Plant Varieties, 57 Fed. Reg. at 22,991; Press Release, Food and Drug Administration, FDA to Strengthen Pre-Market Review of Bioengineered Foods, *at* http://www.fda.gov/bbs/topics/NEWS/ NEW00726.html (May 3, 2000); Draft Guidance for Industry: Voluntary Labeling Indicating Whether Foods Have or Have Not Been Developed Using Bioengineering; Availability, 66 Fed. Reg. 4839, 4840 (Jan. 18, 2001).

89. *See* discussion of the rbST labeling debate *infra* Parts IV.B.1, V.A.1; *see also* Degnan, *supra* note 25, at 301.

90. *See supra* text accompanying notes 13–14.

91. *See supra* text accompanying note 6.

important final decision in many respects. Because the FDA's decision may undergo further scrutiny from opponents of GM technologies, however, it is worthy to review the justification for this recent decision. In so doing, the FDA resolution can be found consistent with its statutory duties under the FFDCA and legal precedent.

A. FDA Decision Is Consistent with Its Statutory Duties Under the FFDCA

Under the FFDCA, the FDA is charged with "protect[ing] the public health by ensuring that . . . foods are safe, wholesome, sanitary, and properly labeled."[92] If a food product poses a significant hazard to public safety, the FDA may ban the product entirely from consumer shelves.[93] If the product creates only a minor risk to public safety, however, the FDA may choose to balance that risk with the benefits of the product,[94] focusing first on whether the product should be sold at all. If the benefits outweigh the risks, the FDA will then properly consider the consumer's right to be made aware of the risks and enforce appropriate warning regulations.[95] Labeling guidelines have generally been established under the FFDCA to alert the consumer to reasonable safety risks[96] with the assurance that only accurate and truthful information

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92. 21 U.S.C. § 393 (1994).

93. As part of the FDA's mission to protect the public health, such activity has been found warranted under the FFDCA. *See* 21 U.S.C. §§ 301–95 (1994); Statement of Policy: Foods Derived from New Plant Varieties, 57 Fed. Reg. 22,984, 22,988–89 (May 29, 1992).

94. *See* discussion *infra* Part IV.A.1. The FDA employed a balancing test, for example, when determining that mandating nutrition content labeling was warranted to assist consumers in lowering weight, reducing coronary heart disease, decreasing cancer rates, managing diabetes, and adhering to religious and other dietary preferences. This mandate was initiated in the face of a cost far exceeding 100 million dollars. *See* Food Labeling; Declaration of Ingredients, 56 Fed. Reg. 28,592, 28,616–17 (June 21, 1991).

95. Whenever a safety risk exists, the FDA requires a warning label identifying the hazard for those products that are approved for sale. *See* Food Labeling; Declaration of Ingredients, 56 Fed. Reg. at 28,615.

> However, FDA is unwilling to require a warning statement in the absence of clear evidence of a hazard. If the agency were to require warnings for ingredients that only cause mild idiosyncratic responses, it is concerned that it would overexpose consumers to warnings. As a result, consumers may ignore, and become inattentive to, all such statements.

Id.

96. The FDA has developed specific guidelines to deal with known risks and the labeling of products that are sufficiently safe to be sold to consumers yet demonstrate a small degree of safety risk. *See generally* 21 U.S.C. §§ 301–95. In particular, the FDA has established particular guidelines to deal with "adulterated" foods, "misbranded" foods, the use of Saccharin in foods, tolerances for "poisonous substances" or "pesticide residues" in food products, food additives, new dietary ingredients, and infant formulas, all of which are designed to offer protection to consumers from harm and to enable

is provided on the label.[97]

Unless a significant safety risk exists or there is a sincere need for consumers to distinguish between food products before purchase, the FDA hesitates to mandate labeling of food products.[98] The FDA generally reserves mandatory labeling for cases where a warning is required to protect the consumer from harm.[99] Labeling has also been required to provide nutritional content information[100] in cases where the consumer has sufficient capacity and knowledge to compare labeling content and therefore choose between different food products. Where no recognized safety risk has been identified or it is determined that label information would not assist a consumer in distinguishing between products, the FDA has focused on establishing voluntary labeling guidelines instead.[101]

In accordance with its duty to protect the public safety and monitor food labeling guidelines, the FDA has decided to treat GM foods just as it treats any other type of food product.[102] In finding no recognizable difference between GM products and their corresponding non-GM products, and no valid safety risk from GM products in general, the FDA has determined that mandatory labeling is not within its power.[103]

The FDA has already approved several GM foods for sale[104] based on a careful review of each individual product's safety. Only after many years of testing and experience with GM foods has the FDA been able to reach its conclusion that GM products are just as safe as comparable unmodified food products.[105] Thus, because the FDA did not find a

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consumers to make healthy food choices. *Id.*

97. *See* 21 U.S.C. § 343 (1994).

98. *See supra* text accompanying notes 93–95; *see also* discussion *infra* Part IV.A.1 (concerning the rbST labeling debate).

99. *See supra* text accompanying notes 95–96.

100. Mandatory nutritional labeling of food products was added to the FFDCA in 1990 under the Nutrition Labeling and Education Act of 1990. H.R. 3562, 101st Cong. (1990) (enacted); *see* 21 U.S.C. §§ 343 (q)–(r), 343-1 (1994).

101. *See* discussion *infra* Part IV.A.1.

102. *See* Statement of Policy: Foods Derived from New Plant Varieties, 57 Fed. Reg. 22,984, 22,989 (May 29, 1992); Press Release, Food and Drug Administration, FDA to Strengthen Pre-Market Review of Bioengineered Foods, *at* http://www.fda.gov/bbs/topics/NEWS/NEW00726.html (May 3, 2000).

103. *See* Press Release, Food and Drug Administration, FDA to Strengthen Pre-Market Review of Bioengineered Foods, *at* http://www.fda.gov/bbs/topics/NEWS/NEW00726.html (May 3, 2000).

104. *See supra* text accompanying note 55. See the FDA Web site for a full list of approved products and a general overview of the FDA's treatment of bioengineered foods *at* http://vm.cfsan.fda.gov.

105. *See supra* text accompanying note 1. The FDA has been reviewing scientific

safety risk or any sort of difference between the final GM food products and their non-GM counterparts, the FDA did not have the power to mandate labeling when properly taking into account the goals of the FFDCA[106] and legal precedent.[107]

B. Legal Precedent Prior to and Following the Decision are Consistent

While the GM food labeling debate is not generally fought in the courtroom, two recent cases are important to settling the labeling debate in the United States. The first, *International Dairy Foods Association v. Amestoy*,[108] decided prior to the FDA's May 2000 decision, involved the rejection of a mandatory labeling law in Vermont that sought to identify biotechnology-enhanced milk products. The second, *Alliance for Bio-Integrity v. Shalala*,[109] decided four months after the FDA's May 2000 decision, rejected outright a challenge to the FDA's policy concerning

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data and voluntary consultation information with GM food producers for close to a decade. *See* Statement of Policy: Foods Derived from New Plant Varieties, 57 Fed. Reg. at 22,984. While the consultation process has been only voluntary up to this point, the FDA claims that "[i]t has been the general practice of the food industry to seek informal consultation" with the FDA before offering a new food product to market. *Id.* at 22,991. In its first policy announcement concerning bioengineered plant products in 1992, the FDA found that "experience over many years (or even centuries)" demonstrated that foods derived from new plant varieties did not require routine safety checks and could be treated like any other food product. *Id.* at 22,988–89. With the May 2000 announcement, however, the FDA has mandated that all food producers consult with the FDA prior to introduction of a new GM food product. *See* Press Release, Food and Drug Administration, FDA to Strengthen Pre-Market Review of Bioengineered Foods, *at* http://www.fda.gov/bbs/topics/NEWS/NEW00726.html (May 3, 2000). The consultation process typically consists of a review of the crop from which the product is derived, the applications or uses of the food, the sources and function of GM material introduced, the intended technological effect of the modification, information concerning known allergenicity and toxicities, and "the basis for concluding that [such] foods . . . can be safely consumed." *See Guidance on Consultation Procedures; Foods Derived from New Plant Varieties*, *at* http://vm.cfsan.fda.gov/~lrd/consulpr.html (Oct. 1997).

106. The main goal of the FDA with regard to GM foods is to ensure food safety under the FFDCA and to work closely with the EPA and USDA in regulating a safe food supply in the United States. *See* Statement of Policy: Foods Derived from New Plant Varieties, 57 Fed. Reg. at 22,985. Under the guidance of the FDA, the United States has developed one of the safest food supplies in the world. *See id.* at 22,988.

107. *See* discussion *infra* Part III.B. For a more detailed scientific analysis of GM foods under the FFDCA, finding that "[c]urrent U.S. policy does not require mandatory labeling of genetically modified (GM) foods as a class," see Goldman, *supra* note 58, at 718. Because GM techniques have been found not to alter the final food product and only to involve a small change in the method of production, and because the FDA can only require mandatory labeling when the final product is different in some identifiable way, the FDA is not required to mandate labeling for GM food products in general. *See id.* at 725.

108. 92 F.3d 67 (2d Cir. 1996); *see also* discussion *infra* Part V.A.1.

109. 116 F. Supp. 2d 166 (D.D.C. 2000).

GM foods in general.[110]

International Dairy Foods evaluated the FDA's findings that rbST-enhanced milk products were as safe and not nutritionally different than other milk products on consumer shelves.[111] The second circuit court used the FDA's position to determine that the state's mandatory labeling law violated the food supplier's First Amendment rights.[112] Like rbST milk, the FDA has determined that GM foods are as safe and not nutritionally different from other similar products on consumer shelves. Therefore, the rejection of mandatory labeling for GM foods is consistent with the FDA's decision not to mandate labeling for rbST milk. It is also consistent with the analysis provided in *International Dairy Foods* that focused on limiting compelled speech to cases where more than a consumer desire to have information exists.[113]

Alliance for Bio-Integrity was filed prior to the May 2000 decision to challenge the FDA's 1992 stance on the issue of GM foods, a stance that is similar to the FDA's current position.[114] The plaintiffs in that case were the first to oppose the FDA's policy on GM food labeling in general, raising issues surrounding the consumers right to know, religious freedom, environmental safety, and FFDCA statutory construction.[115] The district court gave deference to the findings of the FDA and rejected all claims.[116]

Judge Kollar-Kotelly's opinion in *Alliance for Bio-Integrity* sets an important precedent in the labeling debate. The district court reviewed the limits of the FDA's power under the FFDCA and concluded that the FDA has "limited authority to require labeling"[117] when the only "justification

110. *See id.* at 181.
111. *Int'l Dairy Foods Ass'n*, 92 F.3d at 69.
112. *Id.* at 73.
113. *See* discussion *infra* Parts IV.B.1, V.A.1.
114. *See* Statement of Policy: Foods Derived from New Plant Varieties, 57 Fed. Reg. 22,984 (May 29, 1992). The main difference between the 1992 position and the 2000 position is the decision to mandate a consultation process for GM foods to further ensure safety of GM products on consumer shelves. *See supra* text accompanying note 105.
115. *Alliance for Bio-Integrity*, 116 F. Supp. 2d at 170.
116. *Id.* at 181.
117. *Id.* at 178. Under 21 U.S.C. § 321(n), the FDA can only mandate labeling if the product is misbranded because it "fails to reveal facts... material with respect to consequences which may result from the use of the article to which the labeling... relates." 21 U.S.C. § 321(n) (1994). Under the FDA's declaration that GM foods are not "materially" different from non-GM foods, then, a failure to identify the product as GM is not misbranding. *See Alliance for Bio-Integrity*, 116 F. Supp. 2d at 179.

for such a requirement is consumer demand."[118] Judge Kollar-Kotelly discusses when labeling is appropriate, indicating that where "'the product does not differ in any significant way from what it purports to be, then it would be misbranding to label the product as different, even if consumers misperceived the product as different.'"[119] In upholding the FDA's findings that GM foods in general are not materially different than other foods, the court held that the FDA "lacks a basis upon which it can legally mandate labeling, regardless of the level of consumer demand."[120]

Alliance for Bio-Integrity demonstrates the deference that courts will likely give to FDA findings as well as the limitations that those scientific findings place on the FDA when considering labeling initiatives. The FDA has not interpreted the FFDCA to require a review of mere consumer concern when evaluating "misbranded" products. Rather, the FDA finds that its duty lies first in evaluating the scientific risks and nutritional distinctions between products.[121] Only where a material difference can be found will the FDA rightly be able to consider the consumer's interest and institute labeling regulations.[122]

Both *International Dairy Foods* and *Alliance for Bio-Integrity* define the extent of the FDA's power concerning food product labeling where the FDA's scientific findings show no risk of harm to consumers. In these cases, a consumer's desire to know is not enough under the power granted to the FDA by the FFDCA to warrant broad mandatory labeling regulations. These decisions confirm that the FDA acted with the support of legal precedent when determining that mandatory labeling is inappropriate for GM foods in general.

C. FDA Decision Will Set Future Precedent and Regulations

As the courts in *International Dairy Foods* and *Alliance for Bio-*

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118. *Alliance for Bio-Integrity*, 116 F. Supp. 2d at 179.

119. *Id.* (quoting Stauber v. Shalala, 895 F. Supp. 1178, 1193 (W.D. Wis. 1995)).

120. *Id.*

121. This is made clear in its proposed mandatory safety consultation program announced in January 2001. *See generally* Premarket Notice Concerning Bioengineered Foods, 66 Fed. Reg. 4706 (proposed Jan. 18, 2001) (to be codified at 21 C.F.R. pts. 192 & 592).

122. *See Alliance for Bio-Integrity*, 116 F. Supp. 2d at 179.

> Plaintiffs fail to understand the limitation on the FDA's power to consider consumer demand when making labeling decisions because they 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.

Id.

Integrity ruled, courts and states currently reviewing mandatory labeling initiatives must give deference to the findings of the FDA. States may be subject to preemptory challenges, for example, if they adopt legislation contrary to the FDA's GM policies. The focus of future federal legislation, taking into account the FDA's conclusions, will be designed to calm consumer fears and assure consumers that their safety is being considered without mandatory labeling.[123] Several bills have already been proposed that would modify the FFDCA in light of the FDA's recent findings.[124] For example, one U.S. Senate Bill proposes to amend the FFDCA to require premarket consultation and approval of GM foods in accord with the FDA's May 2000 decision to do the same.[125]

The FDA's stance has also prompted a review of European anti-GM regulations[126] and is likely to be important to other countries as they consider whether to develop anti-GM legislation. The decision not to mandate labeling for GM foods, then, is an important precedent in settling the GM food labeling debate for good.

IV. THE CONSUMER'S RIGHT TO KNOW IS NOT ABSOLUTE

The GM food labeling debate, unlike any other in history,[127] brings the consumer's right to know to the forefront. It helps define the limits on the right to know especially as it relates to food products. The consumer's right to know is not absolute and can be evaluated using a balancing approach like that described below.[128] Striking the

123. S. 3184, 106th Cong. (2000) (modifying the FFDCA to require premarket consultation and approval of GM foods); *see also* S. 2315, 106th Cong. (2000); H.R. 3883, 106th Cong. (2000) (called the "Genetically Engineered Food Safety Act," proposing several changes to the FFDCA); H.R. 5095, 106th Cong. (2000) (requiring that the Secretary of Agriculture prepare a report concerning the risks and methods of monitoring GM foods).

124. *See supra* text accompanying note 123.

125. S. 3184, 106th Cong. (2000). The bill was introduced in October 2000 and is called the "Genetically Engineered Foods Act." *Id.*

126. The European Commission indicated that it is time "to accept that GM foods do not pose a serious threat to public health," and thus decided to end its "unofficial 18-month moratorium" on GM foods. Karen Birchard, *European Commission to End De Facto Moratorium on GM Products*, LANCET, July 22, 2000, at 320.

127. The rbST debate considered *infra* Part V.A.1 is the closest relative to the GM food labeling debate.

128. The balance may include the review of several factors not listed and considered here, as the particular case may demand. Nonetheless, a balancing of interests appears to be warranted whenever reviewing the extent of the consumer's right to know.

appropriate balance of rights between consumers and food-product suppliers requires the review of several factors including the consumer's right to a safe food supply,[129] the consumer's right to make knowledgeable food choices,[130] and the consumer's right to freedom of religion,[131] as well as the food supplier's right to freedom of commercial speech and free trade.[132] When applying this delicate balance to the GM food labeling debate, the FDA was justified in finding mandatory labeling inappropriate to protect the consumer's limited right to know.

A. *Rights of the Consumer*

The consumer has the right to consume safe food products.[133] The consumer has the right to make knowledgeable food choices.[134] The consumer also has the right to freedom of religion.[135] Each of these rights becomes important when evaluating the extent of the consumer's right to know about the GM food products he consumes.

1. Consumer Safety

Although the FDA and the scientific community identify GM food products as safe,[136] opponents argue that not enough research into GM

129. Federal regulatory agencies are charged with ensuring the safety of products that reach consumer shelves under the Federal Food, Drug and Cosmetic act (FFDCA). 21 U.S.C. §§ 301–95 (1994). *See supra* text accompanying note 81. *See generally* International Food Information Council Foundation, *Background on Food Biotechnology*, *at* http://ific.org/food/biotechnology.vtml (last visited July 27, 2001). "Under the [FFDCA], companies have a legal obligation to ensure that any food they sell meets the safety standards of the law. . . . If a food does not meet the safety standard, the FDA has the authority to take it off the market." Thompson, *supra* note 29, *at* http://www.fda.gov/fdac/features/ 2000/100_bio.html. The Clinton Administration announced a new Food Safety Initiative in May 2000 designed to expand food safety research efforts. *See* Press Release, The White House, Office of the Press Secretary, Clinton Administration Agencies Announce Food and Agricultural Biotechnology Initiatives: Strengthening Science-Based Regulation and Consumer Access to Information, *at* http://vm.cfsan.fda.gov/~lrd/whbio53.html (May 3, 2000).

130. Under the FFDCA, consumers are guaranteed to have available the essential information with which to make decisions about the products they use. *See generally* Degnan, *supra* note 15.

131. The issue of the right to freedom of religion and its relationship to food labeling is discussed *infra*, Part IV.A.3.

132. For an overview of the rise of the commercial speech right and how such a right is viewed with respect to mandatory labeling initiatives, see Caren Schmulen Sweetland, Note, *The Demise of a Workable Commercial Speech Doctrine: Dangers of Extending First Amendment Protection to Commercial Disclosure Requirements*, 76 TEX. L. REV. 471 (1997).

133. *See supra* text accompanying note 129.

134. *See supra* text accompanying note 130.

135. U.S. CONST. amend. I; *see also* discussion *infra* Part IV.A.3.

136. *See supra* text accompanying note 1.

technologies and the resulting products has yet been conducted to establish that such foods are safe.[137] While more research could be done and is ongoing at this time, no scientific reason has arisen to believe that GM foods are unsafe and should be treated differently from any other food product.[138] Crucial to this finding is the fact that every food product contains DNA,[139] or genetic information. Without a showing of specific hazards, there is no reason to believe that the small genetic deviations that exist in GM food products would create increased risk.[140] In finding no valid data to the contrary, yet taking some precaution by requiring heightened review of GM products in general, the FDA's year-2000 position is consistent with its duty to protect citizens from unsafe products.[141]

2. *Right to Make Informed Food Product Choices*

Mandatory labeling is currently required to provide consumers with the ability to choose products based on nutritional content.[142] The Nutrition Labeling and Education Act of 1990[143] requires food products suppliers to provide particular nutritional information on the label of all food products to assist consumers in "maintaining healthy dietary practices."[144] Key to this legislation was the identification of the consumer's ability to understand the value of nutritional-content information and the need for certain members of the population to

137. *See supra* text accompanying notes 2, 9.
138. *See supra* text accompanying notes 1, 64.
139. *See supra* text accompanying note 31.
140. The FDA has mandated a consultation process to ensure product safety even though it has found no scientifically valid risk that exists with GM products in general. *See* Press Release, Food and Drug Administration, FDA to Strengthen Pre-Market Review of Bioengineered Foods, *at* http://www.fda.gov/bbs/topics/NEWS/ NEW 00726.html (May 3, 2000). The FDA recognized in its 1992 policy that "[t]he established practices that plant breeders employ in selecting and developing new varieties of plants, such as chemical analyses, taste testing, and visual analyses . . . have proven to be reliable for ensuring food safety." *See* Statement of Policy: Foods Derived from New Plant Varieties, 57 Fed. Reg. 22,984, 22,988 (May 29, 1992).
141. *See* Premarket Notice Concerning Bioengineered Foods, 66 Fed. Reg. 4706, 4708 (proposed Jan. 18, 2001) (to be codified at 21 C.F.R. pts. 192 & 592); 21 U.S.C. § 393 (1994).
142. The Nutrition Labeling and Education Act of 1990 amended the FFDCA to require that food products be labeled with various nutritional content information. H.R. 3562, 101st Cong. (1990) (enacted); *see* 21 U.S.C. §§ 343(q)–(r), 343-1 (1994).
143. H.R. 3562, 101st Cong. (1990) (enacted).
144. 21 U.S.C. § 343(q)(1)(E).

distinguish between food products for health reasons.[145] Unlike GM foods in general, when compared only to their non-GM counterparts, the nutritional content of different food products can vary considerably. The consumer has the right, then, to know the content of food products when the consumer can effectively use the information to distinguish between products.[146]

The consumer's right to know, however, is limited by the consumer's capacity to understand and use the information provided.[147] The information provided on labels in accord with the right to know must therefore be limited accordingly to include only that information which is necessary for the individual to make distinctions between products.[148] Also, to avoid an information overload and thus a loss of value in the information itself,[149] the amount of label information must be carefully monitored. Opponents of GM products argue that the consumer has a right to know which products were developed using GM technologies by requiring a "GM" label on each product.[150] A general GM label, however, would not assist consumers in the same way nutritional labels have assisted consumers in maintaining healthy diets.

For instance, there is a large risk that consumers would become numb to the term GM and find no real distinction between products[151]

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145. *See supra* text accompanying note 94.

146. Where no distinction between products exists, labeling that indicates that it does can be held misleading under the FFDCA. *See* Dan L. Burk, *The Milk Free Zone: Federal and Local Interests in Regulating Recombinant bST*, 22 COLUM. J. ENVTL. L. 227, 254 (1997).

147. *See supra* text accompanying notes 94–95. When discussing the effectiveness of warnings in protecting the consumer's right to make accurate judgments of risk from warning labels, it is important to define the audience and to ensure that label information is written so that it can be understood. W. Kip Viscusi & Richard J. Zeckhauser, *Hazard Communication: Warnings and Risk*, 545 ANNALS AM. ACAD. POL. & SOC. SCI. 106, 110–11 (1996).

148. The presentation of information on a label "can affect how well consumers process the information contained." Viscusi & Zeckhauser, *supra* note 147, at 109; *see also* Food Labeling; Declaration of Ingredients, 56 Fed. Reg. 28,592, 28,615 (June 21, 1991).

149. "Overwarning and the overuse of [particular] words may, for example, dilute their importance. If every product in the supermarket carries a hazard warning, no distinctions will be made." Viscusi & Zeckhauser, *supra* note 147, at 108; *see also* Food Labeling; Declaration of Ingredients, 56 Fed. Reg. at 28,614.

150. *See What Are They Hiding*, *at* http://www.gefoodalert.org/html/hiding.htm (last visited Sept. 25, 2000).

151. *See* Food Labeling; Declaration of Ingredients, 56 Fed. Reg. at 28,614; *supra* text accompanying notes 95, 149. At this time, no difference has been found between GM food products and their non-GM counterparts, besides a difference in the method of production. *See supra* text accompanying note 1. Methods of food processing have never formed the basis for labeling of products under the FFDCA because the FDA does not recognize the methods used to produce foods as material elements of the final product. *See* Statement of Policy: Foods Derived from New Plant Varieties, 57 Fed. Reg. 22,984, 22,984 (May 29, 1992). Only where the final product differs in some way

because more than half of the products on consumer shelves would be required to carry such a label.[152] What may be even worse is that the "GM" label, which is likely to be interpreted by consumers as a warning, may be viewed as more important than other more relevant risk factors.[153] The most important problem with the "GM" label, however, is that consumers are not well informed as to what GM really means.[154] A label simply stating that the food is a product of genetic modification does not carry meaning to the average consumer.[155] In fact, the consumer will more likely interpret the label to say that unlike other products on the shelves, GM foods are nutritionally different from other non-GM products.[156] This type of thinking could lead to a belief that other non-GM labeled products on the shelves (designed using traditional cross-breeding technologies for instance) are not generated using any sort of genetic variation.[157] Such inferences are not accurate and could serve to mislead consumers rather than properly inform. Because of this confusion, the "GM" label, without a detailed

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from the common variety does the FDA consider labeling a necessity, and even in those cases, it is the material difference that will be noted, not the process that was used to reach that difference in the label. *Id.* at 22,991.

152. *See* Barboza, *supra* note 17, at A1.

153. "As we provide warnings about increasingly tiny hazards, we make it harder for consumers to notice warnings about the truly consequential ones." Viscusi & Zeckhauser, *supra* note 147, at 112.

154. *See U.S. Consumer Attitudes Toward Food Biotechnology*, *at* http:ificinfo.health.org/foodbiotech/survey.htm (last visited July 14, 2000); *see also* discussion *supra* Part I. The FDA is still taking comments to determine how it will define GM to ensure truthful and nonmisleading use of the term on food labels. *See* Draft Guidance for Industry: Voluntary Labeling Indicating Whether Foods Have or Have Not Been Developed Using Bioengineering; Availability, 66 Fed. Reg. 4839, 4840 (Jan. 18, 2001).

155. *See U.S. Consumer Attitudes Toward Food Biotechnology*, *at* http:ificinfo.health.org/foodbiotech/survey.htm (last visited July 14, 2000). Eighty-six percent of those surveyed in May 2000 agreed with the statement that "[s]imply labeling products as containing biotech ingredients does not provide enough information." *Id.*

156. *See supra* text accompanying note 1 (regarding the FDA's finding that GM food products are as safe as their non-GM counterpart). The FDA's finding that GM products in general are safe is based in part upon the fact that no difference in nutritional content has been found between those GM foods that have been reviewed and their traditional counterpart. *See* Press Release, Food and Drug Administration, FDA to Strengthen Pre-Market Review of Bioengineered Foods, *at* http://www.fda.gov/bbs/topics/NEWS/NEW00726.html (May 3, 2000).

157. Such an argument was posed concerning rbST labeling as well. *See* Burk, *supra* note 146, at 269. A general "contains rbST" label "may incorrectly suggest some health or nutritional difference" which would be "misleading by suggesting that the presence of bST is unusual or worth noting." *Id.*

explanation[158] of scientific technologies, may be inherently misleading and would therefore violate the FFDCA.[159]

The consumer's right to know certainly exists where a safety risk has been identified.[160] This right to be informed of safety risks exists regardless of the fact that many consumers either do not read labels or do not understand what the labels say.[161] When looking at the GM food label and an unidentifiable risk factor, however, it is clear that the consumer's right to know does not include a right to a GM label on food products—that is, until a safety hazard or nuitritional difference exists to be noted. Thus, the FDA was justified in finding that the consumer's right to know does not provide for a right to a "GM" product label. Not only could the "GM" label be inherently misleading and misunderstood by the average consumer, but consumers simply do not have a right to distinguish between products where no real distinction exists.[162]

The FDA rightfully chose instead to protect the consumer's right to know by establishing voluntary guidelines[163] for those food suppliers that desire to distinguish and market their products on a GM basis. The FDA cannot restrict valid, lawful, and nonmisleading communications by banning all GM labeling information.[164] However, the FDA does

158. Due to the lack of awareness of the general public as to what the difference is between GM foods and others, in order for a label to accurately inform it must provide a significant amount of information. *See supra* text accompanying note 155. This was the case in the rbST labeling debate as well. *See* Interim Guidance on the Voluntary Labeling of Milk and Milk Products from Cows that Have Not Been Treated with Recombinant Bovine Somatotropin, 59 Fed. Reg. 6279 (Feb. 10, 1994); *see also* discussion *infra* Part V.A.2.

159. A food is considered "misbranded" under the FFDCA if the label is "false or misleading." 21 U.S.C. § 343(a) (2000). The FDA is currently requesting public comment on whether a clarifying statement is necessary to make products labeled "GM free" or "biotech free" accurate in order to avoid misleading the consumer. *See* Draft Guidance for Industry: Voluntary Labeling Indicating Whether Foods Have or Have Not Been Developed Using Bioengineering; Availability, 66 Fed. Reg. 4839, 4840 (Jan. 18, 2001). There is a concern that such "terms would be misleading if they imply that the food is superior because the food is not bioengineered." *Id.*

160. *See* 21 U.S.C. § 393(b)(2)(A) (1994).

161. Not all labeling information is even read by consumers, nor is all information received properly understood. It has been shown that consumers have trouble understanding common food label words such as "polyunsaturated fat," "hydrogenated," and even "carbohydrates." Viscusi & Zeckhauser, *supra* note 147, at 110–11.

162. *See supra* text accompanying notes 1, 146. In other words, a GM tomato is still a tomato. The final GM product differs from the non-GM tomato only in the way it was produced, much like a test tube baby differs from other babies only in the way it was conceived—the resulting human being we call a baby in either case.

163. *See* Press Release, Food and Drug Administration, FDA to Strengthen Pre-Market Review of Bioengineered Foods, *at* http://www.fda.gov/bbs/topics/NEWS/NEW00726.html (May 3, 2000).

164. The FDA, like any other regulatory body, must respect the right to freedom of speech guaranteed under the First Amendment of the Constitution and cannot ban valid lawful speech without a substantial government interest to protect. *See* U.S.C §§ 301–95

have the power to regulate voluntary communications to ensure that only reliable information reaches consumers.[165] The protection of the consumer's right to know about GM foods, then, lies in monitoring voluntary labeling guidelines for accuracy, not in mandating a meaningless overbroad label. This decision is consistent with other FDA regulations that have explored when voluntary versus mandatory labeling is applicable[166] in relation to the consumer's right to know.

3. Alliance for Bio-Integrity v. Shalala[167]—*The Right to Freedom of Religion*

The right to be free from government interference in the exercise of one's religion[168] can be important when considering the right to make informed food choices. The "Kosher" food label, for example, has been the topic of recent review under the constitutional right to religion.[169] *In Commack Self-Service Kosher Meats, Inc. v. Rubin,*[170] a New York statute was deemed unconstitutional because the labeling guidelines to be enforced by the State of New York required the state to apply "religious authority and interpretation."[171] This requirement was deemed an "excessive entanglement and advance[ment of] religion."[172] In reaching its conclusion, the *Commack* court applied the "three-pronged *Lemon* test,"[173] under which a challenged law must:

(1) "have a secular purpose"[174] and therefore not be "'motivated

(1994); Central Hudson Gas & Elec. Corp. v. Pub. Serv. Comm'n of New York, 447 U.S. 557 (1980).

165. In fact, the FDA has an obligation to do so under the FFDCA. *See* 21 U.S.C. § 343 (1994).

166. *See supra* text accompanying notes 94–96. Mandatory labeling has been reserved for those cases where the benefits outweigh the rights of food suppliers—evidenced by the nutritional content labeling requirements—and for those cases where the public safety is at risk—evidenced by the general provisions of the FFDCA that focus on a review of product safety. Voluntary labeling guidelines have been reserved to ensure accurate commercial communications in cases where mandatory labeling is not warranted. *See* discussion *infra* Parts IV.B.1, V.A.1.

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

168. The right is guaranteed by the First Amendment of the U.S. Constitution. U.S. CONST. amend. I.

169. *See* Commack Self-Service Kosher Meats, Inc. v. Rubin, 106 F. Supp. 2d 445 (E.D.N.Y. July 28, 2000).

170. *Id.*

171. *Id.* at 456.

172. *Id.*

173. *Id.* at 452 (citing Lemon v. Kurtzman, 403 U.S. 602, 612 (1971)).

174. *Id.* (quoting Lemon v. Kurtzman, 403 U.S. at 612).

wholly by religious considerations,'"[175]

(2) "have a primary effect that neither advances nor inhibits religion, and

(3) not [] foster excessive state entanglement with religion."[176]

By defining Kosher as food "prepared in accordance with orthodox Hebrew religious requirements"[177] and by requiring officials to punish the plaintiff for not adhering to those regulations properly,[178] the court determined that the state law violated all three prongs of the *Lemon* test.[179] Under this interpretation of the *Lemon* test, states may not establish regulations that involve "monitoring [] the compliance of vendors"[180] according to guidelines that require the application of a "set of religious dietary laws."[181]

The issue of the right to religion and GM food labeling was presented to the U.S. District Court of the District of Columbia in *Alliance for Bio-Integrity v. Shalala.*[182] The plaintiff claimed that, by failing to mandate labeling, the FDA violated the First Amendment rights of consumers to the free exercise of religion.[183] The court rejected the plaintiff's religious claims.[184] Although the court did not apply the *Lemon* test[185] per se, its decision can be validated by looking at this test and the analysis provided under *Commack.*

Because the FDA has found no valid risk inherent in GM foods, the FDA has no valid governmental interest to protect. Thus, to mandate labeling to protect religious dietary preferences would solely derive from "religious considerations,"[186] which is not a proper purpose for a law under *Lemon.*[187] Also, as in *Commack,* to mandate labeling in accord with religious dietary preferences would require the FDA to interpret

175. *Id.* at 453 (quoting Lynch v. Donnelly, 465 U.S. 668, 680 (1984)).
176. *Id.* at 452–53 (citing Lemon v. Kurtzman, 403 U.S. at 612–13).
177. *Id.* at 449.
178. *See id.* at 448.
179. *Id.* at 454.
180. *Id.*
181. *Id.*
182. 116 F. Supp. 2d 166, 170 (D.D.C. 2000). The suit also claims that GM foods should be treated as food additives and challenges the finding of the FDA that GM foods are "generally recognized as safe" and therefore not considered food additives and subject to regulation under the food additive standards of the FFDCA. *Id.* Plaintiffs raised two religious challenges: the first, claiming that the FDA's decision not to mandate labeling of GM products violates the Free Exercise Clause; and the second, claiming that the FDA's decision violated the Religious Freedom Restoration Act. *Id.*
183. *Id.*
184. *Id.* at 180–81.
185. Lemon v. Kurtzman, 403 U.S. 602 (1971).
186. *Rubin,* 106 F. Supp. 2d at 453.
187. *Id.*

religious principles and to advance religion,[188] thereby fostering an excessive entanglement between states and religion which violates the Establishment Clause of the First Amendment.[189] For these reasons, the *Alliance for Bio-Integrity* religious freedom challenge fails under standard Establishment Clause jurisprudence.[190]

Plaintiffs in *Alliance for Bio-Integrity* also raised a challenge to the FDA's decision under the Religious Freedom Restoration Act (RFRA).[191] The court declared that the FDA was subject to the RFRA but that the plaintiff failed to establish a violation because the plaintiff was unable to show that the FDA regulation "substantially burdened Plaintiffs' religion."[192] The court determined that a substantial burden cannot arise simply because the FDA refuses to "take action to further the practice of individuals' religion."[193] In rejecting the RFRA claim, the court went further, saying that if the FDA did mandate action, it would come "close to violating the First Amendment's Establishment Clause."[194] The inconvenience alleged by the plaintiff was not enough to mandate action by the FDA to protect the right to religious dietary preferences.[195]

One's right to freedom of religion, unless substantially burdened by government action, is not alone sufficient to give the FDA the power to mandate that food suppliers inform consumers about the use of genetic techniques in food production.[196] Voluntary labeling guidelines based

188. *See id.* at 456.

189. *See id.* at 459; *see also* U.S. CONST. amend. I.

190. The court in *Alliance for Bio-Integrity* held that the challenge regarding the right to free exercise of religion was not valid because the FDA's policy was neutral with respect to religion. Even if some burden to exists to the plaintiff, the court determined, as long as the FDA policy is neutral, it does not violate the plaintiff's First Amendment rights. Alliance for Bio-Integrity v. Shalala, 116 F. Supp. 2d 166, 179–80 (D.D.C. 2000).

191. 42 U.S.C. §§ 2000bb–bb-4 (1994).

192. *Alliance for Bio-Integrity*, 116 F. Supp. 2d at 180–81.

193. *Id.* at 180.

194. *Id.* This is similar to what the court held in *Commack* when looking at state legislation that required application of religious principles. *See* Commack Self-Service Kosher Meats, Inc. v. Rubin, 106 F. Supp. 2d 445, 458 (E.D.N.Y. 2000).

195. "While the Court recognizes the potential inconvenience the lack of labeling presents for Plaintiffs, Defendant's decision [not] to mandate labeling of genetically modified foods does not 'substantially' burden Plaintiffs' religious beliefs." *Alliance for Bio-Integrity*, 116 F. Supp. 2d. at 181. "In this case, the Plaintiffs' liberty is not restricted and they are free to choose their food and may obtain their food from the source of their choosing." *Id.*

196. *See id.* at 180–81; *see also* discussion *infra* Part IV.B.1.

on objective, nonreligious standards are more likely to be the source of protection of the consumer's right to freedom of religious dietary considerations.[197] The focus of parties interested in protecting religious freedoms should, therefore, be on how to distinguish new products under "traditional" religious methodologies so that those who wish to label products in accord with those beliefs may be able to do so in a truthful and nonmisleading manner.[198]

B. Rights of the Food Manufacturer or Producer

The rights of the food supplier are crucial to the finding that mandatory labeling is not appropriate for GM foods. When balancing the right of the consumer to know about genetic alterations in foods against the supplier's commercial freedoms of speech[199] and trade,[200] mandatory labeling cannot be found appropriate in this general context. Some degree of governmental interest is required before interference with the supplier's rights is justified.[201] Because no *substantial* government interest can be identified concerning GM foods due to the lack of known risk to the public, the FDA was required to hesitate in mandating action.

1. Freedom of Commercial Speech

The First Amendment right to freedom of speech incorporates both the right to speak freely and the right not to be required to speak against one's will.[202] Similar principles apply when comparing the freedom to

197. Similar guidelines have been established to monitor "Organic" food labeling. *See* generally 7 U.S.C. §§ 6501–6522 (1994); Kenneth C. Amaditz, *The Organic Foods Production Act of 1990 and Its Impending Regulations: A Big Zero For Organic Food?*, 52 FOOD & DRUG L.J. 537 (1997); Terence J. Centner & Kyle W. Lathrop, *Differentiating Food Products: Organic Labeling Provisions Facilitate Consumer Choice*, 1 DRAKE J. AGRIC. L. 30 (1996).

198. Judge Kollar-Kotelly stated, in *Alliance for Bio-Integrity*, that the Plaintiffs' religious challenges would be "better directed at Congress" since the FDA did not have the power under the FFDCA to require action of the sort requested. *Alliance for Bio-Integrity*, 116 F. Supp. 2d at 181.

199. *See* Central Hudson Gas & Elec. Corp. v. Pub. Serv. Comm'n of New York, 447 U.S. 557, 561 (1980) (noting that commercial speech is "expression related solely to the economic interests of the speaker and its audience").

200. Interstate commerce is protected under the Commerce Clause of the U.S. Constitution. U.S. CONST. art. I, § 8, cl. 3; *see* discussion *infra* Part V.4 (discussing the potential interference on interstate trade if individual states were to impose differing mandatory labeling initiatives).

201. This is required under both the constitutional right to freedom of speech and the right to freedom of trade. *See* Int'l Dairy Foods Ass'n v. Amestoy, 92 F.3d 67, 72 (2d Cir. 1996); Dean Milk Co. v. City of Madison, 340 U.S. 349, 354 (1951).

202. *Int'l Dairy Foods Ass'n*, 92 F.3d at 71 (citing Wooley v. Maynard, 430 U.S.

speak with the freedom not to speak.[203] Although commercial speech has been found to deserve less protection than the individual's right to freedom of speech,[204] the right to freedom of commercial speech nonetheless plays heavily into the validation of the FDA's decision not to require GM food suppliers to speak against their will in the form of mandatory labeling.[205]

The right of commercial speech is protected under the *Central Hudson Gas & Electric Corp. v. Public Service Commission of New York* four-part test.[206] Regulation of commercial speech is permitted under this test in cases where:

(1) The speech is [un]lawful and misleading;
(2) A substantial government interest can be identified;
(3) The regulation "directly advances" the asserted interest; and
(4) The regulation is "not more extensive than is necessary to serve that interest."[207]

Under this four-part test, and in light of the relevant application and analysis of the right to be free from compelled speech discussed in *International Dairy Foods Association v. Amestoy*,[208] the FDA decision not to mandate labeling is appropriate. In *International Dairy Foods*, the circuit court reviewed the constitutionality of a Vermont State law mandating labeling of biotechnology-enhanced milk.[209] The court ruled that the state of Vermont had not established a substantial government interest[210] because the reason for the statute consisted merely of a "strong consumer interest and the public's 'right to know.'"[211] Thus,

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705, 714 (1977)).

203. *See id.* at 72.

204. *Central Hudson Gas & Elec. Corp.*, 447 U.S. at 562–63.

205. *See Int'l Dairy Foods Ass'n*, 92 F.3d at 71–73.

206. *Central Hudson Gas & Elec. Corp.*, 447 U.S. at 566. The *Central Hudson* test was employed in *International Dairy Foods* to address a mandatory speech issue in the same manner as it was applied in *Central Hudson* to protect against a ban on speech. *Int'l Dairy Foods Ass'n*, 92 F.3d at 72.

207. *See Central Hudson Gas & Elec. Corp.*, 447 U.S. at 566. Applying this test in *International Dairy Foods*, the court stated, "[W]e must determine: (1) whether the expression concerns lawful activity and is not misleading; (2) whether the government's interest is substantial; (3) whether the labeling law directly serves the asserted interest; and (4) whether the labeling law is no more extensive than necessary." *Int'l Dairy Foods Ass'n*, 92 F.3d at 72.

208. *See Int'l Dairy Foods Ass'n*, 92 F.3d at 71–72.

209. *Id.* at 69.

210. *Id.* at 73.

211. *Id.* (quoting Int'l Dairy Foods Ass'n v. Amestoy, 898 F. Supp 246, 249 (D.Vt 1995)).

under the *Central Hudson* test, the state did not have the power to "compel the dairy manufacturers to speak against their will."[212]

The lack of government interest stemmed from the fact that no "scientific evidence" demonstrated that the biotechnology-enhanced milk product was any different from, or posed any "real" harm to consumers when compared to the nonenhanced product.[213] The court determined that "mere consumer concern is not, in itself, a substantial interest."[214] The commercial-speech analysis ended at the second prong of the *Central Hudson* test when the court discovered no substantial government interest to protect and therefore no state power to interfere with the right of product suppliers to be free from compelled communication.[215] The case demonstrates the limits on the power of regulatory bodies like the FDA to mandate speech under the *Central Hudson* test and the First Amendment.

The FDA adhered to the commercial speech guidelines established in these cases in finding that mandatory labeling is not warranted for GM foods.[216] The FDA was unable to establish a substantial government interest given the fact that no valid scientific evidence demonstrating any risk of harm to consumers from GM foods in general now exists.[217] Due to the rights of farmers and other food product suppliers to be free from compelled communications and the costs of informing the consumer where no risk of harm exists, the FDA could not successfully mandate labeling of GM foods without more.[218] Mere consumer concern is all that exists at this time regarding GM foods and under the *Central Hudson* test, this concern is not enough to warrant mandatory labeling

212. *Id.* at 74.

213. *Id.* at 73. "[A] governmental body seeking to sustain a restriction on commercial speech must demonstrate that the harms it recites [as part of its government interest] are real and that its restriction will in fact alleviate them to a material degree." *Id.* (quoting Edenfield v. Fane, 507 U.S. 761, 770–71 (1993)). Applying this standard, the court held that Virginia failed to establish that its interest was substantial because strong consumer interest alone is not enough to justify a state in restricting a food supplier's constitutional rights. *Id.*

214. *Id.* at 73 n.1.

215. *See id.* at 73.

216. While the FDA did not address constitutional concerns in its recent decision, its decision can be validated on First Amendment grounds as discussed *infra*.

217. *See supra* text accompanying note 1.

218. *See* discussion *infra* Part IV.B.1. "Mandatory labeling of products that contain GMOs or GMO-derived ingredients essentially imposes all of the costs of labeling on those . . . who are willing to continue to use products containing GMOs." Beales III, *supra* note 56, at 113. Essentially, the GM opponents seeking mandatory labeling are looking for "more information than they are willing to pay for." *Id.* Looking solely at information costs, then, voluntary labeling is the more efficient solution. *Id.* "With voluntary labeling, consumers who value the information are the ones who must pay the costs associated with it; those who do not care are not burdened with the cost of information that is of no value to them." *Id.* at 112–13.

and a corresponding interference with the First Amendment rights of food suppliers.

C. Evaluating the Balance for GM Foods—FDA Decision Finds the Appropriate Balance

In evaluating its power to establish mandatory labeling standards for GM foods, the FDA has essentially found that the rights of the product supplier to be free from compelled communication outweigh the limited rights of the consumer.[219] The crucial distinguishing factor is the fact that the risk of harm to the consumer currently consists only of speculation and a fear of technological progress.[220] Or maybe it is a fear by organic food producers that biotechnology may destroy their businesses by offering pesticide-free foods at a reduced cost.[221] Whatever the reason, no evidence currently indicates that GM foods pose any harm to consumers. Thus, the FDA's authority over food suppliers is restricted due to a lack of government interest sufficient to warrant the establishment of mandatory labeling laws.

Neither the consumer's right to safe food products, the right to make knowledgeable food choices, nor the right to religion are sufficient to outweigh the interests of the food suppliers to be free from compelled communications in the case of GM foods. The consumer's right to know is thus limited in the area of GM food regulation. The consumer's right to know is not without force, but this right will be better protected under

219. The FDA has been shy to mandate labeling of food products where nothing but a consumer's desire to know is at stake. *See supra* text accompanying notes 94–96, 213. In requiring a safety hazard or other government interest prior to mandating labeling in the food industry, the FDA must balance the rights of the consumer to enjoy safe food products and to be informed of food product contents with the rights of the food supplier to be free from compelled communications and the costs of informing the public of food product information. *See supra* text accompanying notes 94–96, 213.

220. *See supra* text accompanying note 64.

221. Such a theory has recently been suggested. *See* Douglas R. Johnson, *Anti-Biotech Battle Taking Toll on Maine, at* http://www.bangornews.com/cgi-bin/article.cfm?storynumber=20372 (Sept. 6, 2000); *see also* Douglas T. Nelson, *Case Against Biotech Food Has to Do With Commercialism, Not Safety*, KNIGHT RIDDER/TRIB., Sept. 22, 2000, *available at* LEXIS, News Group File, All. Notice that the Organic Consumers Association is one of the organizations heading the opposition to GM foods. *See* Kreiger, *supra* note 2, *at* 1999 WL 28717179. If such a theory is correct, it may be time to review the history of activity that surrounded the introduction of margarine in a butter market. For an interesting discussion of this issue, see Geoffrey P. Miller, *Public Choice at the Dawn of the Special Interest State: The Story of Butter and Margarine*, 77 CAL. L. REV. 83 (1989).

voluntary labeling guidelines as opposed to mandatory regulations.[222] These guidelines will ensure the protection of food suppliers from unnecessarily bearing the costs of informing an uneducated public about GM foods.[223]

Granted, many product suppliers will choose to provide labeling information to consumers if the desire to be informed on the part of consumers is real. Recognizing this reality, the FDA is currently drafting a set of voluntary guidelines to ensure that the public is not misled by such communications.[224] These voluntary guidelines more appropriately account for the balance in rights of the two opposing parties in the GM food-labeling debate.

D. Organic Food—Consumers Have a Non-GM Food Choice

One of the leading opponents of GM food claims that "[c]onsumers want real food and the right to know and to choose."[225] Greenpeace explains that unpredictable effects, inadequate safety testing, and the precautionary principle demand that consumers be provided the ability to choose to avoid GM products.[226] As of December 2000,[227] consumers will soon be able to reliably choose to avoid GM foods by deciding to buy only "organic" products. Because the National Organic Program's (NOP) new organic guidelines ban the use of genetic engineering in food processing, consumers will have the ability to avoid GM food products.[228]

A decision to buy organic, however, will come at a hefty price since

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222. *See supra* text accompanying notes 6, 105.

223. Although mandatory labeling expenses are avoided, the FDA's proposed consultation process will cost food suppliers more than twenty thousand dollars to introduce a new GM food product that is now required to undergo the consultation process. *See* Premarket Notice Concerning Bioengineered Foods, 66 Fed. Reg. 4706, 4729 (proposed Jan. 18 2001) (to be codified at 21 C.F.R. pts. 192 & 592).

224. *See* Press Release, Food and Drug Administration, FDA to Strengthen Pre-Market Review of Bioengineered Foods, *at* http://www.fda.gov/bbs/topics/NEWS/NEW00726.html (May 3, 2000).

225. *We Want Natural Food!*, *at* http://www.greenpeace.org/~geneng/structur/food.htm (last visited Jan. 11, 2001).

226. *See, e.g., Genetic Engineering*, *at* http://www.greenpeace.org (last visited Feb. 12, 2001).

227. On December 20, 2000, the USDA announced the release of new standards for organic products. *See Secretary Glickman's Remarks at NOP Press Conference Dec. 20, 2000*, *at* http://www.ams.usda.gov/nop/glickremarks.htm. The standards define "organic" under a marketing program called the National Organic Program (NOP) developed by the USDA pursuant to the Organic Food Production Act of 1990. *See National Organic Program Overview*, *at* http://www/ams.usda.gov/nop/facts/overview.htm (Dec. 2000); *Background and History*, *at* http://www.ams.usda.gov/nop/nop2000/nop/background_and_history2.htm (last visited Feb. 12, 2001); *Labeling and Marketing Information*, *at* http://www.ams.usda.gov/nop/facts/labeling.htm (Dec. 2000).

228. *See National Organic Program Overview*, *at* http://www/ams.usda.gov/nop/facts/overview.htm (Dec. 2000).

organic foods generally cost over fifty-seven percent more than traditional food products.[229] It is important to note that paying the higher price does not guarantee that organic foods will not one day give rise to some unpredictable effect; like all food products, no organic food has ever proven to be one hundred percent free of safety or environmental hazard.[230] In fact, when the NOP was announced, Agriculture Secretary Dan Glickman clarified the reality of organic foods by saying, "[t]he organic label is a marketing tool. It is not a statement about food safety. Nor is 'organic' a value judgment about nutrition or quality."[231]

Although the same problems with sorting GM from non-GM products in the food production process exist[232] (as exemplified by the recent Taco Bell taco shell scare),[233] the costs will be borne by the parties that desire to discriminate between foods that were produced using GM and those that were not. By placing the costs of the right to know on the people that truly desire to use such information, (as society has deemed

229. Steven Milloy, *Organic Food Seasoned With Fear*, WASH. TIMES, Jan. 2, 2001, at A13, 2001 WL 4143536. Higher organic food costs could lead to $4000 a year in additional food expenses for a four-member family. *Id.* Because the organic product distinction has never been shown to demonstrate an increase in nutrition, quality, or food product safety, the organic food has been called a "[r]ipoff." *Id.*; *see also* Mary Brophy Marcus, *Organic Foods Offer Peace of Mind—At a Price*, U.S. NEWS.COM, *at* http://www.usnews.com/usnews/issue/010115/nycu/organic.htm (Jan. 15, 2001).

230. The public has seen first hand the uncertainty that surrounds various food products. For example, one day reports say that drinking red wine is recommended and another day new reports claim that those recommendations have been reconsidered and may not be accurate. For up-to-date nutritional information and an example of the confusion that exists with even the most basic foods, see the following nutritional Web sites: http://www.nutrition.gov or http://www.nutrinews.com/public/healthconcerns/index.cfm (last visited Jan. 11, 2001).

231. Milloy, *supra* note 229, at A13; *see also Secretary Glickman's Remarks at NOP Press Conference*, *at* http://www.ams.usda.gov/nop/glickremarks.htm (Dec. 20, 2000).

232. While already being considered, a new regulatory hurdle will arise in how to manage GM pollution—the possibility that a GM plant will contaminate a non-GM neighboring crop or create disease resistant pests that cannot later be controlled. *See generally* Richard A. Repp, Comment, *Biotech Pollution: Assessing Liability for Genetically Modified Crop Production and Genetic Drift*, 36 IDAHO L. REV. 585 (2000). While environmental issues indeed surround the use of GM foods—in the exact same way that such issues arise with the use of traditional food production methods that have been used to introduce new plant varieties to ecosystems for hundreds of years—labeling the final food product for consumer shelves is not a good solution to the problem because environmental damage would already have been done at that point.

233. Certain Taco Shells were recalled due to an unintended mixture of nonapproved GM corn with approved GM corn in late 2000. *See* Kate Devine, *GM Food Debate Gets Spicy: Recalled Taco Shells with Engineered Corn Fuel Controversy*, SCIENTIST, Oct. 30, 2000, at 10.

appropriate for organic and Kosher foods for some time), the majority of the food supply (since the majority contain some sort of genetic enhancement) will not be threatened with the higher costs that would arise if all nonorganic foods had to be labeled GM. In other words, it is more cost effective to label the minority of products GM-free or organic (according to FDA and USDA guidelines) than to label the majority GM. Organic foods thus offer the choice to consumers that opponents claim the consumer right to know and choose demands, again validating that a broad mandatory label is not necessary nor warranted.

V. INDIVIDUAL STATES MUST CONSIDER ALTERNATIVE LEGISLATIVE ACTIVITY TO MONITOR GM FOODS

Several states, including California, Colorado, Michigan, Minnesota, Pennsylvania, and Vermont are currently—or have recently—considered proposed legislation that would mandate labeling for GM foods.[234] However, even advocates for mandatory labeling do not believe that these labeling initiatives should be handled on the state level due to the potential negative impacts on free trade in the United States.[235] Accordingly, mandatory labeling legislation has already started to fail on the state level.[236] As the appropriate balancing tests are conducted with regard to GM foods, opponents of GM foods will be forced to consider alternative forms of regulation.

California, New York, Nebraska, West Virginia and Iowa are already considering alternative legislation that would limit the sales or production of GM foods.[237] As mandatory labeling legislative bills fall, additional states are likely to face bills like these to handle GM concerns. When evaluating such alternatives, states should carefully review proposed legislation to make sure they base decisions not solely on consumer fears and political lobbying efforts but upon valid scientific necessities. States must consider, in addition to a balancing of individual rights, the issues of federal preemption and potential interference on interstate commerce as they consider supplemental legislative actions.

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234. *See supra* text accompanying note 13.

235. "[A] national standard for labeling genetically engineered foods established by the FDA would be preferable to action at the state level." Michael A. Whittaker, Comment, *Reevaluating the Food and Drug Administration's Stand on Labeling Genetically Engineered Foods*, 35 SAN DIEGO L. REV. 1215, 1228 (1998).

236. The California Senate Bill 1513 that would have mandated labeling of GM products failed passage on August 9, 2000. S.B. 1513, 1999–2000 Reg. Sess. (Cal. 2000). Similar bills in Minnesota, Maine, New Hampshire and Vermont have also recently failed. *See* H. 506, 119th Leg., 1st. Reg. Sess. (Me. 1999); H. 3973, 81st. Reg. Sess. (Minn. 2000); H.B. 1204, 156th Sess. (N.H. 2000); H.B. 794, 1999–2000 Sess. (Vt. 2000).

237. *See supra* text accompanying note 14.

A. Balance Should Be Upheld on the State Level—Voluntary, Not Mandatory Labeling is the Solution

While most states have already rightly rejected mandatory labeling efforts in the face of the recent FDA decision,[238] states may again have similar legislation to consider in the future. Hence, the reasoning behind the rejection of such proposals becomes important. Some states may choose to ignore FDA decisions and continue to review mandatory labeling guidelines.[239] However, in so choosing, states run the risk of developing unconstitutional legislation, as Vermont was found to have done in *International Dairy Foods Association v. Amestoy*.[240] States also run the risk of federal preemption or of placing an undue burden on interstate commerce if they establish strict voluntary labeling guidelines which, for example, unnecessarily discriminate between products from other states.[241] To avoid challenge on the grounds of freedom of speech, federal preemption, or Commerce Clause violations, states will thus be forced to review the appropriate balance of rights between the consumer and the food supplier to validate any alternate regulation of GM products.

1. The International Dairy Foods Association v. Amestoy[242] *Risk—First Amendment Rights of Food Suppliers*

Although the FDA approved rbST milk for sale and refused to mandate labeling of this type of milk product, the State of Vermont enacted a statute requiring the labeling of rbST milk "to help consumers make informed shopping decisions."[243] However, because the milk supplier's right to be free from compelled speech was not "given the

238. *See supra* text accompanying note 236.
239. This was the case in Vermont when dealing with the rbST labeling issue. *See* Int'l Dairy Foods Ass'n v. Amestoy, 92 F.3d 67, 69 (2d Cir. 1996); *see also* Burk, *supra* note 146, at 247.
240. 92 F.3d at 74.
241. *See* discussion *infra* Part V.A.4.
242. A mandatory labeling law in Vermont was found unconstitutional under the First Amendment because its only purpose was to protect the consumers desire to know. *Int'l Dairy Foods Ass'n*, 92 F.3d at 73–74. The mere "wish to know" was found insufficient to justify infringement of the food producers' First Amendment freedom from compelled communication. *Id.* at 74.
243. *Id.* at 70.

proper weight,"[244] the U.S. Court of Appeals, Second Circuit, determined that the dairy manufacturers were entitled to an injunction.[245] The statute, the court held, infringed on the milk supplier's First Amendment rights.[246] Like GM foods in general, no proof existed that rbST milk posed any additional risk of harm to consumers when compared to regular milk.[247] It is this lack of harm that led the court to find the right to know of the consumer "insufficient to permit the State of Vermont to compel the dairy manufacturers to speak against their will."[248] The court noted that interested consumers "should exercise the power of their purses by buying products from manufacturers who voluntarily reveal it."[249]

The importance of *International Dairy Foods* to states reviewing legislative regulation of GM food products is clear. Simply, states must consider and weigh the rights of the consumer against the rights of the food supplier when considering which action to take.[250] To lawfully infringe upon the right to be free from compelled speech, the states must first identify a valid state interest that deserves protection.[251] The consumer's mere "desire" to know is not enough to overcome the right of the food producer to choose when to speak.[252] Protection of this First Amendment right is important because, if ignored, there would be "no end to the information that states could require manufacturers to disclose."[253]

At this time, no real safety risk exists with regard to GM technologies in food processing and manufacture.[254] Without evidence to the contrary, and in light of the FDA's finding that GM foods are inherently safe, states will not likely be able to identify a valid state interest to protect. Consequently, mandatory labeling appears to be out of the question on the state level, at least for GM products in general.

Unlike mandatory labeling, a state does have a valid interest to protect

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244. *Id.* at 71.
245. *Id.* at 74.
246. *See id.*
247. For a detailed discussion about the FDA's safety findings for rbST milk and how its decision not to label such products should be reviewed, see Burk, *supra* note 146, at 254.
248. *Int'l Dairy Foods Ass'n*, 92 F.3d at 74.
249. *Id.*
250. *See* discussion *supra* Part IV.B.1. States are likely to see guidelines posed by the FDA concerning voluntary labeling of GM foods which are similar to those provided by the FDA concerning the rbST label. *See* Interim Guidance on the Voluntary Labeling of Milk and Milk Products from Cows that Have Not Been Treated with Recombinant Bovine Somatotropin, 59 Fed. Reg. 6279 (Feb. 10, 1994).
251. *See* discussion, *supra* Part IV.B.1 (discussing the *Central Hudson* test).
252. *Int'l Dairy Foods Ass'n*, 92 F.3d at 74.
253. *Id.*
254. *See supra* text accompanying note 1.

when reviewing GM information that is voluntarily placed on labels.[255] States have an interest in protecting their consumers from misleading or false communications.[256] States can thus exercise the right to review voluntary communications aimed at consumers by developing reasonable guidelines by which to monitor those communications.

2. *Other Lessons from rbST—Appropriate State Action for Dealing with Voluntary Labeling Initiatives*

After finding that rbST milk products were as safe as other milk products and therefore that no mandatory labeling scheme was appropriate for rbST milk products, the FDA provided recommendations to the states on how to best pursue voluntary labeling initiatives on the local level.[257] In handling the rbST debate, the FDA noted that it would "rely primarily on the enforcement activities of the interested States to ensure that rbST labeling claims are truthful and not misleading."[258] Because all milk products contain natural bST, a simple "bST-free"[259] label could imply a difference between milk products and was therefore found to have the potential to mislead consumers without more information.[260] Thus, the FDA determined that to provide accurate labels to consumers, additional information would be required to put the statement "in a proper context"[261] and assure that labels are properly understood.[262] The FDA recommended that states consider the "complete label"[263] and any "[a]vailable data on

255. As the FFDCA mandates, the FDA has a valid interest to protect citizens from false and misleading labeling. *See* 21 U.S.C. § 343 (1994). This interest can be protected most efficiently under the police powers of each state. *See* Burk, *supra* note 146, at 249.

256. *See* 21 U.S.C. § 343.

257. *See* Interim Guidance on the Voluntary Labeling of Milk and Milk Products from Cows that Have Not Been Treated with Recombinant Bovine Somatotropin, 59 Fed. Reg. 6279 (Feb. 10, 1994).

258. *Id.* at 6280. When reviewing food products shipped in interstate commerce, FFDCA section 403(a), requiring labeling to be truthful and not misleading, requires the FDA to review labeling statements on the federal level. *Id.*

259. *Id.*

260. *Id.*

261. *Id.*

262. The FDA suggested, for example, that states require, in addition to a label claiming that the milk was "from cows not treated with rbST," that it also say that "[no] significant difference has been shown between milk derived from rbST-treated and non-rbST-treated cows." *Id.* Listing the commercial purpose for not using rbST was also a recommended way to provide proper context to the label and give it meaning to the consumer. *Id.*

263. *Id.*

consumers' perceptions of the label"[264] when considering appropriate labeling guidelines.

Due to the similarities between the FDA's findings regarding GM foods and rbST milk products, the states are likely to see similar guidelines for dealing with voluntary GM food labeling.[265] States, then, that wish to protect the consumer's right to know about GM foods should consider appropriate voluntary labeling guidelines. The more challenging portion of developing such guidelines pertaining to GM foods lies with the FDA suggestion that states also consider how to establish the validity of labeling claims as part of voluntary labeling initiatives.[266]

Like GM foods in general, when compared to each GM food's traditional counterpart, no identifiable "compositional differences" exist between rbST derived milk and non-rbST derived milk.[267] Therefore, to ensure that labeling is truthful and that "bst-free" claims are accurate, the FDA recommended that states establish record-keeping guidelines for food suppliers and develop inspection procedures under the state's police power.[268] The FDA also suggested that states adopt a certification program to track the use of rbST and to segregate rbST milk from non-rbST milk.[269]

In the face of concerns over the ability to distinguish GM products from non-GM products and the reality that some food suppliers may choose to market their products as non-GM, states should begin addressing GM foods by developing methods to ensure that voluntary labeling communications contain accurate information. Therefore, states could begin by establishing task forces to research consumer perceptions of the "GM" label and how best to provide a truthful and nonmisleading label to consumers that wish to know about GM use in food products. In so doing, as lessons from the rbST guidelines show, states will also have to focus on establishing methods to validate the accuracy of voluntary

264. *Id.*

265. The FDA is still "soliciting comments" on its voluntary labeling "guidance document" for GM food products. Draft Guidance for Industry: Voluntary Labeling Indicating Whether Foods Have or Have Not Been Developed Using Bioengineering; Availability, 66 Fed. Reg. 4839, 4840 (Jan. 18, 2001).

266. *See* 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. at 6280.

267. *Id.*

268. "States could require that firms that use such claims establish a plan and maintain records to substantiate the claims, and make those records available for inspection by regulatory officials." *Id.*

269. *Id.* The FDA claimed that its suggestions "would be necessary not because of any safety concerns about milk from treated cows but to ensure that the labeling of the milk is not false or misleading." *Id.*

labels. These methods may include: (1) defining inspection guidelines for regulatory officials, (2) mandating record-keeping procedures for food suppliers, and (3) establishing certification programs for particular GM food products.

3. Federal Preemption

Although the FFDCA generally does not contain express preemption guidelines,[270] the risk that state legislation will be deemed preempted by the FFDCA is real.[271] Federal preemption is mandated when "Congress intended to occupy" the particular field of legislation, or when state legislation "actually conflict[s]" with federal legislation.[272] In *Grocery Manufacturers of America, Inc v. Gerace,*[273] for example, a New York statute that required the labeling of a particular cheese as an "imitation" was held preempted by the FFDCA.[274] The court determined that complying with the New York statute actually resulted in creating a "misbranded" product, which was a violation of the FFDCA and therefore in actual conflict with the FFDCA.[275]

States must therefore carefully consider any regulation in light of the federal regulations contained in the FFDCA to avoid the possibility that state legislative acts will later be preempted by federal law. This risk definitely exists with any sort of mandatory "GM" labeling policy. An actual conflict would exist between the states' mandate and the FFDCA, which specifically rejects such a regulation. Voluntary labeling guidelines, again, are an acceptable solution, but must not result in misleading or false communications under the FFDCA.[276] Defining appropriate voluntary labeling guidelines will therefore require careful consideration by individual states that choose to enact labeling regulations in addition to those prescribed by the FDA. GM food concerns do not warrant emergency legislation or legislation designed in

270. 21 U.S.C. §§ 301–95 (1994). But an express preemption clause was recently added to the FFDCA under the Nutritional Labeling and Education Act of 1990 to apply to nutritional labeling regulations. *See* 21 U.S.C. § 343-1 (1994). For a more detailed discussion of preemption and the FFDCA, see Burk, *supra* note 146, at 249–75.

271. *See* Grocery Mfrs. of Am., Inc. v. Gerace, 755 F.2d 993 (2d Cir. 1985); Comm. for Accurate Labeling & Mktg. v. Brownback, 665 F. Supp. 880 (D. Kan. 1987).

272. *Grocery Mfrs. of Am.*, 755 F.2d at 999.

273. 755 F.2d 993 (2d Cir. 1985).

274. *Id.* at 1003.

275. *Id.* at 1001.

276. 21 U.S.C. § 343 (1994).

haste. Rather, states must take the time to account for scientific realities and the guidelines established by the FDA when considering which steps to take.

4. Interstate Commerce

State laws concerning GM products must be carefully designed so as not to unnecessarily interefere with interstate commerce. The protection afforded by the Commerce Clause requires that "'one state in its dealings with another [does] not place itself in a position of economic isolation.'"[277] Thus, the protection of the Commerce Clause limits "preferential trade."[278] Where a valid interest in protecting local health exists, however, states may be justified in regulating products sold within their borders as long as the method adopted is reasonable.[279]

Regulations that place restrictions on the sale of GM products in individual states pose the risk of placing an unnecessary burden on interstate commerce. This risk is especially apparent with voluntary state labeling guidelines that may vary from state to state. Multistate variations, like those that would arise if each state developed differing labeling guidelines, stand to make it more difficult for product suppliers to sell products in some states as compared to others.[280] If regulations result in creating "preferential trade areas"[281] then, such state regulations may violate the Commerce Clause and the rights of suppliers to be free to trade in all states. This concern has led some to find that it would be preferable for all states to adhere to one set of guidelines provided by the FDA as opposed to encouraging states to establish individual sets of rules.[282]

States do have the power to protect the interests of their citizens by expanding on legislation provided at the federal level so long as no actual conflict arises.[283] With regard to GM food labeling, the real issue again will become whether the states have a real interest to protect

277. *See* Dean Milk Co. v. City of Madison, 340 U.S. 349, 356 (1951) (quoting Baldwin v. Seelig, Inc., 294 U.S. 511, 527 (1935)).

278. *Id.*

279. *See id.* at 354. The Dean Milk court found that "if reasonable nondiscriminatory alternatives, adequate to conserve legitimate local interests" exist, than such alternative forms of regulation must be used. *Id.*

280. *See supra* text accompanying note 18.

281. *Dean Milk Co.*, 340 U.S. at 356.

282. *See* Whittaker, *supra* note 235, at 1228; *see also* Burk, *supra* note 146, at 273–74. "Th[e] national interests in facilitating interstate commerce and in providing the highest quality goods at the lowest prices would seem to dictate the desirability of uniform labeling on a national scale . . . Th[is] argument is strongest where the state scheme interferes with an FDA requirement." *Id.* at 274.

283. *See* Grocery Mfrs. of Am., Inc. v. Gerace, 755 F.2d 993, 999 (2d Cir. 1985).

considering the lack of scientifically based evidence that such products differ from the foods currently on consumer shelves.[284] Regulations that affect interstate commerce and place any discriminatory burden on such commerce must be validated by an identifiable state interest. The most commonly recognized state interest is the protection of consumer health.

A city ordinance was struck down in *Dean Milk Co. v. City of Madison*,[285] for instance, when the court ruled that the "regulation [was] not essential for the protection of local health interests."[286] The ordinance established specific guidelines for the type of milk that could be sold in the locality[287] thereby restricting the level of competition from outside the state. The court held that the ordinance "erect[ed] an economic barrier protecting a major local industry against competition"[288] and that the regulation could not stand because it created an "undue burden on interstate commerce."[289]

When considering state-level regulation of GM foods, care must be taken to ensure that interstate commerce is not unnecessarily affected by the legislative act. A valid state interest must first exist prior to the development of legislation. Secondly, state action should attempt to be consistent with regulations adopted by other states so as not to create an "economic barrier" to those food suppliers that may not be able to comply with strict regulations that differ from state to state.[290] By using sound scientific analysis in determining what action to take, states are likely to employ consistent regulations that do not inhibit interstate trade.

State mandatory GM labeling initiatives would likely fall in the face of a Commerce Clause challenge simply because no valid state interest in consumer health currently exists. However, if product suppliers choose to include GM information on labels, the issues that surround

284. *See supra* text accompanying note 1.
285. *Dean Milk Co.*, 340 U.S. at 356.
286. *Id.*
287. *Id.* at 350.
288. *Id.* at 354.
289. *Id.* at 353.
290. "Complying with a multitude of state labeling requirements in order to ship goods throughout the country would be at best burdensome and at worst physically impossible." Burk, *supra* note 146, at 273–74. Increased costs due to conflicting requirements could cause producers to "simply cease to sell in that jurisdiction." *Id.* This is a problem that states should seek to avoid in order to ensure that consumers have access to a variety of products and the ability to exercise their right to choose between products.

state regulatory power are different.[291] With an identifiable state interest—protecting consumers from misleading food labels—states may, using reasonable means, monitor voluntary commercial communications without being subject to a charge of violating the Commerce Clause.[292] This is because a state interest in protecting citizens from misleading advertising and labeling probably outweighs any potential burden it places on interstate commerce, provided that the state considers the burden it places on food suppliers when selecting a method to monitor such communications.[293]

The possibility of First Amendment, Commerce Clause, and federal preemption challenges will require states to account for the rights of the food suppliers when devising means to protect the consumer's right to know about GM foods. When balancing the consumer's right to know with the rights of the food supplier, states will be forced to consider solutions other than mandatory labeling, like the FDA has rightfully done, to address the GM labeling debate on a local level.

VI. RECOMMENDATIONS FOR A SMOOTH TRANSITION FROM CONSUMER FEAR TO CONSUMER SATISFACTION WITH GM FOODS

Taking into account the recent FDA decision, a solution to the GM food debate must address the concerns of the public without relying on mandatory labeling. Dealing with consumer fears is in the best interest of all parties including, in addition to the individual consumer, environmentalists, biotechnology companies, and food suppliers. Consumer fears have thus far only put a hold on technological advancement that is harmful on all fronts. The Biotechnology Industry Organization[294] has instituted a national educational effort to calm those fears, which is a good first step towards making progress on this sensitive issue without requiring the drastic step of mandatory labeling. The following discussion suggests goals with which to focus efforts to deal with GM foods that may be appropriate for review on the state level. Compromise based solutions designed to provide consumers with relevant knowledge and to protect the food supplier from unreasonable increased costs of doing business through unnecessary labeling initiatives are also suggested.

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291. *See* discussion *supra* Part V.A.2.
292. *See Dean Milk Co.*, 340 U.S. at 354.
293. *See supra* text accompanying note 213.
294. Several biotechnology companies recently joined forces to establish a marketing campaign in support of bioengineered foods designed to focus on positive advertising and consumer education. *See* Albright, *supra* note 57, at C2.

A. Goals

Following is a nonexclusive list of goals that states should apply when reviewing new initiatives that serve to complement the FDA's recent GM food policy announcement. Alternative actions, designed to offer greater protection to the consumer's limited right to know, should focus on:

(1) Reasonable GM food product safety testing, not mandatory labeling;
(2) Expanded GM food consumer education programs;
(3) Global and interstate harmony based on scientifically sound GM food regulations; and
(4) Managing and maintaining reasonable food costs and supply.

With these objectives in mind, states should focus on generating a nonlabeling method to provide general information about GM food products to respect the consumer's limited right to know. In addition, states should closely review the voluntary labeling guidelines established by the FDA and adopt consistent requirements to protect their citizens from misleading food labels. Finally, states should utilize their resources to develop specific, yet reasonable, testing guidelines for GM food products to ensure the safety of the products produced within their borders.[295]

B. Possible Solutions

No two GM food products are alike. Just like a carrot is not a banana, and a GM tomato is not a GM squash, one broad label is not the answer to calming consumer fears or protecting consumers from any risk that may exist according to opponents of GM foods in general. Each GM product deserves its own review, and corresponding state regulations should be designed to offer flexibility in dealing with a variety of product types. Accordingly, states should focus legislative efforts only on those particular GM products suitable for regulation.

Understandably, states will want to explore different options in light of the public fire that has been raging against GM foods over the last several years. When considering alternative actions, which must be

295. It is ultimately the food producer's responsibility to ensure product safety and to engage in a consultation process with the FDA prior to offering its products for sale in the United States. *See* Statement of Policy: Foods Derived from New Plant Varieties, 57 Fed. Reg. 22,984, 22,985 (May 29, 1992).

consistent with the FDA's expressed position, the states should take special care to consider the four goals described above. Regulations must not be designed to impede scientific progress for fear of the unexpected, but should be focused on scientifically valid purposes and rationales.

Of course, where any valid safety risk is identified in a GM product, more options for state regulation exist. States could rightfully remove such products from consumer shelves or utilize a risk-benefit analysis, like that employed by the EPA when evaluating pesticide use in food production,[296] to determine if the product should merely be labeled for consumer awareness and personal risk analysis. Under the current findings of the FDA, however, GM foods in general do not pose any risk of harm to consumers.[297] Thus, actions in response to GM products already deemed safe should take into account and recognize this scientific finding.[298]

1. Consumer Education and Educational Campaigns

Labeling is not the only way to provide information to a consumer about the food he eats.[299] Especially in the age of information, consumers expect to gain access to information through a variety of mediums. States could focus efforts to appease the consumer's desire to know about GM foods by establishing educational advertising programs using the media, Web sites, toll-free numbers, informational campaign programs in grocery stores, or by providing incentives for food suppliers and manufacturers to voluntarily provide such information to consumers.

Developing an educational campaign for GM foods is not likely to be a simple task due to the uncertainty that exists, even among the scientific community, regarding how to distinguish one GM product from another.[300] States should focus first on establishing and defining what a

296. When evaluating pesticide use in food products and corresponding labeling guidelines, the EPA applies a balancing test much like that posed in this Comment to validate the FDA's decision to adopt voluntary labeling guidelines as opposed to mandatory guidelines. *See* 7 U.S.C. § 136 (1994). For a general discussion of the regulation of pesticide residue labeling, see James Smart, *All the Stars in the Heavens Were in the Right Places: The Passage of the Food Quality Protection Act of 1996*, 17 STAN. ENVTL. L.J. 273, 277–79 (1998).

297. *See supra* text accompanying note 1.

298. *See* discussion *supra* Part V (establishing that states run several risks when adopting scientifically unsound legislation).

299. For a general discussion about effective "hazard communication system[s]," see Viscusi & Zeckhauser, *supra* note 147, at 109.

300. *See supra* text accompanying note 18. The FDA is still not certain how to correctly distinguish between GM and non-GM food products in a truthful and nonmisleading manner. *See* Draft Guidance for Industry; Voluntary Labeling Indicating Whether Foods Have or Have Not Been Developed Using Bioengineering; Availability,

GM food is and consider how it differs from other foods. The audience must then be defined in order to develop an effective educational campaign.[301] Some consumers, for instance, are more sophisticated than others.[302] Care must be taken to deliver a message that is understandable and one that does not create excessive alarm among consumers.[303] Granted, developing such an informational campaign will involve more work than simply mandating a general overbroad label. However, in light of the realities of GM food, nonlabeling methods of communication are a better approach if the consumer's desire to know about GM foods is to be sufficiently addressed.

States could avoid individual state campaigns by focusing on a one-stop information source, like the FDA, for information on GM foods. Under the FFDCA, the FDA is already required to provide information to consumers[304] and currently makes available all safety testing information for the GM products it has reviewed.[305] The Biotechnology Industry Organization has already launched a national educational campaign about the merits of GM technologies[306] on behalf of the scientific community, which may further relieve states of the obligation to do so.

While it is important to inform the consumer about the scientific realities of GM technologies in food production, it is also important to address the moral-emotional "outrage" that has separated the opponents of GM from the scientific proponents of GM.[307] Instead of focusing only

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66 Fed. Reg. 4839, 4840 (Jan. 18, 2001).

301. *See* Viscusi & Zeckhauser, *supra* note 147, at 109.

302. *Id.*

303. "Overwarning introduces dangers. If we exaggerate modest risks, we will have no credible mechanism for alerting people to greater hazards." *Id.* at 109–10.

304. The FDA is required to "conduct[ ] educational and public information programs relating to the responsibilities of" the FDA. 21 U.S.C. § 393 (d)(2)(D) (1994).

305. In its May 2000 announcement, the FDA has agreed to provide all necessary information to consumers concerning GM foods on its Web site. *See* Press Release, Food and Drug Administration, FDA to Strengthen Pre-Market Review of Bioengineered Foods, *at* http://www.fda.gov/bbs/topics/NEWS/NEW00726.html (May 3, 2000). Public disclosure is clearly a priority under the FDA's new policy. *See* Premarket Notice Concerning Bioengineered Foods, 66 Fed. Reg. 4706, 4714 (proposed Jan. 18, 2001) (to be codified at 21 C.F.R. pts. 192 & 592). "In light of the significant public interest in bioengineered foods," the FDA plans to disclose the fact that a food developer is engaged in the consultation process as well as the data and information provided unless the manufacturer establishes that such information is confidential in nature. *Id.*

306. *See supra* text accompanying note 294.

307. Peter M. Sandman, *Two-Way Environmental Education*, *at* http://www.psandman.com/articles/informing.htm (last modified Apr. 2000). Environmental risk has been classified into two groups, 1) "hazard," or the technical facts and data portion of a

on consumer education concerning the scientific background of GM technologies, it has been suggested that a proper risk communication program will also include serious consideration and debate about the social and moral issues that are more likely to be the source of consumer fear.[308] Six tips have been identified for developing a communication campaign about controversial risks: [1] Don't keep secrets . . . , [2] Listen to people's concerns . . . , [3] Share power (give communities more control over the risks) . . . , [4] Don't expect to be trusted. Instead of trust, aim at accountability . . . , [5] Acknowledge errors . . . , and [6] Treat adversaries with respect."[309]

The need for proper education programs that inform the consumer of the benefits of GM technologies in the food market cannot be underestimated. It has been suggested that the reason the public is alarmed about GM foods as compared to GM drug products created using the same genetic techniques yet filling consumer shelves with no indication of concern, is that the benefits of a drug are obvious whereas the benefits of GM in food production are not.[310] The benefits of GM technologies, for instance, are more easily recognized by farmers or animal breeders—those that see first hand the increased product yields GM may offer, those fighting to save their crops or animals from disease and pests, and those that see the effect of farming or grazing on the soil and water surrounding the farm land. Consumers, on the other hand, are likely to see the benefits of GM only as a decrease in cost, and this is not an obvious benefit. By adding a focus on the benefits of GM to an educational campaign, while also addressing the potential risks that exist, people may be more confident that both have been taken into

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debate and 2) "outrage" which focuses on the moral-emotional portion of a debate. *Id.* "The public is preoccupied far more with outrage than with hazard. The engine that propels the fight over safe-versus-dangerous, in other words, is good-versus-evil." *Id.* Thus, taking into account the key issues of outrage—who benefits from a new technology, who controls the use of such a technology, whether those in charge are trustworthy, whether the public had a choice or a voice in adopting the new technology, and finally whether those in charge respond effectively and with respect to the concerns raised—is a good way to begin evaluating a potential GM food informational campaign. *Id.*; *see also* Peter M. Sandman, *Risk Communication: Facing Public Outrage*, *at* http://www.psandman.com/articles/facing.htm (last modified Apr. 2000).

308. Peter M. Sandman, *Risk Communication*, *at* http://www.psandman.com/articles/riskcomm.htm (last updated Apr. 2000).

309. *Id.*

310. *See* Peter A. Singer & Abdallah S. Daar, *Avoiding Frankendrugs*, 18 NATURE BIOTECHNOLOGY 1225 (2000). "[G]enetically engineered drugs, like recombinant human insulin, have been used without controversy, [and], for life-saving drugs at least, the public clearly perceives that their benefits far outweigh any risks." *Id.* It has been suggested that GM pharmaceutical companies should heed the lessons learned from the GM food debate; GM pharmaceutical manufacturers should therefore inform the public of the benefits of using new GM techniques and take consumer concerns seriously. *Id.*

account thereby reducing anxiety over GM foods in general.

2. *Voluntary Labeling Guidelines*

Like the FDA, individual states should focus their efforts on establishing reasonable voluntary labeling guidelines. Non-GM food suppliers are likely to attempt to promote their foods by labeling their products to instill unnecessary fear on the part of consumers against GM foods. Labeling of products as "non-GM" will require just as much review as the labeling of products as "GM" under voluntary guidelines to avoid misleading the public.[311] Challenges in the future are likely to center around making a distinction between GM and non-GM products and identifying the degree of information required for disclosure to avoid misrepresentations to the public.

States may always require more regulation at the state level than exists at the federal level so long as it does not conflict with federal regulation or inhibit interstate commerce.[312] States may therefore require more extensive testing or differing standards for review under the voluntary labeling guidelines as long as a substantial state interest is involved. Establishing voluntary labeling guidelines, research campaigns, or certification programs to track the whereabouts of GM foods may thus be the only appropriate form of legislative activity at the state level in light of the little to nonexistent health concern with current GM food products.

311. This is precisely the focus of current FDA efforts in creating appropriate voluntary labeling guidance to manufacturers. *See* Draft Guidance for Industry: Voluntary Labeling Indicating Whether Foods Have or Have Not Been Developed Using Bioengineering; Availability, 66 Fed. Reg. 4839, 4840 (Jan. 18, 2001). For a general discussion of similar issues in relation to rbST voluntary labeling, see Burk, *supra* note 146, at 268–75; *see also* discussion *supra* Part V.A.2. Defining "GM" foods is the problem: it will require a system not only to segregate GM from non-GM food products, but will require a precise definition of what GM is. For example, guidelines need to be established defining what level of genetic modification used in the final product will lead to the designation GM. Standards, like those established for organic foods, will have to be developed before GM or non-GM designations will be accurate and not misleading. For a review of standards established for organic food labeling, see sources cited *supra* note 197.

312. *See* discussion *supra* Part V.A.3–4.

3. Establish Testing and Research Programs—A Review of California Legislative Activity and Its Food Biotechnology Task Force Solution

Because the real concern over GM foods lies in a dissatisfaction with product safety testing and a fear of the unexpected, states can focus on calming consumer fears by establishing task forces or committees to study GM technologies and the foods they produce. The California legislature has just adopted legislation that creates a Food Biotechnology Task Force to handle GM concerns in a sound scientific manner.[313] The amendment to the California Food and Agricultural Code was designed with a recognition of the federal regulatory framework and the need to review this framework when establishing the role California should play in the regulation of GM food products.[314]

The bill lists several factors that the Task Force would be responsible for evaluating, demonstrating that the California legislature is taking into account federal preemption, the effects on interstate commerce, consumer safety, and potential voluntary labeling procedures. For instance, the Task Force is charged with considering the:

> (1) Definition and categorization of food biotechnology and production processes. (2) Scientific literature on the subject, and the characterization of information resources readily available to consumers. (3) Issues related to domestic and international marketing of biotechnology foods such as the handling, processing, manufacturing, distribution, labeling, and marketing of these products. (4) Potential benefits and impacts to human health, the state's economy, and the environment accruing from food biotechnology. (5) Existing federal and state evaluation and oversight procedures.[315]

Finally, the bill establishes a date, January 1, 2003, for the Task Force to report the information discovered to the governor and legislature.[316]

This bill appears to be a sound scientific solution to managing consumer fears, ensuring consumer safety, and respecting the findings of the FDA all at the same time. Not all California bills have been designed with the same focus however. Arguably, for that reason, they will not be

313. S.B. 2065, 2000 Reg. Sess. (Cal. 2000); S.B. 662, 2001-02 Reg. Sess. (Cal. 2001); *see* CAL. FOOD & AGRIC. CODE § 492 (Deering Supp. 2001). The legislative findings start by saying that "[c]onsumers have an interest in being informed about the benefits and potential quantifiable risks to their health from products they consume. This information must be grounded in sound science, must use informative and effective communications, and shall be consistent with other production technologies." S.B. 2065, 2000 Reg. Sess. § 1, art. 5, 491(a). The findings continue by recognizing the benefits posed by new technologies and the need to balance those benefits with potential risks. *Id.* § 1, art. 5, 491(b).

314. *Id.* § 1, art. 5, 491(c).

315. CAL. FOOD & AGRIC. CODE § 492(d).

316. *Id.* § 492(e).

accepted into law. Senate Bill 1514 for instance, which proposed to establish a task force to inform parents of the use of genetically engineered matter in food served in public schools, was vetoed by the governor of California in September 2000.[317] Senate Bill 1513, which would have mandated "GM" labeling solely to protect the consumers right to know, likewise failed passage.[318]

California recently adopted a rice certification program to better monitor the quality of rice and to identify various types of rice—a step toward being able to distinguish between GM food products and non-GM products.[319] The FDA suggested certification programs as a way to ensure that voluntary labeling of rbST milk products were accurate,[320] and is therefore another example of a good way to focus state legislative efforts.

VII. CONCLUSION

Modern genetic technologies offer great promise to increase the world's food supply, enhance the nutritional value and appeal of foods, reduce the number of toxins and pesticides in food products, and establish sustainable environmental conditions.[321] While GM foods offer significant advantages over traditional foods, the actual difference between GM products and non-GM products is slight.[322] After all, DNA exists in all plant and animal material that humans consume.[323] While DNA can have a drastic impact on the final product produced, its overall effect on humans is not significantly apparent when considering the

317. S.B. 1514, 2000 Reg. Sess. (Cal. 2000). The intent of the bill was to inform the public of issues relating to, among other things, the use of genetically engineered materials in food. *Id.*

318. S.B. 1513, 2000 Reg. Sess. (Cal. 2000).

319. CAL. FOOD & AGRIC. CODE §§ 55000–108 (Deering 1997 & Supp. 2001); Assemb. B. 2622, 2000 Reg. Sess. (Cal. 2000). The regulation derived from the "California Rice Certification Act of 2000." *Id.* The FDA offered the suggestion that certification programs be adopted when dealing with rbST milk, so it is likely that such a program would be consistent with guidelines from the FDA concerning GM food products. *See* Interim Guidance on the Voluntary Labeling of Milk and Milk Products from Cows that Have Not Been Treated with Recombinant Bovine Somatrotropin, 59 Fed. Reg. 6279, 6280 (Feb. 10, 1994).

320. Interim Guidance on the Voluntary Labeling of Milk and Milk Products from Cows that Have Not Been Treated with Recombinant Bovine Somatrotropin, 59 Fed. Reg. at 6280.

321. *See supra* text accompanying notes 20–21.

322. *See supra* text accompanying note 1.

323. *See generally* Phipps, *supra* note 31.

microscale level on which DNA lies and to which modern GM technologies function.

As with all new technologies and products, however, there is no way to test the ultimate effect or outcome of the use of GM technologies on society. This reality leads some to fear the advent of new technologies all together and thus has created the debate over GM foods that troubles the world at this time. The truth of the matter is that modern genetic technologies may hold the key to improving food safety and do not offer any more reason for fear than do traditional food products developed using less efficient GM techniques.

Upon so finding, the FDA has taken reasonable measures to address the GM food labeling debate. Based on the nonexistent risk of harm apparent at this time from GM foods, the FDA was not only warranted in rejecting mandatory labeling of such products, but arguably, was required to do so. Without a verifiable safety risk to consumers, and therefore an identifiable government interest, the FDA does not have the power to trump the right of food suppliers to be free from compelled communications. Instead, the FDA has chosen a policy of mandatory review of GM products and voluntary labeling guidelines to protect consumers from harm and from misleading advertising. This decision is consistent with FFDCA regulation, with the FDA's prior treatment of similar food products, and with legal precedent.

The decision to reject mandatory labeling for GM foods sheds new light on the extent of the consumer's right to know. As has been suggested in this Comment, the consumer's right to know is not absolute and should be reviewed using a balancing test that takes into account the competing rights of all parties involved. After review of the competing interests, the limits on the right to know can be identified and the findings of the FDA—that mandatory GM labeling is not appropriate—can be validated.

In the case of GM foods, the consumer's right to food safety is not at issue because there is no identifiable safety risk at this time.[324] The consumers right to make informed food choices is also not implicated because no nutritional or material difference between GM products and their non-GM counterparts has been found to exist. The consumer's right to

324. Furthermore, the FDA has undertaken more appropriate steps to monitor the safety of new GM products introduced to consumer shelves. *See* Premarket Notice Concerning Bioengineered Foods, 66 Fed. Reg. 4706 (proposed Jan. 18, 2001) (to be codified at 21 C.F.R. pts. 192 & 592); Draft Guidance for Industry: Voluntary Labeling Indicating Whether Foods Have or Have Not Been Developed Using Bioengineering; Availability, 66 Fed. Reg. 4839 (Jan. 18, 2001). Additional testing of GM products will surely offer greater protection to consumer safety then a costly mandatory labeling policy.

freedom of religion may be a valid concern, but the government may not apply religious principles in its regulations and therefore has limited authority to affirmatively protect a consumers religious food preferences without violating the First Amendment.

The consumer's right to know, in the case of GM foods, boils down to a "desire" to be informed about GM foods and nothing more. The mere desire to know has never been enough to mandate speech in the form of food product labeling.[325] Where no safety risk or other reasonably necessary choice between food products exists, there is no significant government interest to protect that can outweigh the rights of the food supplier. Thus, due to the lack of safety risk and the fact that most consumers are not sufficiently sophisticated at this time to understand what GM really means, the FDA did not have the power to mandate labeling under the FFDCA. The consumer's right to know is thus limited to those cases where the consumer's health is at risk or where an otherwise significant government interest exists that outweighs the rights of the party that would be required to provide the consumer with information. In the case of GM foods, the consumer's right to know does not outweigh the food producer's right to freedom of commercial speech and to trade between states. Thus, the consumer's right to know is not sufficient to require mandatory labeling of GM foods.

Although mandatory labeling is not appropriate for GM foods, voluntary labeling provides an alternate source of information for consumers. As the FDA cannot mandate speech without a valid governmental interest, likewise it cannot restrict speech without one.[326] Thus, the FDA cannot forbid labeling that addresses the GM issue. The FDA must, however, regulate voluntary communications to assure that consumers are not misinformed by the information pursuant to the FFDCA.[327] The FDA was therefore warranted in developing guidelines for voluntary labeling that address the issue of possible misbranding and false labeling.

As states consider alternative forms of regulation to address the consumer's limited right to know, states will have to perform a similar balancing test to develop regulations that will not be struck down under the guise of First Amendment, federal preemption, or Commerce Clause challenges. Labeling is not the only method to inform consumers of the

325. *See* discussion *supra* Parts IV.B.1, V.A.1.
326. Int'l Dairy Foods Ass'n v. Amestoy, 92 F.3d 67, 71–72 (2d Cir. 1996).
327. 21 U.S.C. § 343 (1994).

realities of GM foods. States should consider other methods of consumer education that are consistent with FDA guidelines and findings if desiring to further protect the right to know in their own localities.

In developing alternative forms of legislation, states should focus on four specific goals when reviewing proposed legislative activity with regard to GM foods: (1) adequate GM food product safety testing, (2) consumer education designed to manage unreasonable consumer fears, (3) encouraging global and interstate harmony by applying scientifically valid principles, and (4) maintaining reasonable food costs and supplies. When considering these objectives, states will likely foster a smooth transition from the exaggerated consumer fears that exist today to a consumer satisfaction with GM products. Consumer education programs, development of rational voluntary labeling guidelines, and methods to enforce such programs, in addition to further safety testing procedures, are likely to be the best places for states to begin solving the GM debate on a local level.

Globalized technological progress in food processing and supply demands a rational regulatory system, like that rightly established and enforced by the FDA. The reality is that GM foods should not be treated any differently from traditionally modified food products when it comes to labeling policies. Scientific studies and legal precedent, not creative lobbying and economically driven consumer-fear programs, should guide legislative bodies as they continue to address the issues that surround GM food products. The health and safety of a growing human population depend on it.

KELLY A. LEGGIO