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Right to Know: A Diet of the Future Presently Upon Us

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RIGHT TO KNOW: A DIET OF THE FUTURE PRESENTLY UPON US

I. INTRODUCTION

In 1994, the U.S. government approved the first genetically modified ("GM")[1] food product for marketing and sale.[2] In the last decade, the U.S. government has approved over fifty more GM food products.[3] In some parts of the world, particularly Europe, consumers have adamantly rejected GM products, even as the research and development of these foods has increased worldwide.[4] In the United States, GM foods have slipped into grocery stores virtually unnoticed by U.S. citizens, even though the United States is the largest producer of these foods.[5] The

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[1] Scientists are not in consensus about what term should be used to describe what is commonly called "genetically modified." For example, the Society of Toxicology ("SOT"), a non-profit organization made up of scientists from academic institutions, government, and industry, refuses to use "genetically modified" because it says that this term is "misleading, since conventional methods of microbial, crop, and animal improvement also produce genetic modifications . . . ." SOT *ad hoc* Working Group, *The Safety of Genetically Modified Foods Produced Through Biotechnology*, 71 TOXICOLOGICAL SCIS. 2, 2 (2003) [hereinafter SOT, *Safety of GM Foods*]. Instead, the SOT prefers to use the term "biotechnology-derived." *Id.* However, another source says that "biotechnology was coined in 1919 by Karl Ereky, to apply to the interaction of biology with human technology" and traditionally includes "beekeeping and cattle breeding." Kimball R. Nill, Technomic Publishing Co., *biotechterms.org, at* http://biotechterms.org/sourcebook/saveidretrieve.php3?id=239 (last visited Jan. 4, 2005). Therefore, this Note uses the more common "genetically modified" ("GM") and "genetically engineered," interchangeably. Specifically, the definition of "genetically modified organisms" used herein is as follows: "The modification of the genetic characteristics of a microorganism, plant or animal by inserting a modified gene or a gene from another variety or species." European Environment Agency, *EEA Multilingual Environmental Glossary*, *at* http://glossary.eea.eu.int/EEAGlossary/G/genetically_modified_organism (last visited Jan. 7, 2005). The second part of this definition, which this Note does not use because of its narrowing effect, is as follows: "Genetically modified organisms (GMOs) may be microorganisms designed for use as biopesticides or seeds that have been altered genetically to give a plant better disease resistance or growth." *Id.*

[2] U.S. Food and Drug Administration, *List of Completed Consultations on Bioengineered Foods*, *at* http://www.cfsan.fda.gov/~lrd/biocon.html#list (last updated Sept. 21, 2004) [hereinafter *FDA List*].

[3] *Id.*

[4] *See infra* notes 82-84 and accompanying text (regarding effective European consumer movements opposing GM foods); *see also Council for Biotechnology Information; Study Finds Biotech Crops are Being Grown in 18 Countries and Researched in 45*, BIOTECH WK., Jan. 5, 2005, at 212.

[5] *See infra* text accompanying notes 90-91 (regarding U.S. consumers' ignorance concerning GM foods); *infra* note 92 and accompanying text (regarding U.S. consumers' ignorance concerning GM foods); *infra* note 95 and accompanying text (regarding U.S. consumers' ignorance concerning regulation of GM foods); *see also Council for Biotechnology Information; Study Finds Biotech Crops Are Being Grown in 18 Countries and Researched in 45*, BIOTECH WK., Jan. 5, 2005, at 212 (stating that the United States is the leading producer of

United States has had limited exposure to GM foods issues and therefore, as it enters into this dialogue, it would be prudent for it to pay heed to the more formulated thoughts of Europe.[6] Understanding the discussion Europe has had on GM foods will help the United States more thoughtfully sort out its own issues as its citizens become more aware of GM foods, while simultaneously giving the United States insight on how to effectively legislate so as to promote its trade relationships with European countries.[7]

Although the current administration's approach toward GM foods is unquestioningly positive, as has been the case with past administrations, many U.S. consumers who are aware of GM foods oppose them.[8] U.S. consumers oppose GM foods because of societal and moral concerns, as well as health related concerns.[9] For example, consider a mother whose son is born prematurely, and as a result he has dealt with many health problems. The most frightening health problems are his severe allergies and sensitivity to food. Through a series of medical tests and a few inadvertent trials resulting in error that nearly cost the boy his life, the mother finally narrows down several foods that she knows are safe for her son. By eating only these foods he can live free from fear of death by allergic reaction. However, having extensively researched food and allergies, the mother discovers that food manufacturers are genetically modifying some foods. Although many sources have assured her that, so far, GM foods that are properly on the market have not had any known negative effects, the mother has also read that scientists are unsure how genetic modification will affect allergies because allergies are not yet well understood by science. She is now weary with fears that she may expose her son to GM foods she thinks are "safe" but end up being just different enough from the originals that they kill or seriously

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biotech crops selling $27.5 billion in 2003-2004 followed by Argentina selling $8.9 billion, China selling $3.9 billion, Canada selling $2 billion, and Brazil selling $1.6 billion).

6 *See infra* text accompanying note 7.

7 *See infra* notes 82-84 and accompanying text (regarding European opinion of GM foods); *infra* notes 69-73 and accompanying text (describing, for example, non scientific reasons many European citizens are opposed to GM foods); *infra* Part II.D.1 (describing the debate between the United States and European Union at the WTO); *infra* text accompanying notes 245-54 (describing how disclosure would improve trade with Europe).

8 *See infra* note 88 and accompanying text (describing American opposition to GM foods); *infra* note 187 (describing Monsanto's deep roots in Washington D.C. and the administration's consistent support of the biotech industry over the last several presidencies).

9 *See infra* text accompanying notes 41-80 (explaining the myriad of concerns people have with GM foods).

harm him. Currently, the mother has no practical way to guard her son from this risk because GM foods are not labeled.[10]

In response to consumer concerns, Congressmen Dennis Kucinich proposed a series of bills in the summer of 2003 that would impose greater regulation on GM foods.[11] One of the proposed regulations, the Genetically Engineered Right to Know Act ("GERKA"),[12] proposed an amendment to the Federal Food, Drug, and Cosmetic Act ("FFDCA")[13] requiring manufacturers to use labels to disclose food products that are GM.[14] While many U.S. consumers and legislators had supported this bill requiring disclosure before it expired at the end of 2004, the U.S. Administration is presently battling with the European Union at the World Trade Organization ("WTO") because of measures the European Union has taken against foods imported into Europe, including a requirement that GM foods be labeled.[15] The U.S. Administration insists that disclosure by labeling is unnecessary and a violation of free trade because there is no scientific data to support a conclusion that GM foods are harmful.[16]

There are several reasons why this response by the U.S. Administration is insufficient.[17] This Note addresses these reasons as it considers why and how the United States should require disclosure of GM foods. Part II of this Note provides background information on labeling GM foods.[18] Part III of this Note analyzes the statutory authority and constitutionality of requiring disclosure of GM foods, as well as an expired bill that would have required disclosure.[19] Part IV of

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10 This hypothetical, though completely plausible, is in fact fictional.

11 *See infra* note 88 (listing the proposed bills).

12 Genetically Engineered Right to Know Act, H.R. 2916, 108th Cong. (2003).

13 Federal Food, Drug, and Cosmetic Act, Pub. L. No. 108-68, 52 Stat. 1040 (codified as amended in scattered sections of 21 U.S.C.).

14 *See* Genetically Engineered Right to Know Act, H.R. 2916, 108th Cong. (2003); Part III.C (providing the text and an analysis of part of this bill).

15 *See infra* Part II.D.1 (discussing the dispute between the United States and Europe at the WTO).

16 *See infra* notes 166-79 and accompanying text (regarding the United States continuing to dispute with Europe even though the moratorium has been lifted).

17 *See infra* text accompanying notes 263-68 (describing philosophical and other non-scientific reasons that justify requiring disclosure of GM foods); *supra* Part I (describing a hypothetical case in which a mother and her allergy-laden son demonstrate that the lack of negative information does not necessarily justify a lack of disclosure when there is very little information at all); *infra* note 261 and accompanying text (describing how it is a logical fallacy to draw a conclusion based on a lack of information to the contrary).

18 *See infra* Part II.

19 *See infra* Part III.

this Note offers several changes to the expired bill.[20] Finally, Part V of this Note concludes that Congress should again raise the issue of disclosure of GM foods and should pass a modified version of the expired GM bill containing provisions that are consistent with the goals of disclosure and the information currently available on GM foods.[21]

II. BACKGROUND

Analyzing the legal concerns related to labeling GM foods requires consideration of a broad range of information.[22] Section A of this Part offers a basic explanation of GM foods, including both scientific and public understandings and opinions of these foods.[23] Next, Section B explains how the First Amendment impacts commercial labeling.[24] Section C outlines the reasons the government may require labeling and the rationale undergirding voluntary labeling.[25] Finally, Section D explains the two most significant legal issues dealing with GM foods: the dispute at the WTO over GM foods and the possibility of lawsuits resulting from voluntary labeling.[26]

A. GM Foods

Every living cell contains deoxyribonucleic acid ("DNA"), which functions as instructional information.[27] The DNA collectively comprises a genome, which is one complete copy of an organism's genetic material.[28] The organization of the DNA within the genome, referred to as the "genetic code," is primarily responsible for gene expression, which is largely determinative of the traits an organism will display.[29] Scientists are able to identify particular genes for particular traits in one genome, remove these genes, and transfer them into other genomes.[30] A gene that is transferred is called a "transgene."[31] The cell from which a

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20 *See infra* Part IV.
21 *See infra* Part V.
22 *See infra* Part II.
23 *See infra* Part II.A.
24 *See infra* Part II.B.
25 *See infra* Part II.C.
26 *See infra* Part II.D.
27 WAYNE M. BECKER ET AL., THE WORLD OF THE CELL 408 (3rd. ed. 1996).
28 *Id.* at 421.
29 *Id.* at 436. For a general discussion of plant genetics, see PETER H. RAVEN ET AL., BIOLOGY OF PLANTS 121-49 (5th ed. 1992).
30 Krista Weidner, *Science in Your Shopping Cart*, PENN STATE AGRIC., Fall 2002/Winter 2003, at 19.
31 Kimball R. Nill, Technomic Publishing Co., *biotechterms.org*, *at* http://biotechterms.org/sourcebook/saveidretrieve.php3?id=1906. "Transgene" is defined as follows: "A

transgene is removed is the "donor," and the cell into which a gene is transferred is the "host."[32] The consequences of this small move, which is "genetic modification," can result in many interesting and beneficial products.[33]

The main purpose of most GM crops produced to date is to increase crop yield.[34] Many proponents of GM foods are hopeful that increased yields in food resulting from genetic modification can help feed the poor of the world.[35] Beyond the main purpose of increasing crop yield, the

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'package' of genetic material (i.e., DNA) that is inserted into the genome of a cell via gene splicing techniques. May include promoter(s), leader sequence, termination codon, etc." *Id*.

[32] Thomas O. McGarity, *Seeds of Distrust: Federal Regulation of Genetically Modified Foods*, 35 U. MICH. J.L. REFORM 403, 406 (2002). This process can be done in several ways:

> (1) direct DNA uptake by the plant cells mediated by chemical or electrical treatments; (2) microinjection of DNA directly into plant cells; (3) biolistics, or firing tiny metal particles coated with the DNA of interest into plant cells; and (4) infecting the plant with a bacterium that scientists have modified to carry the DNA into plant cells.

Id.

[33] *See infra* notes 34-40 and accompanying text.

[34] Ricki M. Helm, *Food Biotechnology: Is This Good or Bad? Implications to Allergic Diseases*, 90 ANNALS OF ALLERGY, ASTHMA, & IMMUNOLOGY 90, 91 (June 2003). The first approved GM food to hit the market was the Flavr Savr tomato, which made its debut in 1994, and its purpose was "delayed softening due to reduced pectin degradation." *FDA List, supra* note 2. These tomatoes can stay fresher for longer because they can stay firm on the vine longer. Consumer Safety Officer, Biotechnology Policy Branch, HFS-206, Department of Health and Human Services, FDA, to Acting Director, Office of Premarket Approval, HFS-200, Department of Health and Human Services, FDA (May 17, 1994), *available at* http://www.cfsan.fda.gov/~acrobat2/bnfMFLV.pdf. The Flavr Savr tomato was followed by Roundup Ready soy beans and cotton, which are designed to resist herbicides and to act as pesticides. Weidner, *supra* note 30, at 19, 20; *FDA List*, *supra* note 2.

Genetic modification has accomplished the goal of increasing crop yields in several ways. For example, plants with herbicide resistance can tolerate chemical herbicides that kill weeds. McGarity, *supra* note 32, at 412. Other plants are engineered to contain Bt, a pesticide that makes plants resistant to insects. *Id*. at 411. Still others are vaccinated, making them resistant to plant viruses and diseases. *Id.* at 411. Some are even designed in such a way that they are able to grow in unusual temperatures and soils. *Id.* at 413. One of the more interesting genetic engineering inventions is the extraction of a gene responsible for the production of an antifreeze chemical, found in the genome of a flounder (a cold water fish) that is added to the genome of a tomato, resulting in tomatoes that are resistant to freezing weather. *See* Valerie Janlois, *Is There a Fish Gene in Your Tomato?*, ROCHESTER DEMOCRAT AND CHRON., June 10, 1999, at 9A. For a step by step pictorial description of how scientists manage to do this genetic modification, see BBC, *GM Science: How to Add a Fish Gene to a Tomato, available at* http://www.bbc.co.uk/science/genes/gm_genie/gm_science/index.shtml (last visited Jan. 4, 2005).

[35] Haroon Ashraf, *UK Ethicists Say GM Foods Could Help the Poor*, 361 THE LANCET 2051, 2051 (June 14, 2003). Genetic modification as a means to solve hunger issues actually became quite controversial in late June and early July of 2003, when President George Bush said that the European Union's ban on GM food contributed to the famine in Africa.

reduced use of pesticides and herbicides to protect GM crops may be more environmentally friendly and may result in a decreased risk of superweeds.[36]

The future goals for GM foods are aimed at increasing the nutritional value of foods.[37] Some researchers are looking into changing plants in such a way that they can be used as pharmaceuticals, botanical drugs, and functional foods.[38] Other researchers are trying to use genetic engineering to increase the levels of antioxidants in foods or to reduce the amount of *trans* fats.[39] Finally, some developers are focusing on improving the flavor of certain crops.[40]

Michael Thurston, *EU Moves to Ease Transatlantic Row Over Biotech Foods*, AGENCE FRANCE PRESSE, July 2, 2003. In response, Pat Cox, the president of the European Parliament, pointed out that the European Union gives three times more food to Africa than the United States, stating "we don't need to be lectured on humanitarian priorities." *Id.* Furthermore, it is unclear that producing more food will do anything at all to solve hunger issues in the world. *See* Neil E. Harl, *Biotechnology Policy: Global Economic and Legal Issues*, 12 WILLAMETTE J. INT'L L. & DISPUTE RES. 1, 21-22 (2004) (describing how hunger problems result from income, not a lack of food).

[36] Jon Van, *Biotech-crop Firms Seek to Breach Barriers*, CHI. TRIB., Nov. 27, 2004, at C3 (describing how agricultural chemical producers incorrectly thought that environmentalists would embrace genetically modified products because they would reduce the need to spray chemicals to control pests); Helm, *supra* note 34, at 93; Norman Ellstrand, *Superweed Dreams*, NEW SCIENTISTS, Oct. 23, 2004, at 54 (reviewing the book entitled *Introgression from Genetically Modified Plants into Wild Relatives* by H. C. M. den Nijs, et al.). A superweed is "[a] wild plant that has been accidentally pollinated by a genetically-modified plant and now contains that plant's abilities to resist herbicides and kill insects." Paul McFedries, The Word Spy, *at* http://www.wordspy.com/words/superweed.asp (posted on Feb. 16, 2000). For example, Allison Snow of Ohio State University found that GM sunflowers that produce a pesticide have crossed with weeds of sunflowers, and now the weeds also produce the pesticide. Sandi Rutkowski & Natalie Corvington, *Genetically Modified Crops May Pass Helpful Traits to Weeds, Study Finds*, 21 OHIO ST. SYNERGY, 2002-2003, at 10, a*vailable at* http://www.biosci.ohio-state.edu/documents/synergy/2002-2003/snow.php (last visited Jan. 4, 2005).

[37] Helm, *supra* note 34, at 91. *See also generally* Bo Lonnerdal, *Genetically Modified Plants for Improved Trace Element Nutrition*, THE J. OF NUTRITION, 1490S (2003) (describing scientific techniques that can be used to increase the iron and zinc in plant foods). One example of a product with increased nutritional value due to genetic modification is "golden rice," which is vitamin A fortified rice—a product that scientists hope can help cure the vitamin A deficiencies in cultures that rely on rice as a staple food. Bruce Schultz, *From LSU AgCenter . . . . 'Golden Rice' Targets Malnutrition*, DELTA FARM PRESS, Nov. 26, 2004, at 47; Weidner, *supra* note 30, at 19, 23.

[38] *See* Ilya Raskin et al., *Plants and Human Health in the Twenty-First Century*, 20 TRENDS IN BIOTECHNOLOGY 522 (Dec. 2002); *see also* Harl, *supra* note 35, at 5-8 (describing biopharmaceutical issues in the United States).

[39] *See* Monsanto Company, Monsanto Imagine, *at* http://www.monsanto.com/monsanto/layout/products/default.asp (last visited Jan. 4, 2005). *See also generally* M.E.

With endless possible improvements to foods come endless possible threats.[41] In 2003, the Society of Toxicology ("SOT") published a thorough analysis of the possible threats posed by genetic modification.[42] The SOT maintains that, although there is no evidence of any adverse effects resulting from GM foods so far and although these foods are likely as safe as traditional foods, assessing the safety of more complex GM foods that are unlike any traditional foods could pose a greater challenge.[43] Therefore, the emergence of completely new foods will require new toxicological methodologies to ensure safety.[44] With these considerations in mind, the SOT report examined the potential dangers raised by the use of biotechnological science to produce GM foods.[45]

The dangers listed by the SOT range from the safety of transgenes to concerns that the GM process will negatively impact the nutrition of the host.[46] Some scientists are concerned that transgenes themselves may be unsafe, or that the antibiotic "markers" contained within many transgenes may lead to bacterial and human resistance of antibiotics, though the SOT generally dismisses these concerns.[47] The more complicated concern is that the product encoded by transgenes in the host will pose risks, such as the inadvertent production of toxins.[48] Furthermore, the randomness with which transgenes are inserted into hosts could cause problems such as pleiotropic and insertional

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Verhoeyen et al., *Increasing Antioxidant Levels in Tomatoes Through Modification of the Flavonoid Biosynthetic Pathway*, 53 J. EXPERIMENTAL BOTANY 2099 (2002).

40 Helm, *supra* note 34, at 94.

41 *See infra* notes 42-44, 47-54 and accompanying text.

42 SOT, *Safety of GM Foods*, *supra* note 1, at 2.

43 *Id.* The premise of this conclusion by the Society of Toxicology is the concept of "substantial equivalence"—the assumption that new plants or animals are safe if they are not "significantly different from comparable, nonengineered plants or animals used to produce food that is generally considered to be safe for consumers." *Id.*

44 *Id.*

45 *See infra* notes 47-54 and accompanying text.

46 *See infra* notes 47-54 and accompanying text.

47 SOT, *Safety of GM Foods*, *supra* note 1, at 3. The SOT quickly dismisses the concern that a transgene itself is unsafe because a transgene is simply DNA, which is not itself toxic. *Id.* In fact, DNA actually plays a beneficial role in the immune system and the gut function. *Id.* at 3-4. Furthermore, scientists are not too concerned with the threat posed by "markers" because the chances of developing resistance are small, the impact negligible, and scientists are now able to avoid using these markers in most instances. *Id.* at 5.

48 *Id.* at 4. One possible risk is from the production of toxins by the plant. *Id.* For example, some plants are encoded to produce the Bt pesticide. *Id.* So far this has been unproblematic, however, the SOT suggests that each new plant introduced with a gene to produce such a product should be tested for any potential problems on a case-by-case basis. *Id.*

mutagenic effects.[49] Another potential problem is that these new plants will contain unidentified allergens, with effects that could range from mild to deadly.[50] Scientists have made some progress in the detection of

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[49] *Id*. at 5. Pleiotropic effects are changes in the phenotype of the host by a gene, and insertional mutagenic effects are where the insertion of the new gene causes changes in the expression of other genes. *Id.* Usually these effects are apparent in the host plant and so there is very little possibility that such effects would result in increased toxins without being detected before marketing. *Id*. However, toxicology does have limited predictive abilities. *Id*. Toxicology's limitations are demonstrated by a case occurring in the late 1980's and early 1990's where some scientists thought that the genetic modification of an amino acid tryptophan supplement resulted in the production of increased levels of a toxicant in the supplement that was responsible for the deaths of at least thirty-seven people. *Id*.

[50] *Id.* at 4. Allergens are not new, but rather are already contained within many of our conventional foods. *Id*. Allergens are molecules that induce the production of IgE, which binds to certain cells causing sensitization. Helm, *supra* note 34, at 91. Once a person is sensitized, subsequent exposure to the allergen causes the body to produce histamine, which results in an allergic response that can range between mild itching or swelling to deadly anaphylaxis. *Id*. There are many unknowns regarding allergens, such as the dose threshold of sensitization and of allergic reaction. *Id*. at 92. Also unknown is a reliable method for predicting the allergenic risk of novel proteins. *Id*. at 91. However, there are some known characteristics of allergens that can allow scientists to begin to detect them. *Id*. The most prominent trait of allergens is the stability of the protein; in other words, its resistance to heat and enzymatic degradation. *Id.* The World Health Organization has described other approaches to identifying allergy sources, which include characterizing amino acid sequences, developing more exact sequence screening by the identification of those amino acid sequences that define allergens, and using animal models. Anita Bakshi, *Potential Adverse Health Effects of Genetically Modified Crops*, J. TOXICOLOGY & ENVTL. HEALTH 211, 211 (2003). There are two prominent examples of allergens created, and then detected, in GM foods based on characteristics that are common in allergens. The first is the StarLink Corn, which has caused a major stir in the media in the last three years. *See, e.g.,* Chris Clayton, *Starlink Corn Still Shows Up*, OMAHA WORLD HERALD, July 30, 2003, at 1d; Andrew Harris, *Corn Rows*, BROWARD DAILY BUS. REV., Sept. 18, 2002, at A8; Anthony Shadid, *Blown Profits Genetic Drift Affects More than Biology – US Farmers Stand to Lose Millions*, THE BOSTON GLOBE, Apr. 8, 2001, at G1; David Roeder, *Suit Targets Corn Developer; Lax Safeguards for Modified Product Charged*, CHICAGO SUN-TIMES, Dec. 5, 2000, at 54; Marc Kaufman, *Biotech Critics Cite Unapproved Corn in Taco Shells; Gene-Modified Variety Allowed Only for Animal Feed Because of Allergy Concerns*, THE WASHINGTON POST, Sept. 18, 2000, at A02. Starlink corn is the result of the toxin Cry9c being introduced into seed corn DNA in order to provide corn with resistance to the corn borer. Helm, *supra* note 34, at 94. This corn was approved only for animal consumption but not approved for human consumption because its slow digestion made it potentially allergenic. SOT, *Safety of GM Foods*, *supra* note 1, at 5; Krista Weidner, *GMOs in the News: Starlink Corn*, PENN STATE AGRIC., Fall 2002/Winter 2003, at 22 (discussing how farmers were supposedly told that the corn was not meant for human consumption, but somehow the message did not get across to them clearly; the result was contamination of human food supplies and criticism of the methods of regulation). In fact, its accidental introduction into a corn supply meant for human consumption was the possible cause of several illnesses, and StarLink corn has since been recalled and lawsuits have emerged over the issue. SOT, *Safety of GM Foods, supra* note 1, at 5; Clayton, *supra*; Harris, *supra*. The other example is the introduction of a protein from Brazil nuts into soybeans to improve the nutrition of soybeans. Helm, *supra* note 34, at 94.

allergens.[51] However, the information is still sparse and, coupled with the potentially deadly result of allergies, there is no guarantee of safety.[52] A final concern is the possibility that genetic modification will reduce the nutritional value of the host.[53] Nutritional changes detected thus far have not necessarily been significant; however, developers of GM foods should be aware that genetic engineering can result in unexpected changes to the nutrition and safety of foods.[54]

Because the impact of genetic modification of food is far-reaching, further research is necessary to determine all of the effects of GM foods.[55] The SOT found that primary areas in need of further research are developments in methods for testing whole foods (rather than just comparing single components) for allergen identification and methods for understanding proteins, gene expression, and the metabolites of plants and microbes.[56] One possible solution is that "[a]n information and communication technology-based multidisciplinary framework could be put into place to educate the public on foods from genetically modified crops . . . ."[57] This framework would include the tracking of biotech foods so that these foods would be monitored from the seed all the way to marketing.[58]

Regardless of the opinion of many scientists that there is still work to be done in order to ensure and maintain safety in the production of GM foods, some scientists maintain that this new technology is very safe and

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Scientists were able to determine that the introduced protein was in fact an allergen by using a decision tree together with the serum from individuals allergic to Brazil nuts. *Id.*; *infra* note 59 (discussing decision trees).

51 Helm, *supra* note 34, at 95.

52 *Id.*

53 SOT, *Safety of GM Foods, supra* note 1, at 6. For example, Roundup Ready soybeans have a greater amount of the antinutrient trypsin inhibitor than in conventional soybeans. *Id.* Also, Roundup Ready soybeans have reduced amounts of two out of the three major phytoestrogens found in soybeans. Marc Lappe, *Biotechnology and Agriculture*, 10 MICH. ST. U. DETROIT C. L. J. INT'L L. 39, 39 (Spring 2001).

54 Lappe, *supra* note 53, at 39. There are many more examples of unexpected changes that have occurred in plants as a result of transferring genes. *Taking Stock*, THE ECOLOGIST, July/August 2003, at 32. For example a gene that codes for the red pigment in maize was transferred to a petunia, and the petunia not only turned red, it also had more shoots, was less fertile, and was more resistant to fungus. *Id.* Another example is a yeast that was genetically engineered to increase fermentation, but which also produced a toxin that was thirty times greater than in the conventional equivalent. *Id.*

55 SOT, *Safety of GM Foods, supra* note 1, at 7.

56 *Id.* These research developments suggested by the SOT are necessary to detect unexpected changes resulting from bioengineering. *Id.*

57 Helm, *supra* note 34, at 96.

58 *Id.*

may even decrease risks posed by food.[59] However, the general public, as well as many scientists, are concerned not just with the impact of GM foods on human health, but also with the possible detrimental effects that genetic modification may have on the environment.[60] Some members of the public also raise moral and religious objections to genetic modification and express social concerns relating to the control of the world's food supply by those who have patented genetic modification techniques.[61]

Potential environmental harms created by genetic modification include the growth of superweeds,[62] increased use of pesticides,[63] genetic pollution,[64] and a general risk of adverse impacts on biodiversity.[65]

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[59] Andrew Cockburn, *Assuring the Safety of Genetically Modified (GM) Foods: The Importance of an Holistic, Integrative Approach*, 98 J. BIOTECHNOLOGY 79, 85-93 (2002). The assurance of safety of GM foods from scientists is due to the intricate safety assessment procedures scientists have set up for these foods. *Id.* In particular, scientists have developed decision trees which include assessment of the host crop, the transgene, and the gene product. *Id.* Some scientists, who assume substantial equivalence and take the step-by-step decision tree approach, feel confident in concluding that GM foods are just as safe as their traditional counterparts, which have never undergone the same rigorous testing. *Id.* Some data suggests that allergens in food can be identified and removed by genetic modification, indicating that genetic modification may even increase the safety of foods. *See generally* Eliot M. Herman et al., *Genetic Modification Removes an Immunodominant Allergen from Soybean*, 132 PLANT PHYSIOLOGY 36 (May 2003) (describing scientific evidence that Gly m Bd 30 K, a soybean allergen, may be removed without significantly altering the growth and maturation of the soybean plant).

[60] *See infra* notes 62-69 and accompanying text.

[61] *See infra* notes 70-76 and accompanying text.

[62] *Keep Britain GM-Free*, THE ECOLOGIST, July/Aug. 2003, at 38 [hereinafter *Keep Britain GM-Free*]. Not only can genes from GM plants be transferred to related weeds, these GM plants can themselves act like weeds. *Id.* For example, the GM oilseed rape resistant to herbicides has been created and grown in Canada since 1998 and now GM oilseed rape is out of control. *Id.*; Rutkowski & Corvington, *supra* note 36, at 10 (regarding sunflower superweeds).

[63] *Keep Britain GM-Free*, *supra* note 62, at 38. Insects can quickly adapt to pesticides, so that plants that produce the pesticides will no longer be effective and additional pesticides will be required. *Id.*

[64] *Id.* GM crops may reduce overall diversity by contaminating species that are wild. *Id.* For example, in the case of oilseed rape, genes from modified crops can "jump" the species barrier and cause mutations. Antony Barnett, *GM Genes 'Jump Species Barrier,'* THE OBSERVER, May 28, 2000, at 1 (discussing the four year study of German zoologist Hans-Hinrich Kaatz, who found that the transgene used in oilseed rape had transferred to bacteria living in the inside of the guts of bees). Kaatz did not publish this information in a scientific journal for fear that he would be ostracized from the scientific community much like Dr. Arpad Pustzai, who was fired for publishing damaging information on the effects of GM potatoes to the lining of rats' stomachs. *Id.*; *see also infra* note 75 (discussing a case in Canada where Monsanto sued Percy Schmeiser for using its GM rape seed).

[65] Blake A. Biles, *Agriculture Biotechnology: The U.S. Perspective*, 18 NAT. RESOURCES & ENV'T 12, 12 (Summer 2003). The concern is that GMOs would reduce the gene pool due to

Likewise, genetic modifications may pose risks to non-target organisms.[66] For example, plants encoded to produce the pesticide Bt have been reported to cause some unfavorable health effects in butterflies, moths, beetles, and flies.[67] Greenpeace is campaigning against genetic engineering because scientists do not have adequate information on how GM organisms will affect the environment, and because once GM organisms are introduced into the environment, they cannot be recalled.[68] Organic farmers are also opposed to genetic engineering because the general approach organic farmers have toward the environment precludes this rather domineering attitude.[69]

The Agriculture and Environment Biotechnology Commission ("AEBC"), an organization set up to give independent advice to the UK's government regarding biotechnology, recently reported that many lay people were morally opposed to GM animals.[70] Moral objections to genetic engineering include that it is like "playing God,"[71] it "violates the integrity of living organisms" by showing no respect for the "otherness" of animals and by using them purely as an object or a research

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the promotion and use of fewer types of seeds, which could eventually result in the loss of knowledge and cultivation of local varieties and lead to their ultimate demise. Kim JoDene Donat, Note, *Engineering Akerlof Lemons: Information Asymmetry, Externalities, and Market Intervention in the Genetically Modified Food Market*, 12 Minn. J. Global Trade 417, 423-24 (2003); *infra* note 75 (regarding the importance of saving seed to maintain biodiversity).

66 SOT, *Safety of GM Foods, supra* note 1, at 6.

67 Bakshi, *supra* note 50, at 219. Specifically, some evidence indicates that Bt is harmful to Monarch butterfly larvae. SOT, *Safety of GM Foods, supra* note 1, at 6. However, the actual amount and level of exposure that the Monarch butterfly larvae has to Bt plants is limited, so that the actual harm is likely to be minimal, particularly as compared to the spraying of Bt. *Id*. at 6-7.

68 Greenpeace, *Genetic Engineering*, *at* http://ge.greenpeace.org/international_en/campaigns/intro?campaign%5fid=3942 (last visited Jan. 4, 2005) [hereinafter Greenpeace, *Genetic Engineering*].

69 Henk Verhoog, *Naturalness and the Genetic Modification of Animals*, 21 TRENDS IN BIOTECHNOLOGY 294, 296 (2003). To organic farmers, farming has a "cognitive component, which is ecologically and holistically inspired" and an "emotive component, related to a non-anthropocentric, positive attitude towards nature, in which the animal (and nature in general) is seen as a more or less 'autonomous' partner with whom the farmer should cooperate." *Id*. This approach also includes a "[r]espect for species barriers." *Id.*

70 *See* Verhoog, *supra* note 69, at 294. Henk Verhoog of the Louis Bolk Institute explains some of the ethical arguments against the use of genetic modification of animals and plants, dealing primarily with the intrinsic morals concerns. *Id*.; Agriculture and Environment Biotechnology Commission, *Animals and Biotechnology*, Sept. 3, 2002, *at* http://www.aebc.gov.uk/aebc/pdf/animals_and_biotechnology_report.pdf.

71 Verhoog, *supra* note 69, at 294-96. In other words, genetic engineering is "blasphemous" or is "human hubris." *Id*.; Alliance for Bio-Integrity, *Why the Genetic Engineering of Our Food Offends Principles of Most Religions*, *at* http://www.bio-integrity.org/RelReject.html (last visited Jan. 4, 2005).

instrument,[72] and that it is "unnatural."[73] Some people are opposed to genetic modification because it entails patenting life, which they believe should not be allowed because it gives corporations too much control over life.[74] Still others focus their concern on the impact genetic modification has on small farmers and farmers in developing nations.[75]

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[72] Verhoog, *supra* note 69, at 294; s*ee also* Ron Epstein, *Genetic Engineering and Its Dangers*, *at* http://online.sfsu.edu/%7Erone/GEessays/gedanger.htm#Ethical (revised Mar. 2004). Ron Epstein, Research Professor of Berkeley, describes biotechnology-related concerns as they run into ethical and religious beliefs. *Id*. For example, he says that genetic engineering disregards the intrinsic value of living organisms, which allows for a proprietary view towards living things. Ron Epstein, *Redesigning the World: Ethical Issues About Genetic Engineering, in* ETHICAL ISSUES IN BIOTECHNOLOGY 47, 58-59 (Richard Sherlock & John Morrey eds., 2002). He also says that the very assumptions of Buddhism consider the risks of biotechnology as not just physical risks but also spiritual risks, which is cause for great concern for Buddhists. Ron Epstein, Talk entitled "Buddhism and Biotechnology" delivered as part of "Spiritual Dimensions of our Technological Future" AHIMSA Sixth Annual Conference, International House, University of California at Berkeley (Oct. 3, 1998) *at* http://online.sfsu.edu/~rone/GEessays/Buddhism%20and%20Biotechnology.htm. Epstein discusses four assumptions of Buddhism that are incompatible with biotechnology. *Id*. First, is the notion of ahimsa, which means "non-harming" and "is the principle of respect for the intrinsic value of the life of all sentient beings, not just human life." *Id*. This notion precludes use of sentient beings as instruments, a practice that is necessary for biotechnology. *Id*. The second is transcendence, which is a notion that science cannot address. *Id*. The third is that "the cosmos is an open system," which is opposed to scientific research that assumes the cosmos is a closed system; the open system assumption, therefore, sees science as much more limited than do those people coming from a scientific methodology viewpoint. *Id*. Finally, Buddhism is non-Cartesian, which means that biotechnology will affect not only the physical but also the spiritual, because the two are not distinct from each other. *Id*.

[73] Verhoog, *supra* note 69, at 294-95. Genetic modification is "unnatural" in that it is counterintuitive to common sense, and that speaking of something as being natural or unnatural is never just descriptive—there is always a normative component. *Id.*

[74] *See, e.g.,* Greenpeace, *Genetic Engineering*, *supra* note 68. Greenpeace states the following:

> We . . . oppose all patents on plants, animals and humans, as well as patents on their genes. Life is not an industrial commodity. When we force life forms and our world's food supply to conform to human economic models rather than their natural ones, we do so at our own peril.

Id.; *see also* ActionAid, *Food Rights, at* http://www.actionaid.org/docs/FoodRights2004.pdf (last visited Jan. 7, 2005) [hereinafter ActionAid, *Food Rights*] (describing how patents on plant varieties are monopolized by four big companies, so that poor farmers can no longer freely save, exchange and sell seeds). ActionAid is an international development agency trying to eradicate poverty by forming partnerships with poor people from whom they learn so as to help them. ActionAid, *About Us*, http://www.actionaid.org/aboutus/index.html (last visited Jan. 4, 2005).

[75] *See* ActionAid, *Food Rights*, *supra* note 74. In its briefing papers for the WTO ministerial conference for 2003, ActionAid made the following statements:

> Traditionally, poor farmers reduced the risk of total crop failure by planting a wide range of crop varieties. Their use of seeds with

These people argue that, based on the present status of intellectual property law, genetic engineering benefits the rich, not the hungry, by making small farmers more dependent on agribusiness.[76]

> differing traits allows future generations to select and breed plants that are best adapted to changing environmental, economic, and social pressures. In contrast, intellectual property laws, by encouraging the development of seeds with a large commercial potential have lead to an increase in monoculture and the reduction of environmental heterogeneity. This poses a danger to farmers and food security because of the increased risk of wholesale crop failure inherent in agriculture using such a narrow genetic base. For most developing countries, widespread crop failure spells nothing less than disaster.

ActionAid, *Trade Related Intellectual Property Rights*, *at* http://www.actionaid.org.uk/wps/content/documents/trips2.pdf (Jan. 4, 2005). *See also generally* Shubha Ghosh, *Traditional Knowledge, Intellectual Property, and Indigenous Culture*, 11 CARDOZA J. INT'L & COMP. L. 497 (describing the conflict between intellectual property rights and traditional knowledge).

A current example of the effect that patenting practices can have on small farmers is the effect it has had on Percy Schmeiser. In May 2004, the Supreme Court of Canada handed down a 5-4 decision in which it determined that Monsanto's patent of Roundup Ready Canola is patentable, rejecting Schmeiser's argument that the subject matter in the patent is unpatentable. Monsanto Canada Inc. v. Schmeiser, 2004 S.C.C.D.J. Lexis 31, 15-17. The court also concluded that Schmeiser "used" Monsanto's patent when he intentionally collected those seeds that fell on his property that he knew were Roundup Ready Canola seeds, and then proceeded to use them in the next year. *Id.* at 33-48. However, the court decided 9-0 that Monsanto should not be awarded damages because it could not prove that Schmeiser in any way benefited from using the seeds. *Id.* at 51. The dissent argued that because the patent did not include the regenerated plant or its progeny, and therefore, because of the lack of notice given to the public, the patent should not extend to use of the plant. *Id.* at 56-63, 74.

The results of the case are unclear, but Percy Schmeiser counts his case a victory in a couple different ways. First, he does not have to pay damages, and likewise, it may be difficult for Monsanto to successfully sue farmers in the future because, after this case, it is clear that Monsanto must prove that the farmer benefited from the illegal use of the patent in order for Monsanto to receive damages. Percy Schmeiser, Monsanto v. Schmeiser, *Percy Schmeiser Claims Moral and Personal Victory in Supreme Court Decision*, http://www.percyschmeiser.com/decisioncomments.htm (last visited Jan. 4, 2005). Furthermore, Schmeiser surmises that if Monsanto owns the patent on the plants, then Monsanto should also be responsible for them. *Id.* Accordingly, Schmeiser's wife, Louise, has filed suit against Monsanto in a small claims court for $140, the amount it cost her to remove Roundup Ready Canola seeds from her nearby organic garden. Monsanto v. Schmeiser, *Schmeiser's Wife Takes on Monsanto,* http://www.percyschmeiser.com/Wife.htm (last visited Jan. 4, 2005).

The Schmeisers are not the only small farmers Monsanto has sued. A farmer from North Dakota, Rodney Nelson, spent over $200,000 on attorney's fees when Monsanto unsuccessfully sued him for saving Roundup Ready soya beans from the previous year. *Where Did GM Go Wrong?*, WESTERN MORNING NEWS (Plymouth), Oct. 14, 2003, at 32. What is worse is that the Roundup Ready soya Nelson used produced substantially less yield than the conventional seed. *Id.*

[76] *See generally* Carlos Scott Lopez, *Intellectual Property Reform for Genetically Modified Crops,* 20 J. CONTEMP. HEALTH L. & POL'Y 367 (2004) (describing how the main problem with

Furthermore, scientists disagree on a basic assumption regarding genetic engineering: whether GM foods should be assessed based on substantial equivalence.[77] Substantial equivalence assumes that new plants or animals are safe if they are "not significantly different from comparable, nonengineered plants or animals used to produce food that is generally considered to be safe for consumers."[78] Although many scientists agree that substantial equivalence is a reasonable method to use to determine the safety of new products developed by genetic modification, some scientists do not agree with this basic assumption because genetic modification often produces unintended and potentially undetected results.[79] Also, some scientists do not adhere to the substantial equivalence assumption because the term "substantial

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genetically modified crops is that they are inconsistently and inadequately managed because of the current intellectual property system, and offering five guiding principles for creating a new framework for intellectual property law as it pertains specifically to genetically modified crops). *See also* Katrin Dauenhauer, *Activists Say U.S. Manipulating Meeting to Promote GM Food*, INTER PRESS SERVICE, June 23, 2003. Anuradha Mittal of Food First, an organization based in California, said:

> It is a myth that science and technology play a critical role in reducing hunger in developing countries. The claim that we must accept genetically engineered foods if we are to feed the poor in the Third World is simply 'poorwashing' . . . . Hunger is a complex phenomenon that cannot be solved by technology alone. We need political commitment and not technology. Countries suffering from hunger need basic social economic change.

Id. Opposition to GM foods, and more generally to subsidies to American and European farmers, resulted in riots in Cancun, Mexico disrupting the WTO trade talks being conducted there in September of 2003. Dennis Byrne, *The Problem with Subsidies from Governments,* CHI. TRIB., Sept. 15, 2003, at 19; Letta Tayler, *Bracing for Violence; Mexicans Fear Riots at WTO Summit*, NEWSDAY (NEW YORK), Sept. 12, 2003, at A22. Protestors in India destroyed a Monsanto Greenhouse, which according to M.D. Nanjundaswamy, president of the farmers' union Karnataka Rajya Raitha Sangha, was done "to protest against the WTO meeting at Cancun and to oppose the setting up of monopolies by multinational companies." Subramaniam Sharma, *Monsanto India's Shares Decline After Attack on Greenhouse*, BLOOMBERG NEWS, Sept. 12, 2003, *available at* LEXIS, News Library, ALLBBN File.

[77] *See infra* notes 78-80 and accompanying text.

[78] SOT, *Safety of GM Foods*, *supra* note 1, at 2.

[79] Many scientists believe that substantial equivalence is reasonable. SOT, *Safety of GM Foods*, *supra* note 1, at 2 (stating that support for the use of substantial equivalence is part of the safety assessment of biotechnology-derived foods); Cockburn, *supra* note 59, at 79 (stating that international efforts for determining safety have focused on changes in nutrients, anti-nutrients and toxicity as compared to the traditional counterparts). However, many scientists question substantial equivalency. Lappe, *supra* note 53, at 39 (explaining that "there are subtle differences between engineered and nonengineered crops," which "calls into question the issue of equivalence"); *see supra* note 54 and accompanying text (regarding unexpected changes resulting from genetic modification).

equivalence" is not clearly defined, leaving room for misguided interpretation.[80]

The public perception of GM foods, like that of the scientific community, is certainly not uniform, especially across the Atlantic.[81] In Europe the public sentiment has been quite negative.[82] Between 1992

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[80] Sheldon Krimsky & Nora K. Murphy, *Biotechnology at the Dinner Table: FDA's Oversight of Transgenic Food*, 584 ANNALS AM. ACAD. POL. & SOC. SCI. 80, 92 (Nov. 2002); McGarity, *supra* note 32, at 430 (saying that critics to the substantial equivalence doctrine are particularly disturbed by its subjectivity in that there is no standardized objective test to measure what is substantial and what is not).

[81] *Compare infra* notes 82-84 and accompanying text, *with infra* notes 85-88 and accompanying text.

[82] Maria K. Magnuson & Ulla-Kaisa Koivisto Hursti, *Consumer Attitudes Towards Genetically Modified Foods*, 39 APPETITE 9, 10 (2002) (reporting studies done on consumer attitudes towards GM technology).

At first, Monsanto was careful, realizing that it needed to gradually win the trust of the public. Kurt Eichenwald, *Redesigning Nature: Hard Lessons Learned; Biotechnology Food: From the Lab to Debacle*, THE NEW YORK TIMES, Jan. 25, 2001, at A1. However, in 1990, Robert Shapiro was named head of the agriculture division, and he took a very aggressive approach, which was strategically a very bad decision. *Id*. Will Carpenter, who was the head of Monsanto's strategy group until 1991, said: "Somewhere along the line, Monsanto specifically and the industry in general lost the recipe of how we presented our story . . . . When you put together arrogance and incompetence, you've got an unbeatable combination. You can get blown up in any direction. And they were." *Id*. American critic of GM Foods Jeremy Rifkin, who is also a consultant to EU leaders on biotech issues, explains why biotech companies are having such a difficult time in Europe:

> What Monsanto lost sight of is that food is a deep statement of culture in all the countries that make up Europe. The way people process and prepare food is the story of who they are. In a world of globalization, where people feel increasingly that they are losing control over so many aspects of their lives, the one place they feel they still have some control is the food they put on the table—and damned if they are going to give that up for globalization.

William Greider, *A High Level Food Fight*, THE NATION, Nov. 3, 2003, at 16. Europe's lack of confidence seems to go hand-in-hand with the arrogance of the United State's biotech companies. McGarity, *supra* note 32, at 473. McGarity explains:

> The U.S. biotechnology industry entered the GM food debates with an arrogance reminiscent of the nuclear power industry in the 1950s. Early in the highly contentious controversy in Europe over GM Foods, a public relations specialist hired by an American biotechnology company told critics that "people will have Roundup Ready soya, whether they like it or not." An executive for another American company told the technical manager of a British supermarket chain that he was a "backward European" who should "just accept that this is right for your customers." This arrogance backfired in Europe (the supermarket chain made arrangements with Brazilian suppliers of non-GM foods, as did many of its competitors), and by the late 1990s, it was beginning to have a negative effect in the U.S. as well.

Id. (footnotes omitted).

and 1996, consumers in Europe formed activist groups that protested the new foods, and by fall of 1999, successfully convinced the UK and EU regulatory agencies to place moratoriums on the growth of these products and to stifle their import.[83] Furthermore, Europeans appear to be becoming less supportive of biotechnology in general.[84] In contrast,

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[83] Kim Brooks, *History, Change and Policy: Factors Leading to Current Opposition to Food Biotechnology*, 5 GEO. PUBLIC POL'Y REV. 153, 154 (2000) (proposing reasons why the United Kingdom has so vehemently rejected GM foods). Consumer concern has also been effective in convincing McDonald's to not use beef from cows that have been fed with GM foods in its Big Macs in Europe. Tom Carter, *EU Aide Suggests Labeling Products; Officials Disagree on Identifying Altered Foods*, THE WASHINGTON TIMES, Oct. 19, 2003, at A09. Furthermore, other large food producers, such as Heinz and Kraft, have stopped using GM ingredients in the products they sell in Europe. *Big Food Backtracks on Frankestein Projects*, MKTG. WK., Oct. 23, 2003, at 22. In Australia, George Weston Foods, Bakers Delight, Muffin Break and Kellogg's all have a GM-free policy, and Dairy Farmers, Domino's Pizza, Starbucks and the Cheesecake Shop are headed in that same direction. *GM Foods: What Consumers Want*, SYDNEY MORNING HERALD, Sept. 12, 2003, at 14. Still, some attribute the European resistance to GM products by officials to trade protectionism because of Europe's technological disadvantage. *See* Lawrence A. Kogan, *Ducking the Truth About Europe's GMO Policy*, INT'L HERALD TRIB., Nov. 27, 2004, at 6. The moratorium has effectively been lifted as the European Commission has allowed the import of corn this past summer and rape-seed this past winter. Jonathan Stearns, *Monsanto Moves Closer to Winning EU Rapeseed Approval*, BLOOMBERG NEWS, Dec. 20, 2004, *available at* LEXIS, News Library, ALLBBN File.

[84] Centre National De La Recherche Scientifique, *Changes in European Attitudes Towards Genetically Modified Organisms*, *available at* http://www.cnrs.fr/cw/en/pres/compress/ogm/ogmevolution.htm (last visited Jan. 4, 2005). The results from the Eurobaromter 2000 indicated that in 2000, 41% of people thought that biotechnology would improve our lives over the next 20 years (down from 47% in 1997) and 23% thought that it would worsen our lives (up from 19% in 1997). *Id*. The people who thought biotechnology would not affect our lives in the next 20 years was 10% in 2000 (same as in 1997), and the number of people who didn't know was 26% in 2000 (up from 24% in 1997). *Id*.

This sentiment is fostered by information available to the people of Europe in magazines and newspapers. A London based environmental journal, "The Ecologist," recently gave five reasons why Britain should be kept GM-free: GM will remove consumer choice, health risks have not been disproved, farmers will be destroyed, the environment will suffer, and GM crops will not feed the poor. *Keep Britain GM-free*, *supra* note 62, at 34-39. Furthermore, a writer for THE ECOLOGIST criticized the UK government on its handling of public opinion, suggesting in particular that the public debates offered by the government were a sham, as is obviated by the fact that they lasted only a short time and were finished before results of farm-scale trials were published. Andy Rowell, *Debate, What Debate?*, THE ECOLOGIST, July/August 2003, at 30. These farm-scale trials, the results of which came out in October of 2003, in fact showed that two out of three of the GM crops tested may disadvantage wildlife. Defra, *Environmental Protection*, *available at* http://www.defra.gov.uk/environment/gm/fse/results/fse-summary.pdf (last visited Jan. 4, 2005).

The newspaper, THE GUARDIAN, has also kept the public informed of the "dirty tricks campaign" of one of the largest producers of GM foods, Monsanto. George Monbiot, *The Covert Biotech World: The Battle to Put a Corporate GM Padlock on Our Foodchain is Being Fought on the Net*, THE GUARDIAN, Nov. 19, 2002, at 19; George Monbiot, *Corporate Phantoms: The Web of Deceit Over GM Food Has Now Drawn in Tony Blair's Speechwriters*, THE GUARDIAN, May 29, 2002, at 17; Zac Goldsmith, *Environment in a Spin*, THE GUARDIAN, May

the attitude of Americans is more positive toward GM foods than in Europe.[85] People in the United States generally support agricultural technology and are confident in the products and their regulation.[86] However, both U.S. consumer support and paradoxically, opposition to GM foods, seem to be decreasing.[87] Still, many in the United States are not in favor of GM foods; grassroots efforts have begun to lobby Congress and the President to pass legislation that would require GM foods in the United States to be labeled and more tightly regulated.[88]

16, 2002, at 19; George Monbiot, *The Fake Persuaders: Corporations are Inventing People to Rubbish Their Opponents on the Internet*, THE GUARDIAN, May 14, 2002, at 15. These articles describe how some computer gurus discovered that some unknown person using computers at Monsanto or subsidiaries of Monsanto was creating fake citizens who were allegedly activists in favor of biotechnology and were fiercely opposed to the critics of GM foods. *Id.*

85 Magnuson & Hursti, *supra* note 82, at 9.

86 Biles, *supra* note 65, at 13.

87 The Mellman Group, *The Pew Initiative on Food and Biotechnology*, Sept. 15, 2003, *available at* http://pewagbiotech.org/research/2003update/2003summary.pdf. As of August 2003, the numbers indicate that 25% of U.S. consumers polled supported the use of GM foods (down 1% from 2001) and 48% opposed the use of GM foods (down 10% from 2001). *Id.*

88 *See* The Campaign to Label Genetically Modified Foods, *at* www.thecampaign.org (last visited Jan. 4, 2005); Organic Consumers Association, *Genetically Engineered Food*, *at* http://www.organicconsumers.org/gelink.html (last visited Jan. 4, 2005); Mothers for Natural Law, at http://www.safe-food.org (last visited Jan. 4, 2005); *see also* Emily Marden, *Risk and Regulation: U.S. Regulatory Policy on Genetically Modified Food and Agriculture*, 44 B.C. L. REV. 733, 753-56 (2003) (describing Mothers for Natural Law, Center for Food Safety, Campaign to Label Genetically Engineered Foods, and the case *Alliance for Bio-Integrity v. Shalala*). Many food products in the United States are currently void of GM materials due to consumer concern, including the following: select Beech Nut baby foods, select Gerber baby foods, select Heinz baby food, Bob's Red Mill Pancake and Waffle Mixes, Alvarado Street breads, French Meadow breads, Shiloh Farms breads, Health Valley granola bars and cereals, Barbara's Bakery cereals and cookies, and many more foods. *See* GreenPeace, *True Food Shopping List*, *available at* http://www.truefoodnow.org/shoppersguide/guide_printable.html (last visited Jan. 4, 2005).

Dr. Lawrence Busch argues that biotechnology has caused people to question several assumptions: that all new technologies are beneficial, that the public will acquiesce, that what is good for farmers is good for consumers, and that whatever is economically viable is socially acceptable. Lawrence Busch, *Assumptions About Biotechnology and Agriculture*, 10 MICH. ST. U. DETROIT C. L. J. INT'L L. 57 (Spring 2001). Furthermore, Congressman Dennis Kucinich drafted a series of bills addressing problems resulting from genetic engineering, but which expired at the end of 2004: Genetically Engineered Food Right to Know Act, H.R. 2916, 108th Cong. (2003) (amending the FFDCA, the Federal Meat Inspection Act, and the Poultry Products Inspection Act to mandate labeling of food that contains GM material or was produced using GM material); Genetically Engineered Food Safety Act, H.R. 2917, 108th Cong. (2003) (amending the FFDCA regarding the safety of genetically engineered foods); Genetically Engineered Crop and Animal Farmer Protection Act of 2003, H.R. 2918, 108th Cong. (2003) (ensuring fair dealing by biotech companies and protecting farmers and ranchers from economic harm resulting from genetically engineered seed, plants, or

Although Americans have a relatively more positive outlook on GM foods, they are generally less informed on the issues surrounding GM foods than are Europeans, and their knowledge is not necessarily increasing.[89] According to the Pew Initiative On Food and Biotechnology ("Pew Initiative"), 58% of people polled said they had not eaten GM foods.[90] Yet, according to an estimate by the Grocery Manufacturers of America, 70-80% of processed foods contain GM ingredients.[91] In January of 2001, the Pew Initiative revealed that 44% of those polled had heard a "great deal" or "some" about GM foods, compared with the August 2003 report where the percentage dropped ten points to 34%.[92] Moreover, Americans seem to be generally in favor of government regulation of GM foods.[93] Most Americans have faith in the regulatory system in the United States concerning GM foods.[94] However, again, most Americans have very little knowledge as to how GM foods are regulated.[95] Furthermore, regardless of Americans' general faith in regulation, Americans clearly desire that GM foods be labeled.[96]

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animals); Genetically Engineered Organism Liability Act of 2003, H.R. 2919, 108th Cong. (2003) (making biotech companies liable for injury resulting from the release of genetically engineered organisms into the environment); Real Solutions to World Hunger Act of 2003, H.R. 2920, 108th Cong. (2003) (ensuring that the use of genetically engineered animals and crops to address world hunger issues will actually help developing countries); Genetically Engineered Pharmaceutical and Industrial Crop Safety Act of 2003, H.R. 2921, 108th Cong. (2003) (prohibiting the cultivation of genetically engineered pharmaceuticals in the open air and creating a tracking system to regulate pharmaceutical and industrial crops).

89 *See infra* text accompanying notes 90-91 and notes 92, 95 and accompanying text.

90 The Mellman Group, *supra* note 87.

91 *Id.*

92 *Id.* Ipsos-Reid research supports the Mellman Group survey, indicating that in 2000 66% of Americans had heard of the issue, but only 4% felt they "kn[e]w a lot" about the issue, and 15% say they have some understanding. Ipsos-Reid, *Awareness of Genetically Modified Foods Wide But Knowledge Inch Deep,* June 8, 2000, *available at* http://www.angusreid.com/pdf/media/mr000608_2ch.pdf.

93 The Mellman Group, *supra* note 87. The Pew research revealed that 89% of all people surveyed agreed that any GM foods that reach the market should have to submit safety data to the FDA. *Id.*

94 *Id.* According to the survey, 83% of consumers said they trusted what the FDA concluded "a great deal" or "some." *Id*.

95 *Id.* Only 44% of Americans have heard anything about how the government regulates these foods, and only 9% said they knew a great deal about it. *Id*.

96 A 2001 telephone poll conducted by ABC News found that 93% of Americans believe that the government should mandate labeling of GM foods. Gary Langer, *Behind the Label*, ABC NEWS.COM, June 19, 2001, *at* http://abcnews.go.com/sections/scitech/DailyNews/poll010619.html; The Center for Food Safety, *Compilation and Analysis of Public Opinion Polls on Genetically Engineered (GE) Foods*, *at* http://www.centerforfoodsafety.org/new_nation.

GM foods are innovative developments that could potentially benefit humanity in many ways.[97] However, GM foods come with risks and raise ideological concerns.[98] It is therefore unsurprising that, at the very least, most consumers desire disclosure regarding these foods.[99] However, in order for disclosure to be required, the government must have proper authority to mandate such disclosure.[100]

B. Authority to Legislate Mandatory Labels

In order for Congress to create law, it must have the proper authority. This authority involves a two-prong inquiry.[101] The first question is whether the Constitution has granted Congress authority to create the particular legislation at issue.[102] The second question is whether the legislation at issue would violate another doctrine or provision of the Constitution.[103]

Congress's constitutional authority to mandate labeling of food products is based on the Commerce Clause, through which Congress has created the FFDCA.[104] Congress has given the Food and Drug Administration ("FDA") the authority to mandate the labeling of food products; however, the FDA has chosen not to use this authority to label in the specific instance of GM food products.[105] Therefore, if labeling of

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cfm (last visited Jan. 4, 2005) (indicating that 88% of U.S. consumers want labels on GM foods as of a 2002 poll).

97 *See supra* text accompanying notes 34-40.

98 *See supra* text accompanying notes 42-54.

99 *See supra* note 96 and accompanying text (describing how most Americans believe GM foods should be labeled).

100 *See infra* Part II.B.

101 ERWIN CHEMERINSKY, CONSTITUTIONAL LAW 91 (2001); *see also* U.S. CONST. art. II, § 1, cl. 8; U.S. CONST. amend. 10.

102 CHEMERINSKY, *supra* note 101, at 91.

103 *Id.*

104 U.S. CONST. art. I, § 8, cl. 3; Federal Food, Drug, and Cosmetic Act, Pub. L. No. 108-68, 52 Stat. 1040 (codified as amended in scattered sections of 21 U.S.C.); U.S. v. Walsh, 331 U.S. 432, 434 (1946).

105 Although the FDA does not mandate labeling of GM products, it has the statutory authority to do so. McGarity, *supra* note 32, at 459-63. The FDA's substantial equivalency assumption directly impacts its decision that GM foods generally do not need to be labeled, in that the FDA maintains that GM foods do not have any material changes that foods derived from traditional breeding methods do not also have. For the text of 21 U.S.C. § 321(n), see *infra* note 151. In its 1992 Statement of Policy, the FDA says that "the new techniques are extensions at the molecular level of traditional methods" and that "[t]he agency is not aware of any information showing that foods derived by these new methods differ from other foods in any meaningful or uniform way, or that, as a class, foods developed by the new techniques present any different or greater safety concern than foods developed by traditional plant breeding," thus concluding that "the agency does not

GM foods is to be mandated, Congress would need to be convinced of its necessity and create legislation specifically requiring the FDA to generate such rules.[106] The main constitutional concern Congress would encounter if it decided to mandate labeling of GM food products would be that such legislation would violate the First Amendment, which protects commercial speech.[107]

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believe that the method of development of a new plant variety (including the use of new techniques including recombinant DNA techniques) is normally material information within the meaning of 21 U.S.C. 321(n) and would not usually be required to be disclosed in labeling for food." Statement of Policy: Foods Derived From New Plant Varieties, 57 Fed. Reg. 22984, 22991 (May 29, 1992) [hereinafter *May 1992 Policy*].

In a subsequent statement made in 2001 the FDA concluded that "[w]e are still not aware of any data or other information that would form a basis for concluding that the fact that a food or its ingredients was produced using bioengineering is a material fact that must be disclosed under sections 403(a) and 201(n) of the act." Draft Guidance for Industry: Voluntary Labeling Indicating Whether Foods Have Not Been Developed Using Bioengineering, 66 Fed. Reg. 4839, 4840 (Jan. 18, 2001) [hereinafter FDA, *Draft Guidance*]. However, if the FDA chose to do so, it clearly has authority to mandate the labeling of GM foods. McGarity, *supra* note 32, at 459-63; Alicia T. Simpson, Note, *Buying and Eating in the Dark: Can the Food and Drug Administration Require Mandatory Labeling of Genetically Engineered Foods? Alliance for Bio-Integrity, Et. Al. 116 F. Supp. 2d 166 (2000)*, 19 TEMP. ENVTL. L. & TECH. J. 225 (2001) (concluding that the FDA currently has the authority to label genetically engineered foods based on the application of the FDA's "materiality test").

For example, when considering whether irradiated food should be labeled, the FDA was primarily concerned with what information the public thought was important. McGarity, *supra* note 32, at 459. The FDA has not distinguished why it would not use this same reasoning with GM foods in which the public is also concerned. *Id.* This ambiguity is "very aggressive reliance on the substantial equivalence principle" and "effectively deprives consumers, who are likewise unaware of practical methods to assess the allergenic potential of such foods, of the option of playing it safe by avoiding such foods." *Id*. at 460. Furthermore, the decision in *Alliance For Bio-Integrity* allows, though does not require, the FDA to mandate labeling if genetic modification results in any "uniform changes" to food. *Id.* at 462. This opinion essentially allows for labeling of any GM food because most GM plants are changed in some way by the GM process. *Id*. Instead, the only mandatory labeling required by the FDA of GM foods is the same as that of other foods; in 2001, the FDA made clear that special labeling is mandatory where absence of material information poses health or environmental risks, misleads the consumer based on statements made on the label, or misleads the consumer on the nutrition based on its similarity to another food. FDA, *Draft Guidance, supra*, at 4840. Yet, the effects of mandatory special labeling is minimal because the FDA still assumes that GM products are GRAS. *May 1992 Policy, supra,* at 22988.

106 *See infra* Part III.A.

107 If the government were to force disclosure of GM foods, it is possible that companies would not contest the regulation because of any negative attention they could receive. However, it is just as possible that companies would challenge forced disclosure as the Supreme Court has established that the First Amendment generally protects the right to not speak. *See, e.g.,* Wooley v. Maynard, 430 U.S. 705 (1977) (finding unconstitutional New Hampshire's enforcement of a statute prohibiting people from covering the motto "Live Free or Die" on their license plates); Int'l Dairy Foods Ass'n v. Amestoy, 92 F.3d 67 (2d Cir.

Commercial speech is generally protected by the First Amendment under the theory that such speech promotes the free flow of information to consumers, particularly regarding consumer concerns that are basic to living.[108] However, the Supreme Court recognizes that commercial

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1996) (finding a Vermont statute requiring disclosure of the use of a GM hormone in milk violated the First Amendment right to not speak); U.S. v. Frame, 885 F.2d 1119, 1132-33 (3d Cir. 1989) (implicating the First Amendment, beef producers were required to help fund commercial advertisement of which they did not necessarily subscribe). Furthermore, the Court protects commercial speech, such as labels on products. *See supra* notes 108-22 (discussing compelled commercial speech).

[108] Commercial speech has not always been protected. *See* Valentine v. Christensen, 316 U.S. 52, 54 (1942) ("[T]he Constitution imposes no restraint on government as respects purely commercial advertising."). However, the Supreme Court eventually recognized that commercial speech is afforded protection under the First Amendment. *See* Bigelow v. Virginia, 421 U.S. 809, 825 (1975) (concluding that the Virginia courts erred in assuming that advertisements were not afforded any First Amendment protection).

The Supreme Court decided this protection of commercial speech was necessary so as to allow the free flow of information to the public, especially regarding those things essential to life. *See* Central Hudson Gas & Elec. Corp. v. Pub. Serv. Comm'n of New York, 447 U.S. 557 (1980). The Court said:

> Commercial expression not only serves the economic interest of the speaker, but also assists consumers and furthers the societal interest in the fullest possible dissemination of information .... Even when advertising communicates only an incomplete version of the relevant facts, the First Amendment presumes that some accurate information is better than no information at all.

Id. at 561-562; s*ee also* Zauderer v. Office of Disciplinary Counsel, 471 U.S. 626, 651 (1985) ("[T]he extension of First Amendment protection to commercial speech is justified principally by the value to consumers of the information such speech provides."). Also, the Court in *Bolger v. Youngs Drug Products Corp.* found that "[b]ecause the proscribed information 'may bear on one of the most important decisions' parents have a right to make, the restriction of 'the free flow of truthful information' constitutes a 'basic' constitutional defect regardless of the strength of the government's interest." 463 U.S. 60, 75 (1983) (citing Linmark Ass'n v. Willingboro, 431 U.S. 85, 95-96, 97 (1977)). In *Linmark Ass'n v. Willingboro* the Court found that an ordinance prohibiting homeowners from posting "For Sale," for the purpose of preventing panic selling on the part of white homeowners, was constitutionally defective because the prohibited advertising was of "vital interest" to residents and would "bear on one of the most important decisions they have a right to make: where to live and raise their families." 431 U.S. 85, 96 (1977).

In order to properly analyze speech's First Amendment protection from regulation, a court must determine the status of the speech in question. *See Bolger*, 463 U.S. at 65 ("Because the degree of protection afforded by the First Amendment depends on whether the activity sought to be regulated constitutes commercial or non-commercial speech, we must first determine the proper classification of the mailings at issue here."). If the Court finds that the speech is compelled commercial speech but is intertwined with non-commercial speech, the Court will apply the standard used for fully protected speech and thus the regulation will likely be considered content-based and struck down. *See* Riley v. Nat'l Fed'n of the Blind, 487 U.S. 781, 795 (1988) (stating that "[m]andatory speech that a speaker would not otherwise make necessarily alters the content of the speech" and is therefore "content-based regulation of speech"). However, speech that is inherently misleading is not afforded any protection at all. *In re R.M.J.*, 455 U.S. 191, 203 (1982).

speech is fundamentally different from other kinds of speech because it is motivated by profit, and therefore, the Court applies a less-than-strict scrutiny to commercial speech.[109] The Court developed the test for commercial speech in *Central Hudson Gas & Elec. Corp. v. Pub. Serv. Comm'n of New York*,[110] under which courts must determine the following: (1) whether the speech is concerning lawful activity and is not misleading,[111] (2) whether the government's interest is substantial,[112]

Furthermore, although the government may altogether prohibit misleading advertising, it "may not place an absolute prohibition on certain types of potentially misleading information . . . if the information also may be presented in a way that is not deceptive." *In re R.M.J.*, 455 U.S. at 203.

The Supreme Court in *Bolger* held that commercial speech encompasses more than just an advertisement, a reference to specific products, and economic motivation. *Bolger*, 463 U.S. at 65, 66-67 (1983). However, the combination of all these factors indicates that the speech is probably commercial speech. *See Bolger*, 463 U.S. at 66-67. Regarding advertisement, although the Supreme Court has defined commercial speech as expression that "propose[s] a commercial transaction," Erwin Chemerinsky suggests that commercial speech cannot just be advertisement because that would be both overinclusive (would include some political speech) and underinclusive (would not include direct solicitation by lawyers). CHEMERINSKY, *supra* note 101, at 1061.

Although the application of these criteria—whether it is an advertisement, a reference to a specific product, and whether there is economic motivation—to labeling is not clear, in *Rubin v. Coors Brewing Co.*, both parties agreed that beer labels indicating alcohol content are commercial speech. Rubin v. Coors Brewing Co., 514 U.S 476, 481 (1995). While not the same as promoting a particular product or service, labels "may affect purchasers in deciding whether to buy a particular product." CHEMERINSKY, *supra* note 101, at 1066. Therefore, if a label affords consumers more information regarding the product and seems to affect whether or not consumers buy the particular product, it seems that the label should be analyzed as commercial speech. *See, e.g., Amestoy*, 92 F.3d at 79-80 (Leval, J., dissenting) (describing why plaintiffs were erroneous in arguing that a sign informing consumers of the use of a GM hormone in the production of milk was fully protected speech).

[109] *Central Hudson*, 447 U.S. at 562-564. Under this test, the burden for justifying a regulation on commercial speech is on the party seeking to uphold the restriction. Edenfield v. Fane, 507 U.S. 761, 770 (quoting Bolger v.Youngs Drug Products Corp., 463 U.S. 60, 71, n.20 (1983) and citing Board of Trustees of the State University of New York v. Fox, 492 U.S. 469, 480 (1989)) ("It is well established that 'the party seeking to uphold a restriction on commercial speech carries the burden of justifying it.'").

[110] 447 U.S. 557 (1980).

[111] The First Amendment does not protect speech that concerns unlawful activity or speech that is misleading. *Central Hudson*, 447 U.S. at 563-64. In *Central Hudson*, the Court stated that "there can be no constitutional objection to the suppression of commercial messages that do not accurately inform the public about lawful activity" so that "[t]he government may ban forms of communication more likely to deceive the public than to inform it . . . or commercial speech related to illegal activity . . . ." *Id.* The government may also ban advertising that is true, but still misleading. *See, e.g.*, Friedman v. Rogers, 440 U.S. 1 (1979) (upholding a state law that prohibited optometrists from practicing and advertising under trade names because they offered no real information to the public but could be very misleading by attracting the public to a name that *was* associated with a particular optometrist but is no longer).

(3) whether the regulation directly and significantly advances the governmental interest asserted,[113] and (4) whether the regulation is not more extensive than is necessary to serve that interest.[114]

Furthermore, the Court's approach to regulations that do not limit speech but rather compel speech is different than the test articulated in *Central Hudson*.[115] According to *Zauderer v. Office of Disciplinary Counsel*,[116] although government *restrictions* on commercial speech may infringe the First Amendment because they impede information flow to consumers, government *compulsion* of commercial speech has just the opposite effect, increasing information flow to consumers.[117] The Court held that although "unjustified or unduly burdensome disclosure requirements might offend the First Amendment by chilling protected commercial speech . . . an advertiser's rights are adequately protected as long as disclosure requirements are reasonably related to the State's interests in preventing deception of consumers."[118] In applying this deferential standard, the Court in *Zauderer* upheld a state requirement that an attorney advertising services on a contingent-fee basis must also disclose to clients that they will still have to pay for costs even if their case is not successful.[119] Without this clarification, the advertising would

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112 *Central Hudson*, 447 U.S. at 566.

113 *Id.* Justice Stevens added that the regulation must *significantly* advance the government's interest. 44 Liquormart, Inc. v. Rhode Island, 517 U.S. 484, 506 (1996).

114 *Central Hudson*, 447 U.S. at 566. The fourth prong of the test is less than clear. In *Fox,* the Court explicitly said that a literal least restrictive means test was not necessary. Bd. of Tr[s]. of State Univ. of New York v. Fox, 492 U.S. 469, 477 (1989). In *44 Liquormart*, the Court basically applied a reasonableness standard. 517 U.S. 484 at 507. However, in *Rubin*, the Court again used the language found in *Central Hudson* and said that "a valid restriction on commercial speech" is "no more extensive than necessary to serve [the governmental] interest." Rubin v. Coors Brewing Co., 514 U.S. 476, 486 (1995).

115 *See supra* notes 116-20 and accompanying text.

116 471 U.S. 626 (1985).

117 *Compare supra* note 108 and accompanying text (describing how commercial speech has not always been protected, but the Supreme Court ultimately decided to protect it so as to allow the free flow of information to consumers), *with Zauderer*, 471 U.S. 626. The Court in *Zauderer* stated:

> [C]onstitutionally protected interest in not providing any particular factual information in . . . advertising is minimal. Thus, in virtually all our commercial speech decisions to date, we have emphasized that because disclosure requirements trench much more narrowly on an advertiser's interests than do flat prohibitions on speech, 'warning[s] or disclaimer[s] might be appropriately required . . . in order to dissipate the possibility of consumer confusion or deception.'

Zauderer, 471 U.S. at 651 (citing to In re R.M.J., 455 U.S. 191, 201 (1985)).

118 *Zauderer*, 471 U.S. at 651.

119 *Id.* 652.

be misleading and perhaps unprotected under the first prong of *Central Hudson*.[120]

Although *Zauderer* has implications in cases where further information is necessary to rectify incomplete, misleading commercial speech, the *Zauderer* paradigm arguably does not fairly describe all mandatory labeling of GM foods, especially unadvertised whole foods.[121] Thus the more stringent *Central Hudson* test may be more appropriate, which is the test used by the Second Circuit in *Int'l Dairy Foods Ass'n v. Amestoy*.[122]

In *Amestoy*, dairy manufacturers challenged a Vermont statute mandating labeling of milk containing the hormone rBST.[123] The district court denied the dairy manufacturers' motion for a preliminary injunction of the law, but the Second Circuit reversed, finding that the manufacturers would likely have success on the merits because the government did not have a substantial interest in requiring this regulation, and thus, the law would fail the second part of the *Central Hudson* test.[124] To justify this holding, the court noted that the only reason the government offered for mandating this labeling was "consumer curiosity," which the court said was not enough to overcome the First Amendment right to not speak because there was no indication of any real harm.[125]

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120 *See* note 111 and accompanying text (discussing the first prong of *Central Hudson*). Disclosure requirements are a less restrictive alternative to actual suppression on speech.[121]

See generally Int'l Dairy Foods Ass'n v. Amestoy, 92 F.3d 67 (2d Cir. 1996) (applying *Central Hudson*, not *Zauderer*, to a statute requiring milk producers to disclose milk containing the hormone rBST). *But see infra* note 277 (describing how even a generic labeling such as "apple" is arguably misleading because most people would not assume that the apple is a GM); *see also supra* notes 90-91 (showing that most people think they are not eating GM food).

122 92 F.3d 67 (2d Cir. 1996).

123 *Id.*

124 *Id.* at 73-74. This holding effectively nullified the law; it was terminated March 30, 1998 pursuant to 1993, No. 127 (Adj. Sess.), § 4, as amended by 1997, No. 61, § 272i.

125 *Amestoy*, 92 F.3d at 73-74. Regarding the right to not speak, the Second Circuit relied upon *Wooley v. Maynard*, 430 U.S. 705, 714 (1977) ("[T]he right of freedom of thought protected by the First Amendment against state action includes both the right to speak freely and the right to refrain from speaking at all."). The Second Circuit also relied upon *West Virginia State Bd. v. Barnette*, 319 U.S. 624, 633 (1943), and *Harper & Row, Publishers, Inc. v. Nation Entm't.*, 471 U.S. 539, 559 (1985). To justify the necessity of real harm, the court relied upon *Edenfield v. Fane*, 507 U.S. 761, 770-71 (1993) ("[A] governmental body seeking to sustain a restriction on commercial speech must demonstrate that the harms it recites are real and that its restriction will in fact alleviate them to a material degree.").

However, Judge Leval, in a dissenting opinion, found several flaws with the majority's reasoning.[126] First, he said that the court ignored evidence of the important governmental purposes for such labeling, which extended beyond just consumer curiosity to include consumer concerns regarding possible adverse health affects, health risks to cows, the economic impact on small dairy farmers from the increase in milk production, and philosophical objections to biotechnology made by the public.[127] Second, Judge Leval said that the majority took out of context the assertion made by the district court that the basis of passing the law was not health-related.[128] He explained that the context of the district court's statement indicated that the district court meant that because the state does not know what harm may be caused by rBST, the consumers' interest to know is not just based on curiosity, but rather is a real health-related concern.[129] Third, Judge Leval determined the majority was dangerous in suggesting that any concerns people may have regarding the health risks of rBST must not be real since the FDA has thus far found no health risks.[130] He noted that the biotechnological techniques used to make rBST are new and controversial, and although the FDA has done "thorough" testing on rBST, the testing has not been performed on a long-term basis and arguably not as thoroughly as necessary based on inadequate amounts of time, money, and scientific advancement.[131] Citing *Zauderer*, Judge Leval also pointed out that the purpose of protecting commercial speech is to increase disclosure, and that in this case, the manufacturers are "invok[ing] the Amendment's protection to accomplish exactly what the Amendment opposes."[132]

Amestoy raises the First Amendment objection a statute requiring labeling of GM products would likely face. Furthermore, the split between the majority and dissent in *Amestoy* parallels the differing approaches toward GM food taken by the governing forces in Europe and the United States.[133] The reasoning behind a government's

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126 *Amestoy*, 92 F.3d at 76-78 (Leval, J., dissenting).

127 *Id.* at 78.

128 *Id.* at 76. The statement the majority took from the district court is that the state "does not claim that health or safety concerns prompted the passage of the Vermont Labeling Law," but rather "bases its justification . . . on strong consumer interest and the public's 'right to know.'" *Id.*

129 *Id.*

130 *Id.*

131 *Id.* at 76-77. Judge Leval also noted that "[f]orty years ago, when I (and nearly everyone) smoked, no one told us that we might be endangering our heath." *Id.* at 77.

132 *Id.* at 81; *supra* note 108 and accompanying text (discussing the Court's purpose for extending First Amendment protection to commercial speech).

133 *See infra* Part II.D.1.

mandatory or permissive product labeling further clarifies the distinction between these differing approaches towards GM food.[134]

C. Reasons for Labeling

Essentially, products are either labeled because the government forces a company to do so or because a company volunteers the information.[135] Governments may force companies to label for various reasons, but to do so, the government, at least in the United States, must have statutory authority and be consistent with the First Amendment.[136] Furthermore, the government may have to regulate voluntary labeling in order to avoid misleading commercial information.[137]

1. Mandatory Labeling

Because markets never work as flawlessly as theory would suggest and never account for all of the concerns of humanity and society, government regulation of markets is sometimes necessary.[138] More specifically, the two main reasons governments regulate product labeling are to increase efficient information dissemination and to promote consumer protection.[139]

Governments may require companies to label their products in order to decrease the transactional costs involved with gathering information.[140] Businesses, and people in general, gather and rely upon information every day in order to make educated and resourceful purchasing decisions.[141] The economy is less productive if consumers have to bear all of the time and expense of gathering information.[142]

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134 *See infra* Part II.C.

135 *See infra* Parts II.C.1, II.C.2.

136 *See infra* notes 140-54 and accompanying text.

137 *See infra* notes 155-59 and accompanying text.

138 *See* JEFFREY L. HARRISON ET AL., REGULATION AND DEREGULATION: CASES AND MATERIALS 25-26 (West Publishing Co. 1997). *See also generally* JOSEPH E. STIGLITZ, THE ROARING NINETIES (2003) (explaining the relationship between government regulation in the United States and market behavior through the end of the twentieth century).

139 *See infra* notes 140-47 and accompanying text.

140 HARRISON ET AL., *supra* note 138, at 210.

141 *See, e.g.,* BizRate.com Comparison Shopping, *at* http://www.bizrate.com (last visited Jan. 10, 2005).

142 This inefficiency is evidenced by the fact that there are companies that collect and organize information that they sell to others. *See, e.g.,* Dublin Metadata Core Initiative, *at* http://dublincore.org (last visited Jan. 5, 2005). Dublin Metadata Core Initiative is an online company whose purpose is to categorize information by creating a "core set of semantics for Web-based resources" in order that information may be more readily retrievable. *Id. at* http://dublincore.org/about/history/ (last visited Jan. 5, 2005).

Therefore, it is in the government's best interest for information dissemination within the market to be as cost efficient as possible.[143] In order to lower the transactional cost of information gathering, the government has implemented regulations that place a degree of the duty to gather and disclose information on sellers and service providers.[144]

The second reason that governments regulate product labeling is to promote health, safety, and other consumer interests.[145] In situations where a product is questionable, rather than directly regulating the product, the government may require that companies label the product to disclose the potential danger, detriment, or concern.[146] This requirement not only informs the public of the potential problem, but also results in public pressure on companies to improve quality and safety.[147]

A recent example of the government mandating disclosure of information to the public regarding products is a final rule promulgated by the FDA on July 11, 2003.[148] This final rule states that as of January 1, 2006, *trans* fatty acids must be included on the nutritional label of foods so that consumers are better able to avoid ingesting too much of this

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143 HARRISON ET AL., *supra* note 138, at 210. Transactional costs are all the factors involved in actually making a transaction happen, including time spent negotiating, money spent in developing a product or idea and any other necessary efforts. *Id*. at 28-29.

144 *Id*. For example, car dealers are required to report expected gas miles of new vehicles, and many professionals are required to get certified or licensed. *Id*. at 29.

145 *See, e.g., infra* text accompanying notes 148-54 (discussing the FDA mandating labeling of *trans* fatty acids); s*ee also* Diane Thue-Vasquez, *Genetic Engineering and Food Labeling: A Continuing Controversy*, 10 SAN JOAQUIN AGRIC. L. REV. 77 (2000). For example, in the case of protein hydrosylates, the FDA mandated labeling based on possible religious or moral conflicts with consumption of milk-derived protein. *Id*. at 90; Food Labeling; Declaration of Ingredients, 56 Fed. Reg. 28592, 28,599 (proposed June 21, 1991) (to be codified at 21 C.F.R. pts. 101, 130, 131, 133, 135, 136, 137, 139, 145, 146, 150, 152, 155, 156, 158, 160, 161, 163, 164, 166, 168, and 169). Furthermore, in regards to labeling irradiated foods, the FDA said that "[w]hether information is material . . . depends not on the abstract worth of the information but on whether consumers view such information as important and whether the omission of label information may mislead a consumer." Food Labeling; Foods Derived From New Plant Varieties, 58 Fed. Reg. 25,837, 25,838 (Apr. 28, 1993) [hereinafter *Foods From New Plants*].

146 *See generally* Seema Arora & Timothy N. Cason, *An Experiment in Voluntary Environmental Regulation: Participation EPA's 33/50 Program*, 28 J. ENVTL. ECON. & MGMT. 271 (1995) (discussing an approach the EPA used to decrease industrial release of toxic substances through pressure created by increasing public awareness).

147 *See generally id.* (discussing an approach the EPA used to decrease industrial release of toxic substances through pressure created by increasing public awareness).

148 Food Labeling: Trans Fatty Acids in Nutrition Labeling, Nutrient Content Claims, and Health Claims, 68 Fed. Reg. 133, 414334, 41434, 41436 (July 11, 2003) (to be codified at 21 C.F.R. pt. 101) [hereinafter Labeling Trans Fatty Acids].

particular type of fat, as research suggests that *trans* fatty acids increase the risk of coronary heart disease.[149] In the commentary to its rule, the FDA addressed its statutory authority for making changes to the labeling requirements.[150] The FDA cited several statutes from the FFDCA and concluded that food labels not including information regarding *trans* fatty acids are misleading and misbranded and thus violate the Act.[151] In response to comments that this rule would violate the First Amendment, the FDA maintained that it is necessary that *trans* fatty acids be disclosed.[152] To not disclose this information would omit a material fact regarding the nutrition of a product, which would be misleading to consumers, whose assumption is that the nutritional label contains all of the information necessary to make decisions regarding the effect of the food on their health.[153] Thus, the FDA's rule requiring disclosure of *trans* fatty acids in food is an example of the government mandating labeling for the overall benefit of consumers; however, there are many instances in which companies are motivated to provide this type of information voluntarily.[154]

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149 Labeling Trans Fatty Acids, 68 Fed. Reg. at 41434, 41436.

150 *Id.* at 41437-38.

151 *Id.* Both 21 U.S.C. § 371(a) (2000) and 21 U.S.C. § 343(q)(2) (2000) vest general authority to the Secretary to enforce the act. 21 U.S.C. § 321(n), which helps define whether a label is false or misleading, provides:

> If an article is alleged to be misbranded because the labeling or advertising is misleading, then in determining whether the labeling or advertising is misleading there shall be taken into account (among other things) not only representations made or suggested by statement, word, design, device, or any combination thereof, but also the extent to which the labeling or advertising fails to reveal facts material in the light of such representations or material with respect to consequences which may result from the use of the articles to which the labeling or advertising relates under the conditions of use prescribed in the labeling or advertising thereof or under such conditions of use as are customary or usual.

21 U.S.C. § 321(n)(2000). The FDA concluded that because *trans* fat in foods may increase or decrease the consumer risk of developing Coronary Heart Disease, information regarding *trans* fat in food is material. Labeling Trans Fatty Acids, 68 Fed. Reg. at 41438.

152 *Id.* at 41439.

153 *Id.* One comment suggested that the cost of labeling to the companies may be an unjustified burden upon which the First Amendment imposes limitations because the rule does not "materially alleviate a genuine harm of potential consumer deception." *Id.* The FDA maintained that the omission of information on *trans* fatty acids would likely mislead consumers because the reasonable consumer would expect the FDA to provide this information. *Id.* This First Amendment conclusion by the FDA supports Judge Leval's dissenting opinion in *Amestory*. *See supra* text accompanying notes 126-32.

154 *See infra* Part II.C.2.

2. Voluntary Labeling

There are several reasons companies voluntarily give consumers information regarding their products.[155] One reason companies voluntarily label is to avoid tort liability by warning people of potential dangers or instructing them of the proper and improper uses of a product.[156] Another reason companies provide additional information is to promote features of their products that are attractive to some or all of their buyers.[157] This additional voluntary information can potentially be misleading, or at least ambiguously favorable to a company's interests or unfavorable to other companies' interests, and can result in unfair business practice.[158] Thus, the government not only compels information disclosure through regulation, but also regulates, to some extent, information that is voluntarily offered by companies.[159]

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155 *See infra* notes 156-59 and accompanying text.

156 *See* VINCENT R. JOHNSON & ALAN GUNN, STUDIES IN AMERICAN TORT LAW 688-92 (2d ed. 1999) (discussing several liability issues related to a company's failure to warn of any dangers related to its products).

157 For example, products may be labeled Kosher, environmentally friendly, non-toxic, organic, low-carb, sugar-free, fortified, or made of recycled paper. *See* My Kosher Food.com, *at* http://www.mykoshermarket.com (last visited Jan. 5, 2005); Printable Promotions, *at* http://www.printablepromotions.com/Articles/Green.htm (last visited Jan. 5, 2005) (promoting "Environmentally Friendly Promotional Products"); Safe 2 Use, *at* http://www.safe2use.com (last visited Jan. 5, 2005) (promoting environmentally and people-safe products including non-toxic products); Organics, *at* http://www.oraganic.com/ (last visited Jan. 5, 2005) (selling only certified organic products); Holsum, *at* http://www.holsumaz.com/breads-low-carb-buns.php (last visited Jan. 5, 2005) (advertising low carb buns); Candy Warehouse, *at* http://www.candywarehouse.com/sugarfreecandy.html (last visited Jan. 5, 2005) (advertising sugar free candy, but with the following disclaimer: "Consumption of sugar-free products may cause mild laxative effects. We recommend starting with a small serving size."); Fortified Products.com, *at* http://www.fortifiedproducts.com/fp_about.html (last visited Jan. 5, 2005) (stating that it is "in the business of fortifying and modifying different foods"); Treecycle Recycled Paper, *at* http://www.treecycle.com (last visited Jan. 5, 2005) (using the term "post-consumer waste" so often that they posted a notice that they would instead use the acronym "PCW" throughout their website).

158 *See, e.g.*, Ass'n of Nat'l Advertisers, Inc. v. Lungren, 44 F.3d 726 (9th Cir. 1994). The Ninth Circuit upheld a statute regulating different environmental labeling terms such as "biodegradable" and "recyclable," finding that the statute met the *Central Hudson* test because these terms had been used differently within the industry, creating confusion and the opportunity for abusive practices by businesses. *Id.* at 727-28, 737; *supra* notes 108-14 and accompanying text (regarding the *Central Hudson* test).

159 The extent to which the government should be allowed to regulate labeling in general is not without debate. *See* James O'Reilly & Amy Dalal, *Off-Label or Out of Bounds? Prescriber and Marketer Liability for Unapproved Uses of FDA-Approved Drugs*, 12 ANN. HEALTH L. 295, 297 (discussing the challenges the FDA faces in regulating off-label drugs as it tries to

D. Legal Issues Concerning Labeling GM Foods

The two major legal concerns regarding GM food labeling are whether labeling can be mandated and what types of voluntary labeling of GM foods can be allowed without being misleading.[160] On a global scale, the WTO is currently addressing whether labels on GM foods can be mandated.[161] Within the United States, the FDA has addressed how companies should label GM or non-GM foods in order to not mislead the public, and there has been at least one lawsuit regarding whether volunteered information on labels is indeed misleading.[162]

1. WTO Dispute and Mandatory Labeling

On August 8, 2003, the United States, together with Canada and Argentina, requested that the WTO establish a panel to address a matter entitled "European Communities—Measures Affecting the Approval and Marketing of Biotech Products."[163] The United States was concerned with a moratorium the European Communities had placed on the approval of agricultural biotechnology products in October of 1998.[164] This moratorium resulted in severe European restrictions of agricultural and food imports from the United States.[165]

In early July 2003, the European Parliament, in an attempt to bring an end to the moratorium, approved regulations to set up strict labeling

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balance the desires of special interest groups that more information be disclosed with the desires of drug marketers to be free from regulation).

160 *See infra* Parts II.D.1, II.D.2.

161 *See infra* Part II.D.1.

162 *See infra* Part II.D.2.

163 *European Communities – Measures Affecting the Approval and Marketing of Biotech Products – Request for the Establishment of a Panel by the U.S.*, WT/DS291/23 (Aug. 8, 2003) [hereinafter *EC – Request for Panel*]. The United States first brought this issue to the WTO on May 13, 2003 by requesting consultations on the issue. *European Communities – Measures Affecting the Approval and Marketing of Biotech Products – Request for Consultations by the United States*, WT/DS291/1 (May 20, 2003) [hereinafter *EC – Request for Consultations*]. Several other interested nations attended these consultations including Peru, Colombia, Mexico, Argentina, New Zealand, Australia, India, Canada, Brazil, and Chile. *European Communities – Measures Affecting the Approval and Marketing of Biotech Products – Acceptance by the European Communities of the Requests to Join Consultations*, WT/DS291/22 (June 19, 2003). The consultations failed to resolve anything, and the United States decided to go forward with filing a formal complaint with the WTO. Reuters, *U.S. to Seek WTO Ruling on Biotech Goods Ban*, LOS ANGELES TIMES, June 20, 2003, at 4.

164 *EC – Request for Consultation*, WT/DS291/1 (May 20, 2003). This moratorium was primarily the result of public pressure. *See supra* note 83 and accompanying text.

165 *EC – Request for Consultations*, WT/DS291/1 (May 20, 2003).

standards for GM foods.[166] The United States found that this attempt by the European Parliament did not alleviate the violation of trade agreements, and thus, went forward in requesting a WTO panel to address the issue.[167] The European Communities responded that its new rules were in full compliance with WTO rules.[168]

The United States alleges that the European Union is violating WTO law in three ways: by suspending consideration for application and granting of biotech imports, by blocking applications already in the approval process from final approval, and by allowing member states to ban or restrict national marketing and importation of biotech products.[169] The United States says that the European Union is violating the Agreement on Technical Barriers to Trade,[170] which does not allow for technical regulations to create unwarranted trade barriers.[171] Furthermore, the United States argues the European Union is violating the Sanitary and Phytosanitary Measures,[172] which requires:

> [Members of the WTO only take] measures to protect human life or health if based on scientific principles, and, if scientific information is not available, a member may adopt measures provisionally but must seek additional information within a reasonable time.[173]

Because the United States believes that it has already given the European Union a reasonable amount of time to seek additional information, the debate now comes down to current scientific

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166 John Rega, *EU Parliament Votes to Label More Gene-Altered Food*, BLOOMBERG NEWS, July 2, 2003, *available at* LEXIS, News Library, ALLBBN File.

167 *EC – Request for Panel*, WT/DS291/23 (Aug. 8, 2003); *see also* Rega, *supra* note 166. Bob Stallman, who is the head of the American Farm Bureau Federation, said of EU's new labeling laws, "It's commercially impossible to comply with the rule, it's not justified by any scientific analysis and it's just as WTO-inconsistent as the biotech ban that the EU says it will replace." Rega, *supra* note 166.

168 Dave Williams, *EU Rejects US Trade Suit Over GM Food*, MORNING STAR, Aug. 9, 2003, at 4. European commission spokeswoman Beate Gminder said: "We very much regret this decision . . . we think that our system of GMO authorisation is clear, transparent and non-discriminatory and complies with WTO rules." *Id.*

169 *EC – Request for Consultations*, WT/DS291/1 (May 20, 2003).

170 Agreement on Technical Barriers to Trade, Apr. 12, 1979, 31 U.S.T. 405.

171 *See* Stuart S. Malawer, *Put Down the Genetically Modified Tomatoes: It's No Time to Pick a Trade Fight over Biotech Foods*, LEGAL TIMES, Sept. 1, 2003, at 44.

172 Agreement on the Application of Sanitary and Phytosanitary Measures [hereinafter SPM Agreement], Apr. 15, 1994, arts. II and V (basic rights and obligations and assessment of risk).

173 *Id.; see also* Malawer, *supra* note 171, at 44 (explaining the basic contentions by the United States against the EU, and why this is a bad time to create a dispute).

information.[174] The international standard for determining the scientific validity of restrictions created by the European Union is the consistency of the restrictions with the standards suggested by the Codex Alimentarius Commission ("Codex").[175] The Codex has recently adopted risk assessment guidelines that include pre-market safety evaluations as well as systems that can trace foods, neither of which the United States currently implements.[176] Stuart S. Malawer, the Distinguished Service Professor of Law & International Trade at George Mason University's School of Public Policy, suggests that, based on the Codex as well as a number of other factors, the outcome does not look promising for the United States.[177] Still, the United States says that it has no choice but to take the case to the WTO, concluding that the trade barrier was still intact with these new rules.[178] Despite the fact that the European Commission has effectively lifted the ban, the United States has not withdrawn its dispute from the WTO.[179]

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[174] U.S. Agriculture Secretary Ann Veneman said, "We have been extremely patient with the Europeans for almost five years . . . . We have had exhaustive discussions with the Europeans and it is now time to let the dispute settlement process work." David Clarke, *Bush Cranks Up Efforts*, THE JOURNAL (Newcastle, U.K.), Aug. 11, 2003, at 1.

[175] Malawer, *supra* note 171. The Codex is an international organization created in 1963 by the Food and Agriculture Organization and the World Health Organization. *Id.*; *see also* SPM Agreement, art V.

[176] Malawer, *supra* note 171; Codex Alimentarius, *Current Official Standards*, *at* http://www.codexalimentarius.net/web/standard_list.do?lang=en (last visited Jan. 5, 2005) (providing the Principles for the Risk Analysis of Foods Derived from Modern Biotechnology, Guideline for the Conduct of Food Safety Assessment of Foods Derived from Recombinant-DNA Plants, and Guideline for the Conduct of Food Safety Assessment of Foods Produced Using Recombiant-DNA Microorganisms, in reference numbers CAC/GL 44, CAC/GL 45, and CAC/GL 46 respectively).

[177] Malawer, *supra* note 171. Other factors that Malawer pointed out that favor the EU are the labeling requirements that would allow for importation of these foods, the EU's 2002 regulatory framework, which the EU claims is based on scientific evidence, and the suit brought by the EU against eleven member states in July. *Id.*; Sara Lewis, *Failure to Apply Biotech Rules Lands 11 Member-States in Court*, FOOD CHEMICAL NEWS, July 28, 2003, at 1 (describing how the European Commission brought 11 member states to court for not adopting legislation regarding the deliberate release of bioengineered crops); *see also infra* note 179 and accompanying text (describing how the European Commission has already effectively lifted the ban).

[178] Clarke, *supra* note 174. The U.S. Trade Representative Robert Zoellick said that "[t]his trade barrier harms farmers and consumers around the world by denying them the benefits of productive, nutritious and environmentally friendly biotech products." *Id.*

[179] Jonathan Stearns, *Monsanto Moves Closer to Winning EU Rapeseed Approval*, BLOOMBERG NEWS, Dec. 20, 2004, *available at* LEXIS, News Library, ALLBBN File (describing how the moratorium has effectively been lifted as the European Commission has allowed the import of corn this past summer and rape-seed this winter). On November 2, 2004, the WTO postponed the estimated time for issuing final reports on the dispute until June of

The root of the problem between the United States and the European Union regarding GM foods and products is that the approach each takes to regulating such foods is dramatically different.[180] The approach taken by the United States is very lenient towards manufacturers of such foods so as to encourage scientific development, whereas the approach taken by the European Union is one of caution and suspect.[181]

The current regulatory scheme in the United States on GM foods, or more generally, for biotechnological research and products, is called the "Coordinated Framework for Regulation of Biotechnology."[182] Under this scheme, three agencies regulate biotechnology: the U.S. Department of Agriculture ("USDA"), the Environmental Protection Agency ("EPA"), and the FDA.[183] Generally, the role of the USDA is to regulate biotech plants.[184] However, if biotech plants produce pesticides, the EPA has primary control.[185] And not surprisingly, the FDA regulates food produced by GM plants.[186] Finally, producers of GM plants and foods retain an element of self-regulation.[187]

2005. *European Communities – Measures Affecting the Approval and Marketing of Biotech Products – Communications from the Chairman of the Panel,* WT/DS291/27 (Nov. 2, 2004).

[180] *See generally* Nathan W. Eckley, *Reaping the Benefits of Agricultural Biotechnology Through Uniform Regulation,* 35 J. MARSHALL L. REV. 433, 443-51 (2002) (describing how the regulatory systems of the United States and the EU are "out of tune" and suggesting a comprised "Hybrid International Regulatory System").

[181] *Id. Compare infra* text accompanying notes 187-203, *with infra* text accompanying notes 204-220.

[182] Coordinated Framework for Regulation of Biotechnology, 51 Fed. Reg. 23,302 (June 26, 1986).

[183] *See generally* Rebecca M. Braspies, *Consuming (F)ears of Corn: Public Health and BioPharming*, 30 AM. J. L. & MED. 371 (2004) (describing the current regulatory system for biopharming, concluding it is inadequate, and offering corrective changes to it). *See also* Marden, *supra* note 88, at 745-87 (describing the current administrative implementation of the policy for GM technology); Stanley H. Abramson & J. Thomas Carrato, *Crop Biotechnology: The Case for Product Stewardship*, 20 VA. ENVTL. L. J. 241, 245 (2001) (reviewing the government's oversight program of plant biotechnology).

[184] Abramson & Carrato, *supra* note 183, at 247 (describing the regulation of plants by the USDA and in particular by the Animal and Plant Health Inspection Service under the Plant Protection Act).

[185] *Id.* at 253-55 (describing the regulation of "pesticide-plants" by the EPA under the Federal Insecticide, Fungicide, and Rodenticide Act).

[186] *Id.* at 249-53 (describing the regulation of food by the FDA under the Food, Drug, and Cosmetic Act).

[187] *See id.* at 259-66 (describing the role of "product stewardship" in the regulation of the plant technology); *infra* note 194 and accompanying text (describing how the FDA allows companies to determine whether a product is GRAS or not). When the biotech leader, Monsanto, was first introducing its new GM science, it requested Vice President George Bush to regulate it so as to improve public trust. Eichenwald, *supra* note 82. That administration, as well as the two that followed it, made sure that Monsanto, a company

The authority for regulation of GM foods by the FDA, the agency most directly responsible for labeling foods, is governed by the FFDCA,[188] under which the FDA regulates "adulterated foods."[189] More specifically, the FDA asserts its power to regulate GM foods based upon its authority to regulate food additives.[190] The FDA characterizes many food additives as being "generally recognized as safe" ("GRAS"), in which case they are not subjected to formal review in order to be marketed.[191] The FDA's policy toward GM foods assumes substantial equivalency, and so essentially holds the position that there is no distinction between food resulting from genetic modification by conventional breeding and that done by genetic engineering.[192] Either way, the FDA assumes that the insertion of genetic material is GRAS.[193] Although the FDA encourages companies producing new foods to consult the FDA if it has a question regarding a new food's status,

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with deep ties to Washington, got exactly the regulation that it wanted: "If the company's strategy demanded regulations, rules favored by the industry were adopted. And when the company abruptly decided that it needed to throw off the regulations and speed its foods to market, the White House quickly ushered through an unusually generous policy of self-policing." *Id.*

188 Federal Food, Drug, and Cosmetic Act, Pub. L. No. 75-717, 52 Stat. 1040 (codified as amended in scattered sections of 21 U.S.C.).

189 McGarity, *supra* note 32, at 434. Adulterated foods include foods in which "any valuable constituent has been in whole or in part omitted or abstracted therefrom" and foods in which "any substance has been substituted wholly or in part therefor." 21 U.S.C. § 342(b)(1)-(2)(2000).

190 McGarity, *supra* note 32, at 436-37; *see also* 21 U.S.C. § 348(a)(2)(2000).

191 *May 1992 Policy*, *supra* note 105, at 22989. Cynthia D. Fisher suggests that when the FDA grants the GRAS exception, it violates the Due Process Clause of the Fourteenth Amendment by taking away the general public's right to know exactly what is in our food, a right that has been developed through a series of cases that establish personal autonomy of certain decisions regarding family, self, and private interests. Cynthia D. Fisher, Note and Comment, *The Genie Is out of the Bottle: Consumers Demand Mandatory Labeling on Genetically Engineered Foods*, 4 J. LEGAL ADVOC. & PRAC. 88, 116-119 (2002).

192 *May 1992 Policy*, *supra* note 105, at 22985 ("In most cases, the substances expected to become components of food as a result of genetic modification of a plant will be the same as or substantially similar to substances commonly found in food."); *see supra* notes 77-80 and accompanying text (discussing substantial equivalency); *supra* note 105 (stating that the FDA's substantial equivalency assumption directly impacts its decision that GM foods generally do not need to be labeled).

193 McGarity, *supra* note 32, at 440; *see also May 1992 Policy, supra* note 105, at 22988. Cynthia D. Fisher argues that genetic engineering is *not* just an extension of conventional breeding because traditionally the only organisms that have been crossed have been done naturally, whereas "genetic engineering ignores nature's *fundamental safeguard against genetic uniformity* . . . ." Fisher, *supra* note 191, at 91-92 (emphasis original).

companies ultimately decide themselves whether an additive is GRAS before the food goes to market.[194]

In 2000, in *Alliance For Bio-Integrity v. Shalala*,[195] over twenty scientists and religious leaders questioned the assumption by the FDA as depicted in its 1992 statement that transgenes are presumed to be GRAS.[196] Not allowing into the record any scientific documentation made after the 1992 statement regarding whether transgenes should be considered GRAS, the D.C. Circuit Court found that the FDA's GRAS assumption was not inconsistent with the statutory requirements of the FFDCA.[197] Following this decision, the FDA decided to hold public hearings to revisit the 1992 policy, after which it issued a new statement in which it proposed mandatory pre-market notification on the part of manufacturers.[198] At the present time, however, the 1992 policy is still in effect.[199]

The approach taken by the European Union and its member states is very different from that of the United States.[200] The major assumption of the European Union regarding GM foods could be described as the "precautionary principle," which basically maintains that "pro-active measures must be taken to reduce the risk of uncertain scientific

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194 *May 1992 Policy*, *supra* note 105, at 22989 ([T]he "FDA has traditionally encouraged producers of new food ingredients to consult with FDA when there is a question about an ingredient's regulatory status . . . even though such consultation is not legally required."). The goal of the most recent draft guidance released by the FDA on biotech food safety is simply to provide an optional scientific framework for evaluating the safety of new proteins in food early in the process. *See generally* Draft Guidance for Industry: Recommendations for the Early Food Safety Evaluation of New Non-Pesticidal Proteins Produced by New Plant Varieties Intended for Food Use, 69 Fed. Reg. 68381 (Nov. 24, 2004).

195 116 F. Supp. 2d 166 (D.D.C. 2000).

196 *Id*.; Alliance for Bio-Integrity, *Landmark Lawsuit Challenges FDA Policy on Genetically Engineered Food*, *at* http://www.bio-integrity.org/Lawsuit.html (last visited Jan. 5, 2005).

197 *Alliance For Bio-Integrity*, 116 F. Supp. 2d at 177-78. The court also found that the FDA was not required to label under the statute, nor was the 1992 statement by the FDA a violation of the Religious Freedom Restoration Act or free exercise of religion. *Id*. at 178-81.

198 McGarity, *supra* note 32, at 440; *see also* FDA, *Draft Guidance*, *supra* note 105; Christine Cochran, Note, *Premarket Notice Concerning Bioengineered Foods: A Proposed Regulation Satisfying Some of the Players, Some of the Time*, 12 WASH. U. J.L. & POL'Y 173 (2003) (discussing the proposal by the FDA and useful changes to it).

199 McGarity, *supra* note 32, at 441. As soon as the George W. Bush administration took over, Chief of Staff Andrew H. Card wrote a memo asking agencies to withdraw all proposed and final regulations not yet published, but the 1992 proposed policy regulations had already been published, and presumably will still be reviewed. *Id*.

200 *See* Eckley, *supra* note 180.

dangers."[201] Based on this assumption, the risk assessment conducted by the European Union on GM foods is very thorough and the regulation is extensive.[202]

The European Union's GMO legal framework has four main legal instruments, which regulate work on genetically modified microorganisms in closed environments, release of GMOs into the environment and placement on the market, the placing of GMO food or feed on the market, and the movement of GMOs between EU member states and third countries.[203] One of these legal instruments, Directive

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[201] Eckley, *supra* note 180, at 443. The precautionary principle is defined many ways along a continuum, where on the one end the term is defined in such a way that its impact is weak, so that anyone would accept it, and on the other end the term is defined so that the impact is strong, possibly requiring fundamental changes in regulation. Cass R. Sunstein, *Beyond the Precautionary Principle*, 151 U. PA. L. REV. 1003, 1011-12 (2003). Oftentimes Europe is seen as much more precautionary than the United States; however, there are many areas in which the United States is very precautionary "including particulate air pollution, mad cow disease in blood, youth violence, and terrorism." Jonathan B. Weiner, *Whose Precaution After All? A Comment on the Comparisons and Evolution of Risk Regulation Systems*, 13 Duke J. Comp. & Int'l L. 207, 209 (2003). Cass R. Sunstein argues that the precautionary principle should be abandoned altogether, "not because it leads to bad directions, but because, read for all that it is worth, it leads in no direction at all." Sunstein, *supra*, at 1004.

[202] *See infra* notes 203-14 and accompanying text (describing the extensive regulatory scheme of the EU); *see also* Annex II of European Parliament and Council Directive 2001/18/EC, 2001 O.J. (L106/1), *available at* Westlaw at OJ 2001 L106/1 (describing the step-by-step risk assessment process to be conducted on GMOs: (1) identify any characteristics of GMOs that may have adverse affects, (2) evaluate potential consequences of those adverse effects, (3) evaluate the likelihood that those adverse effects will occur, (4) estimate the risk, (5) apply management risk strategies from deliberate release, (6) determine the overall risk of the GMO); European Union, *Questions and Answers on the Regulation of GMOs in European Union*, Aug. 11, 2004, *available at* http://europa.eu.int/comm/food/food/biotechnology/gmfood/qanda_en.pdf [hereinafter EU, *Q & A*].

[203] EU, *Q & A, supra* note 207. The first instrument is Directive 90/219/EEC, as amended by 98/81/EC, which regulates work on GM microorganisms in closed environments such as laboratory research and work activities in laboratories. *Id.; see also* Council Directive 90/219/EEC, 1990 O.J. (L117/1), *available at* Westlaw at OJ 1990 L117/1; Council Directive 98/81/EC,1998 O.J. (L330/13), *available at* Westlaw at OJ 1998 L106/1. The second instrument, Directive 2001/18/EC, regulates the experimental release of GMOs into the environment and the placing of GMOs on the market. EU, *Q & A, supra* note 202; *see also* Council Directive 2001/18/EC, 2001 O.J. (L106/1), *available at* 2001 WL 301L0018 [hereinafter Directive 2001/18]. Regulation (EC) No 1829/2003, the third instrument, regulates the placing of GMO food or feed on the market. EU, *Q & A, supra* note 202; *see also* European Parliament and Council Regulation (EC) No1829/2003, 2003 O.J. (L268/1), *available at* Westlaw at OJ 2003 L268/1 [hereinafter Reg 1829/2003]. The fourth main instrument, Regulation (EC) No 1946/2003, regulates the intentional and unintentional movement of GMOs between EU member states and third countries. EU, *Q & A, supra* note 202; *see also* European Parliament and Council Regulation (EC) No 1946/2003, 2003 O.J. (L287/1), *available at* Westlaw at OJ 2003 L287/1.

2001/18/EC,[204] introduces the principles of environmental risk assessment.[205] This Directive also calls for member states to establish a regulatory scheme that mandates post-marketing monitoring requirements, mandates information to the public, and requires that member states ensure GM foods be labeled and traceable at all stages.[206] Member states must consult with Scientific Committees and consult with the European Parliament in determining whether to authorize the release of GMOs, with the possibility that the Counsel of Ministers could change the decision of a member state by a qualified majority vote.[207]

Not only is labeling part of Directive 2001/18/EC, but the European Union has also passed several more specific regulations regarding traceability and labeling of GM foods.[208] Regulation (EC) No 1830/2003 requires that the operator sending a product containing GMOs ensure to send the receiver of the product information, in writing, that the product contains GMOs.[209] A product containing GMOs must also have a unique identifier.[210] In the case that the product was produced by GMOs, the operator must transmit to the receiver of the product an indication of which ingredients or materials of the product were produced from GMOs, if the information is available, and otherwise to transmit the general message that the product is produced from GMOs.[211] For pre-packaged products containing or consisting of GMOs, the label on the product must have on its label the following: "This product contains genetically modified organisms" or "This product contains genetically modified organisms [name of organism(s)]."[212] Furthermore, products going to the final consumer that are not packaged must have information permanently and visibly displayed next to the product.[213] These labeling

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204 Directive 2001/18, *supra* note 203.

205 EU, *Q & A, supra* note 202; *see also* Directive 2001/18, *supra* note 203.

206 EU, *Q & A, supra* note 202; *see also* Directive 2001/18, *supra* note 203.

207 EU, *Q & A, supra* note 202; *see also* Directive 2001/18, *supra* note 203.

208 EU, *Q & A, supra* note 202; *see also* Directive 2001/18, *supra* note 203. Regulations are different from directives in that regulations are specific laws that govern every member state in the EU, whereas directives are objectives given to each member state that can be enforced in different ways by each member state. KLAUS-DIETER BORCHARDT, THE ABC OF COMMUNITY LAW 65 (2000).

209 EU, *Q & A, supra* note 202; *see also* Directive 2001/18, *supra* note 203; European Parliament and Council Regulation (EC) No 1830/2003 Amending Directive 2001/18/EC, 2003 O.J. (L268/24), *available at* Westlaw at OJ 2003 L268/24.

210 EU, *Q & A, supra* note 202; *see also* Directive 2001/18, *supra* note 203.

211 EU, *Q & A, supra* note 202; *see also* Directive 2001/18, *supra* note 203.

212 EU, *Q & A, supra* note 202; *see also* Directive 2001/18, *supra* note 203; Reg 1829/2003, *supra* note 203.

213 EU, *Q & A, supra* note 202; *see also* Directive 2001/18, *supra* note 203; Reg 1829/2003, *supra* note 203.

and traceability requirements would only apply to products containing GMOs in the amount of 0.9% and above.[214]

The European Union believes that its new labeling laws demonstrate that it has lifted the moratorium on GM foods, yet the United States has decided to continue to pursue the dispute against the European Union at the WTO because the United States believes the labeling restrictions are still too prohibitive to trade.[215] Because of the philosophical differences between the EU and U.S. systems, accord seems difficult. However, agreement is not impossible and a compromise on the part of the United States would reconcile many of the labeling discrepancies to the benefit of both the European Union and the United States.[216] Part IV of this Note discusses in greater detail how this reconciliation is possible.[217]

2. Voluntary Disclosure

Although the FDA does not currently mandate labeling of GM foods, it does give guidance as to how to label foods voluntarily in the Guidance for Industry Voluntary Labeling Indicating Whether Foods Have or Have Not Been Developed Using Bioengineering Draft Guidance ("Guidance").[218] The Guidance gives examples of how a company who wants to say that its product is genetically engineered may label the product in ways that are not misleading.[219] The Guidance also notes that most "consumers would prefer label statements that disclose and explain the goal of technology," such as, "This product contains high oleic acid soybean oil from soybeans developed using biotechnology to decrease the amount of saturated fat."[220] However, in describing the goal, the labels must not be misleading.[221] For example, if a label contains "These tomatoes were genetically engineered to improve

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214 EU, *Q & A*, *supra* note 202.

215 *See supra* notes 174-79 and accompanying text (describing the status of the current debate between the EU and the United States).

216 *See* Genetically Engineered Right to Know Act, H.R. 2916, 108th Cong. (2003). This bill would have mandated the labeling of GM foods. *Id*.

217 *See infra* Part IV.

218 *See generally* U.S. FOOD AND DRUG ADMINISTRATION CENTER FOR FOOD SAFETY AND APPLIED NUTRITION, Guidance for Industry Voluntary Labeling Indicating Whether Foods Have or Have Not Been Developed Using Bioengineering (2001), *available at* http://www.cfsan.fda.gov/~dms/biolabgu.html (last visited Jan. 30, 2004) [hereinafter *Guidance*].

219 *Guidance, supra* note 218. For example, a label could say "Genetically engineered" or "This product contains cornmeal that was produced using biotechnology." *Id*.

220 *Id.*

221 *Id.*

texture," the label would be misleading if the consumer would not be able to notice a textural difference.[222]

The Guidance also gives suggestions to companies that want to indicate to consumers that their product does not contain GM foods.[223] The FDA suggests that because many people do not know the acronyms GMO or GM, the label should spell out the meaning of this information.[224] The FDA also suggests that "GMO free" be avoided for several reasons besides its inclusion of an obscure acronym.[225] First, the phrase is not accurate because "genetically modified" is sometimes used broadly to include conventional methods of food production.[226] Second, most foods do not contain organisms, so it is inaccurate to indicate that a food product does not have organisms as it implies that some food products do have organisms. And finally, "free" implies "zero," which may be difficult to substantiate, and all claims on labels should be verifiable.[227] The FDA gives suggestions of what would be appropriate, including, "We do not use ingredients that were produced using biotechnology" or "This oil is made from soybeans that were not genetically engineered."[228] The FDA has further made clear that it does not want any label to mislead people into thinking that foods that are not genetically engineered are any better than those which are genetically engineered.[229]

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222 *Id.*

223 *Id.*

224 *Id.*

225 *Id.*

226 *Id.*

227 *Id.*

228 *Id.*

229 *Id.* ("[A] label statement that expresses or implies that a food is superior (e.g., safer or of higher quality) because it is not bioengineered would be misleading."). This approach by the FDA clearly leaves open the possibility of lawsuits against food producers wanting to show that their food is not GM. In fact, Monsanto brought just such a claim against Oakhurst Dairy in July of 2003, suing it for deceptive labeling practices. *See* Bruce Mohl, *Got Growth Hormones? Dairies Play on Fear in Marketing Milk Without the Additive*, THE BOSTON GLOBE, Sept. 28, 2003, at J1. Oakhurst Dairy put the following label on its milk: "Our farmers' pledge: No artificial growth hormones." *Id.* Monsanto claimed that the FDA has recommended that labeling regarding this hormone should contextually or explicitly indicate that there is no difference between use of the hormone or not, and because it does not do this, it is deceptive. Matt Wickenheiser, *Maine AG Steps in to Back Oakhurst*, PORTLAND PRESS HERALD, Aug. 28, 2003, at 1A. D. Mark Jackson, lawyer for the U.S. Department of Labor in San Francisco, argued that Oakhurst has a First Amendment freedom to disclose this information about their milk, and that it is not misleading because enough information calls into question the scientific safety of this milk. D. Mark Jackson, *Why the First Amendment Protects a New England Dairy's Right to Use a Milk Label Proclaiming Its Product to Be Growth-Hormone-Free*, FINDLAW, Aug. 14, 2003, *at* http://writ.corporate.

The FDA's approach to GM foods, including its position on voluntary labeling of GM foods, together with the approach taken by the European Union to mandate labeling of GM foods, are determinative to the conclusions that GM foods should be labeled and that labeling GM foods is consistent with the First Amendment.[230] Likewise, the public and scientific perceptions of GM foods as well as the general governmental purposes for labeling are also pertinent to the conclusion that GM foods should and may be labeled.[231]

III. ANALYSIS: THE UNITED STATES SHOULD MANDATE LABELING OF GM FOODS

In order for Congress to mandate labeling, it must have the constitutional authority to so legislate and the legislation must not be in conflict with any other constitutional doctrine or provision.[232] Congress has already created legislation that gives the FDA the necessary authority to mandate labeling of GM foods; however, it is not required to, nor does it, use this authority.[233] Therefore, because Congress has significant reasons for requiring the FDA to mandate labeling of GM foods, and doing so would not be counter to the First Amendment, it should pass legislation that would accomplish this goal.[234] However, in

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findlaw.com/commentary/20030814_jackson.html. Furthermore, consumer advocate Ralph Nadar said the suit is "frivolous harassing litigation" and provided free legal advice to Oakhurst through his foundation that supports free speech. Paul Livingstone & Matt Wickenheiser, *Nadar Enters Ring in Oakhurst Corner*, PORTLAND PRESS HERALD, Aug. 14, 2003, at 1A. In 1994 Monsanto sued dairy farmers in Texas and Illinois over this same issue, but settled after the companies changed their labels. Mohl, *supra.* Oakhurst Dairy and Monsanto eventually settled the case when Oakhurst Dairy agreed to add "used" to its label making it "Our farmers' pledge: No artificial growth hormones used" and included the disclaimer that the FDA has found no significant difference between cows treated with BST and those not treated with the hormone. *Beltway Notebook*, FOOD CHEMICAL NEWS, Jan. 5, 2004, at 5.

230 *See supra* notes 159, 166; *supra* Part II.D.2; *infra* Parts III.A, III.B.

231 *See supra* note 96 and accompanying text (regarding Americans wanting labeling of GM foods); *see infra* Parts III.A, III.B.

232 *See supra* text accompanying notes 101-03 (two-prong inquiry). Furthermore, in order for the FDA to make rules mandating labeling, it must consider both its statutory authority and the First Amendment. *See supra* note 150-53 and accompanying text (describing how the FDA addressed both the statutory authority and the First Amendment in determining that *trans* fats should be labeled).

233 *See supra* note 105 and accompanying text (describing the FDA's authority to require mandatory labeling and its refusal to do so).

234 *See infra* Parts III.A, III.B.

so doing, Congress should make sure the legislation correlates to the information available regarding GM foods.[235]

A. Establishing Statutory Authority

While the FDA continues to forgo the use of its authority to mandate labeling of GM foods, Congress could pass measures that would require the FDA to do so, and moreover, Congress *should* require the FDA to mandate labeling of GM foods, based on a myriad of substantial reasons.[236] First, legislation requiring mandatory labeling of GM foods would be economically beneficial for the United States because it would reduce the transactional costs involved in trying to obtain information regarding products that contain GM materials.[237] Currently, unless information is volunteered for marketing purposes, or unless consumers or producers of multi-ingredient products have leverage to contractually require producers to promise that their products will not contain genetic engineering, consumers have no way of knowing if foods are GM.[238] This lack of consumer power seriously limits manufacturers' incentive to produce the amount of food not containing GM materials that would be demanded in the United States and Europe if all GM information regarding foods were mandatorily disclosed. Full disclosure of this information is essential to encouraging free markets.[239]

Additionally, transactional costs could increase if the public's confidence in the FDA is undermined, which could occur if the FDA does not make GM labeling mandatory. Currently, Americans trust that the FDA is regulating food properly and disclosing pertinent information.[240] However, people also feel that GM food should be labeled accordingly.[241] And, people are generally unaware of the fact

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235 *See infra* Part III.C.

236 *See supra* note 105 and accompanying text (describing the FDA's authority to require mandatory labeling and its refusal to do so); *supra* note 88 (listing several expired bills that would have regulated GM foods); *infra* text accompanying notes 237-68.

237 *See supra* text accompanying notes 138-44 (regarding disclosure decreasing transactional costs).

238 *See supra* note 88 and accompanying text (listing many companies that are pledging to not use GM foods); *supra* Part II.D.2 (discussing the Guidance on how to properly volunteer information about genetic engineering on a product); *supra* note 83 (describing how McDonald's has a contract with farmers in which the farmers are not to use GM products).

239 *See supra* Part II.C.1 (discussing why governments mandate labeling).

240 *See supra* note 94 and accompanying text (regarding general trust in the FDA regulation of GM foods).

241 *See supra* note 96 and accompanying text (describing the general view of Americans that GM foods should be labeled).

that much of the food that they are and have been consuming is GM.[242] If people begin to become educated on this fact, and that education is not by the FDA, they will foreseeably lose confidence in the FDA.[243] Consequently, the public will feel that if it wants trustworthy information, it has to find it on its own, which would increase transactional costs within the market.[244]

Moreover, by mandating labeling of GM foods, the United States would smooth the progress of international trade, which would help resolve the dispute with the European Union.[245] If the United States were to require labeling, it could be in compliance with the directives set forth by the European Union, dissipating the current dispute between the United States and the European Union.[246] The decision that the WTO renders regarding this dispute will affect whether or not the United States has the option to label products going to Europe, though it will not necessarily resolve whether or not it is wise for the United States to do so.[247] Presumably, if the WTO finds that the ban has been lifted and that the labeling laws are legitimate, the United States will have to comply if it desires to legally sell food in Europe.[248] If, however, the WTO finds that the labeling is still effectively a moratorium, the result might still be less than desirable for the United States because many Europeans may just stop buying *all* food from the United States so as to not risk buying GM foods.[249]

Furthermore, a decision rendered against the European Union would leave an indelibly negative mark on Europeans' view of the United States. Although the release of GM foods into the market is only

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242 *See supra* text accompanying notes 89-92 (describing how Americans generally do not know they are eating GM foods).

243 The FDA required disclosure of irradiated foods because of consumer concern and consumer expectations of the FDA. *See supra* notes 105, 145. The need for transparency in regulation is essential to generating public trust. McGarity, *supra* note 32, at 477-78. However, currently the FDA is not transparent as is demonstrated by its policies limiting participation by and notice to the general public. *Id*. at 478.

244 *See supra* text accompanying notes 138-44 (regarding disclosure decreasing transactional costs).

245 *See infra* text accompanying notes 245-54 (describing the potential for better trade relations with the EU).

246 *See supra* text accompanying notes 200-214 (describing the EU's labeling requirements).

247 *See supra* Part II.D.1 (depicting the United States-EU dispute at the WTO).

248 *See supra* text accompanying notes 200-214 (describing the EU's labeling requirements).

249 This proposition is not unrealistic given the strong and active public sentiment against GM foods in Europe. *See supra* notes 82-84 and accompanying text.

one of many trade disputes that the United States currently has with Europe, unlike trade conflicts between the United States and Europe on other products, food is much more personal to the Europeans and also, more visibly affects every European.[250] Not only are Europeans greatly concerned with food as a tradition, many also have heightened moral interests and are perplexed with the many other complicated implications of allowing this food.[251] This concern has resulted in grassroots action that the European politicians have been unable to ignore.[252] Consequently, it seems unwise for the United States to be heavy-handed with Europe on this particular trade issue.[253] If, on the other hand, the United States decides to require full discloser, it might eventually find that it is able to gain the trust of the European people regarding GM products.[254]

Another reason policy makers should seriously consider requiring the labeling of GM foods is that polls make clear that people in the United States believe this type of information should be revealed.[255] For that very reason, the FDA required that irradiation of foods be disclosed—consumers thought the information was important.[256] Similarly, the FDA should also disclose information as to whether food is GM.

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[250] *See* Tony Capaccio, *EADS Dispute Could 'Taint' Tanker Contest, Roche Says*, BLOOMBERG NEWS, Jan. 6, 2005, *available at* LEXIS, News Library, ALLBBN File (describing the debate between the EU and the United States over government aid to plane makers); *New Report Points to a Number of "Significant" US Trade Barriers*, EUROPEAN REPORT, Dec. 24, 2004, at 2924 (describing EU's 20th annual report on U.S. trade barriers noting that the United States has a long way to go in removing obstacles to transatlantic trade); Greider, *supra* note 82 (quoting Jeremy Rifkin who explains why biotech companies are having such a difficult time in Europe).

[251] *See supra* notes 70-73 and accompanying text (elaborating on an AEBC report).

[252] *See supra* text accompanying note 83 (describing successful grassroots pressure in the United Kingdom).

[253] *See supra* notes 82, 177.

[254] *See supra* note 84 and accompanying text (showing that European faith in GM foods is not increasing). Thomas N. Urban, retired chairman and chief executive of Pioneer Hi-Bred International, explains:

> Monsanto forgot who their client was . . . . If they had realized their client was the final consumer they should have embraced labeling. They should have said, 'We're for it.' They should have said, 'We insist that food be labeled.' They should have said, 'I'm the consumer's friend here.' There was some risk. But the risk was a hell of a lot less.

Kurt Eichenwald, *Redesigning Nature: Hard Lessons Learned: Biotechnology Food—From the Lab to a Debacle*, THE NEW YORK TIMES, Jan. 25, 2001, at A1.

[255] *See supra* note 96 and accompanying text (stating that Americans want GM foods to be labeled).

[256] *See supra* notes 105, 145 (describing FDA's approach toward irradiated foods).

The reasons people want to know information about GM foods lend support to why Congress should require the FDA to mandate the labeling of GM foods.[257] Some people, such as the mother of the allergy-plagued son described in the introduction of this Note, want to know because they are concerned about possible adverse health affects.[258] Although biotech companies argue that science has not shown any health problems related to the genetic modification of foods, science has also not shown that health problems are out of the realm of possibilities.[259] In fact, these new techniques may be creating more detrimental allergies without detection.[260] The safety and long-term effects of genetic modification are simply unknown, and it is a logical fallacy to think that, because nothing indicates harm thus far, safety can be assumed.[261] Thus, at the very least, people should be informed that what they are consuming is new, because the safety of these foods has not been proven by science.[262]

In addition to concerns about health, some people want to know about genetic modification because of personal beliefs.[263] Some are morally opposed to genetic modification.[264] For others, their religious

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[257] *See infra* text accompanying notes 258-67.

[258] *See supra* notes 47-54 and accompanying text (describing health related concerns).

[259] *Compare supra* note 59 and accompanying text (describing how some scientists believe GM foods are more beneficial than conventional foods) *with supra* notes 47-54 and accompanying text (describing possible health risks).

[260] *See supra* notes 50-52 and accompanying text (regarding allergies).

[261] *See supra* note 127 and accompanying text (containing Judge Leval's argument for caution); *supra* note 201 and accompanying text (regarding the precautionary principle). In addressing the logical fallacy issue, Dr. Winfriend Corduan of Taylor University says:

> We must be careful to avoid the fallacy of "appeal to ignorance" (ad ignorantium): X has not been proven; therefore X is false; or X has not been disproven; therefore X is true. So, science cannot take the absence of proof or disproof to be an indicator of truth or falsehood, per se.

Email from Dr. Corduan, Professor of Philosophy and Religion, Taylor University (Oct. 6, 2003, 14:29:54 CST) (on file with author). Dr. Corduan qualifies this logical argument by explaining that scientific claims are not made in isolation but are made within entire systems of knowledge that are assumed without scientific proof. *Id*. For this reason, it would be reasonable for a scientist to assume that atoms in Portugal behave in the same way as those in Spain without empirical evidence. *Id*. It would also be reasonable to assume that one need not believe a claim that the earth has a second moon without empirical evidence. *Id*.

[262] *See supra* notes 47-54, 62-68 and accompanying text (regarding possible health and environmental problems with GM foods).

[263] *See supra* notes 69-76 and accompanying text (describing personal belief objections to GM foods).

[264] *See supra* notes 71-73 and accompanying text (describing moral objections to genetic engineering, particularly of animals).

beliefs are in conflict with genetic modification.[265] And still others have misgivings based on philosophical ideas or concerns for the environment.[266] It is unreasonable that many people have belief-based objections to GM foods and yet are denied access to information on GM foods, even when food is so basic and necessary to survival that it is unavoidable.[267] Although the reasons Congress should require the FDA to enforce mandatory labeling of GM foods are many, Congress must ensure that labeling of GM foods be done carefully so as to avoid infringement on First Amendment rights to free speech.[268]

B. The First Amendment Does Not Hinder Mandatory Labeling of GM Foods

Mandatory labeling of GM foods is essentially compelled commercial speech.[269] The Court in *Zauderer* used a very deferential standard for compelled commercial speech where a state required disclosures be added to existing marketing information provided by an advertiser because that information would otherwise mislead the

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[265] *See, e.g., supra* note 72 (describing Buddhist objections to genetic engineering).

[266] *See supra* notes 69, 74-80 and accompanying text (describing several ideological objections).

[267] McGarity, *supra* note 32, at 500-01. McGarity argues that consumers should be informed on the food they are eating and be aware of any risks even if insignificant, rather than having to trust paternalistic companies. *Id*. Consumers should have this knowledge in case they have belief-based reasons to object. *Id*. Furthermore, these foods should be labeled so that epidemiologists can study the effects on populations exposed versus populations not exposed. *Id*. Dr. Marc Lappe agrees with Paul Thompson of Purdue that consumers' rights to get out of the system if they are opposed to GM foods is penultimate. Lappe, *supra* note 53, at 40. Diane Thue-Vasquez explains some of the controversies surrounding the issue of labeling GM foods as of 2000, and concludes that labeling GM foods is ethically required. Diane Thue-Vasquez, *Genetic Engineering and Food Labeling: A Continuing Controversy*, SAN JOAQUIN AGRIC. L. REV. 77 (2000).

[268] *See, e.g., supra* notes 152-53 and accompanying text (describing how the FDA addressed First Amendment concerns when mandating *trans* fatty acid labels).

[269] Both *Bolger* and *Rubin* establish a strong argument that GM labeling is commercial speech, particularly in light of the indicators discussed in *Bolger*—advertisement, referencing specific products, and economic motivation. *See supra* note 108 (describing how the Court has defined commercial speech). First, GM labeling is, or could be, advertisement in many cases. In fact, the FDA gives directions to companies on how to label their GM products for advertisement purposes. *See supra* Part II.C.2. However, even where labeling of GM foods is not for the purpose of advertisement, GM labeling may still be commercial speech. *See supra* note 108. Second, labeling of GM foods would reference specific products—the food on which the labels appear. Finally, the main reasons that agricultural companies would not want to include this type of labeling—alarming consumers, impracticality of keeping crops separated, and frustrating biotechnology—are all primarily economically based. *See infra* text accompanying notes 296-99. In other words, labeling or not labeling specific information, such as GM or non-GM, bears on whether or not a consumer will purchase the product and on other financial considerations. *See supra* note 108.

consumer.[270] However, in the case of mandatory labeling of GM products, the government may be requiring disclosure of information where normally no information is provided at all, or where only the basic information is provided, and thus the labeling would not necessarily cure a problem of misleading advertising.[271] Therefore, the deferential *Zauderer* standard may be somewhat inappropriate for some labeling requirements of GM foods, especially where the foods are not already being advertised. The more stringent *Central Hudson* test will thus be utilized in this Note to determine the constitutionality of mandatory labeling of GM products.[272]

The first prong of the *Central Hudson* test, determining whether or not the speech concerns lawful activity and is not misleading, is difficult to apply to mandatory labeling.[273] A company arguing that a law mandating the labeling of GM foods violates the First Amendment would not be saying that the company should be free to speak about its product, but rather it would be arguing that the speech mandated by the government misleads consumers.[274] A court could respond to this argument by the company in any of the following ways: (1) the disclosure required by the statute is necessary to avoid speech that is misleading, (2) the disclosure required by the statute is itself potentially

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[270] *See* text accompanying notes 116-20.

[271] For example, tomatoes that are GM may be sold without packaging and simply placed in a store with a sign designating them as "tomatoes." Not designating the tomatoes as "GM tomatoes," though arguably misleading in that this information may be important to a consumer's decision to purchase or not, is not necessarily inherently misleading in the same sense as discussed in *Zauderer*. Unlike in *Zauderer* where the attorney's advertisement for contingency-fee-based representation, which inaccurately implied no costs to the client without success, not including "GM" with "tomatoes" does not somehow make the tomatoes not tomatoes. It simply makes them a different kind of tomatoes than what consumers likely expect. Of course, *Zauderer* may be more applicable for GM products that are truly a mix of two different species but are advertised using only the name of one of the species.

[272] *See supra* notes 123-34 and accompanying text (discussing *Amestoy*); *see also* Borgner v. Brooks, 284 F.3d 1204, 1206 (11th Cir. 2002) (applying the *Central Hudson* test to a state disclosure requirement that mandated dentists to include a disclaimer with any advertisement including specialty areas not recognized by the state or including non-state approved credentialing organizations).

[273] The Second Circuit did not address the first prong in *Amestoy*. However, had they addressed it, the outcome would probably have been the same because at that time the state law in Vermont was not congruent with the FDA on whether disclosure of the use of GM products is necessary. *Compare* Int'l Dairy Foods Ass'n v. Amestoy, 92 F.3d 67 (2d Cir. 1996), *with supra* text accompanying note 193 (regarding the FDA's decision that GM foods are GRAS).

[274] *See infra* text accompanying notes 296-99 (discussing potential arguments of biotech companies against legislation requiring labeling of GM products).

misleading, (3) the disclosure is not necessarily misleading nor is the disclosure required to avoid being misleading.

If a court were to conclude that the disclosure required by the statute is necessary to avoid a misleading message, it would uphold the statute since the First Amendment does not protect misleading speech.[275] If a court were to conclude the disclosure required by the statute itself might make the commercial message misleading, this threshold first prong would not bar a claim challenging the statute, and the court would continue the *Central Hudson* analysis, factoring in that the required disclosure is potentially misleading.[276] Finally, if a court were to find that the disclosure mandated by the statute has no effect on whether or not the commercial message is misleading, a claim challenging the statute would not be precluded nor would the first prong weigh against the government in the subsequent prongs of the *Central Hudson* analysis.

In addressing this first prong, courts should and most likely would give deference to the government and determine that without the mandatory disclosure the speech is misleading, if this were the government's basis for legislating.[277] Given this great deference, the

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[275] *See supra* note 111 (describing how the First Amendment does not protect misleading speech).

[276] Arguably, the court in *Amestoy* followed this approach, though the court never specifically discussed how the statute at issue faired under the first prong of *Central Hudson*, but just went on to strike the statute down under the rest of the *Central Hudson* analysis. *See* Int'l Dairy Foods Ass'n v. Amestoy, 92 F.3d 67 (2d Cir. 1996). This conclusion is implied by the court's conclusion that "[b]ecause Vermont has demonstrated no cognizable harms . . . its statute is likely to be held unconstitutional." *Id.* at 74.

[277] *See supra* text accompanying note 197 (describing how the D.C. Circuit Court reviewed the case against the FDA using only the scientific documentation to which the FDA had access when making its decisions).

Not disclosing the GM nature of foods is misleading because science has not yet determined the long-term effects of these products, people generally have no idea that they are eating these foods, and in general people believe that this information is important. *See supra* note 261 and accompanying text (explaining how not enough time has lapsed for science to conclusively determine that all GM foods are safe); *supra* notes 90-91 and accompanying text (showing that most people think they are not eating GM foods); *supra* note 96 and accompanying text (describing how people think this information is important). Even where companies who do not normally label the food at all, such as with whole foods, companies would not be able to avoid at least a general labeling of a product, such as "apple," in which case Congress or the FDA could still argue that to not say that the apple is GM is misleading, because most people would assume that it is not. *But see supra* notes 271-72 and accompanying text (describing how using *Zauderer* is less prudent for a statute mandating disclosure of GM foods than is *Central Hudson* because requiring labeling of GM foods would be requiring speech where none was previously made in the case of whole foods rather than regulating already existing speech).

inquiry would be over because misleading speech (or non-speech) is not protected and therefore the First Amendment claim against the statute would be refuted.[278]

However, the court may find that GM foods not labeled as such are not necessarily misleading. Currently, there is little if any proof that GM products are fundamentally altered to ultimately be harmful.[279] Rather, the basis of legislation mandating disclosure of the GM nature of foods is precaution: Sufficient time has not yet elapsed to confidently conclude that the alterations made to the foods will ultimately not be harmful.[280] Therefore, because science is not conclusive either way, a court could reasonably conclude that mandatory labeling of GM foods is neither necessary nor misleading and continue the *Central Hudson* analysis considering other factors.

Upon continuing the *Central Hudson* analysis, a court should find that mandatory labeling of GM foods satisfies the second part of the test, which requires the government to have a substantial interest in requiring disclosure of the GM status of foods.[281] The government has several substantial interests: reducing transactional costs—including decreasing the likelihood of increased transactional costs, eliminating trade issues with Europe, increasing European consumer confidence in GM products, and providing information consumers want to know and feel is important.[282] These interests are substantial because they affect

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One potential conflict arises where a state mandates speech requiring disclosure that the federal government explicitly concludes is not necessary to avoid misleading consumers. *See, e.g., Amestoy*, 92 F.3d 67 (2d Cir. 1996). However, the statute this Note proposes does not face this issue as it puts forth that the federal government, rather than states, should issue the statute requiring labeling of GM foods.

The problem of illegality is not present in this situation, however it could arise if the United States made any GM foods illegal. *See supra* note 88 (describing bills proposing tighter regulation); *supra* note 111 (describing how speech that encourages illegal activity is not protected by the First Amendment).

278 *See supra* note 111 (describing how the First Amendment does not protect misleading speech); *see also* Zauderer v. Office of Disciplinary Counsel of Supreme Court, 471 U.S. 626 (1985). The Court in *Zauderer* first determined whether the advertisements as presented without certain disclosures were misleading. *Id*. at 639-40.

279 *See supra* notes 54, 59 and accompanying text.

280 *See supra* note 132 (Judge Leval's argument for caution); *supra* note 261 and accompanying text (regarding the logical fallacy of assuming safety simply because there is no proof of harm).

281 *See supra* text accompanying note 112 (stating the second prong of the *Central Hudson* test).

282 *See supra* text accompanying notes 236-67 (describing reasons Congress should mandate labeling); *see also* Genetically Engineered Right to Know Act, H.R. 2916, 108th Cong. § 2 (2003).

fundamental aspects of American life in both financial and ideological ways.[283]

In light of these interests, the Second Circuit erred in *Amestoy* by holding that mandatory disclosure of a GM hormone in milk failed the second prong of the *Central Hudson* test.[284] First, the court overlooked many of the reasons offered by Vermont as to why the statute was substantially important when it concluded that Vermont's only purpose in requiring such labeling was "consumer curiosity."[285] The dissent in *Amestoy* made clear that Vermont did not just require labeling of GM hormones in milk to suffice consumer curiosity, but also because of the possible adverse health affects to people, health risks to cows, negative economic impacts, and philosophical objections—all clearly substantial reasons as they affect the life, liberty, and livelihood of the citizens of Vermont.[286] Second, the court in *Amestoy* was clearly wrong in not emphasizing the purpose of protecting commercial speech—to facilitate disclosure.[287] Although it may not be appropriate to use *Zauderer* exclusively to determine the constitutionality of mandatory labeling of all GM foods, the basic point it makes is certainly useful in this second prong of *Central Hudson*: Because the importance of disclosure was the reason the Supreme Court extended First Amendment protection to commercial speech in the first place, a law requiring disclosure of the GM status of foods would in no way conflict with that purpose, and in fact would promote it.[288]

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[283] Along these same lines, people have the right to know whether food is GM or not based on the Due Process Clause of the Fourteenth Amendment. *See supra* note 191 (describing Fisher's Fourteenth Amendment argument). Food is basic to life. The FDA has secured the faith of the people that it is properly regulating food in the United States and is providing the public with all material information regarding food. *See supra* note 94 and accompanying text. And yet, the FDA leaves a great deal of discretion up to biotech companies, who are self-interested rather than consumer interested. *See supra* text accompanying note 187 and note 194 and accompanying text. Also, the FDA does not require disclosure of any information regarding genetic modification, even though people obviously want it. *See supra* notes 96, 105 and accompanying text. This lack of disclosure is an omission of a material fact on an essential aspect of life—food. *See supra* note 191.

[284] *See supra* text accompanying note 124 (describing the holding in *Amestoy*).

[285] *See supra* text accompanying notes 125-32 (describing the dissent in *Amestoy*).

[286] *See supra* text accompanying notes 126-32; *supra* note 191 (containing Fisher's Fourteenth Amendment argument).

[287] *See supra* text accompanying note 132; note 108 and accompanying text (describing how commercial speech was originally protected because of the value of free flow of information).

[288] *See supra* text accompanying notes 116-20 (discussing *Zauderer*); *supra* note 108 and accompanying text (discussing the purpose of protecting commercial speech); s*ee also* Int'l Dairy Foods Ass'n v. Amestoy, 92 F.3d 67, 81 (2d Cir. 1996) (Leval, J., dissenting) ("They

Furthermore, the substantial interests raised by the government in *Amestoy* are even more significant today. Since *Amestoy* was decided in 1996, the undisclosed presence of GM foods has become a greater public concern.[289] Further scientific responses to GM foods also make it more obvious that its safety is contested within the scientific community.[290] Therefore, a court would have a much more difficult time overlooking and down-playing these concerns than did the court in *Amestoy*. Because the government will not be able to ignore the pressing concerns that genetic modification raises, and because mandatory labeling would only facilitate disclosure furthering the goals of the First Amendment, the government has a substantial interest in requiring disclosure of the GM status of foods.[291]

Mandatory labeling also survives the third prong of the *Central Hudson* test, whether the labeling would directly and significantly advance the government's interests.[292] One goal of the government is disclosure, which depends on truthful, accurate, and trustworthy information being presented to the public.[293] Requiring that companies themselves disclose the GM content of their own products would be the most effective and accurate way for the government to accomplish this goal.[294]

Nevertheless, biotech companies argue that the government's substantial interests would not be furthered for several reasons.[295] First, they argue that there is no legitimate reason to label GM foods because the foods are substantially equivalent, so labeling would just confuse or mislead the public into believing illegitimate fears regarding GM foods, rather than provide them with meaningful information.[296] Biotech

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invoke the Amendment's protection to accomplish exactly what the Amendment opposes."); Adrian Michael Simm, D.D.S. v. Louisiana State Bd. Of Dentistry, 2002 U.S. Dist. LEXIS 1299, * 19-20 (using *Zauderer* to inform the state's interest in a disclosure requirement it was analyzing under *Central Hudson*).

289 *See supra* note 96 and accompanying text (regarding polls indicating Americans' desire for disclosure).

290 *See supra* notes 77-80 and accompanying text (describing disagreement in the scientific community on the notion of substantial equivalence).

291 *See supra* text accompanying notes 237-68 (describing the reasons Congress should mandate labeling of GM foods).

292 *See supra* note 113 and accompanying text (the third prong of the *Central Hudson* test).

293 *See supra* text accompanying notes 139-47 (describing why governments mandate labeling in general).

294 *See supra* notes 140-44 and accompanying text (describing how the overall transactional costs are lowest when companies have the burden of providing information).

295 *See infra* text accompanying notes 296-99.

296 McGarity, *supra* note 32, at 499-500.

companies could also argue that the result of such labeling would be a loss in sales for U.S. farmers and food processors of GM products.[297] Furthermore, mandating labeling would be costly because it would require that GM foods be kept separate from non-GM foods throughout all stages of transport.[298] Finally, biotech companies could argue that the labeling of GM foods would just impede the progress of biotechnology.[299]

These arguments by biotech companies inaccurately describe the current status of GM foods as well as how labeling GM foods would actually affect the market. First, mandatory labeling of GM foods would provide meaningful information to consumers. Not all scientists agree with the FDA's assumption that all GM foods are GRAS.[300] Consumers, many of whom are also concerned with whether GM foods are in fact just like traditional foods, should not be forced to trust biotech companies, but should be made aware of *any* possible risks.[301] Furthermore, the public has concerns beyond just the equivalency of GM foods, and thus disclosure is important regardless of whether the end product is vaguely regarded as "substantially equivalent."[302]

Second, mandatory labeling would not necessarily result in the loss of sales for U.S. farmers and food processors. In fact, labeling in compliance with the European Union's standards may increase sales by U.S. farmers and food processors because it would help open the

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297 Carter, *supra* note 83 (describing how McDonald's has made it a policy to use only non-GM beef in Europe due to consumer concern).

298 McGarity, *supra* note 32, at 501.

299 An unidentified official from the U.S. government said that the new labeling laws of the EU "are calculated to frustrate the development of biotechnology." Brian McGee, *U.S. May Challenge New EU Gene-Label Rules at WTO, WSJ Reports*, BLOOMBERG NEWS, July 15, 2003, *available at* LEXIS, News Library, ALLBBN File.

300 *See supra* text accompanying notes 77-80 (discussion on substantial equivalence). The FDA most likely decided that GM foods are GRAS based on suggestions from biotech companies. *See supra* note 194 and accompanying text; *see also* McGarity, *supra* note 32, at 500.

301 *See, e.g.*, note 50 and accompanying text (describing allergens as a potential problem with GM foods).

302 *See supra* notes 69-80 and accompanying text (describing philosophical and moral objections to GM products). Although the precautionary principle more naturally leads to required disclosure, substantial equivalency need not necessarily preclude it, particularly in light of the non-health related concerns people may have regarding GM foods. *See supra* notes 69-80 and accompanying text.

European market to U.S. farmers and food processors, even for food that contains GM material.[303]

Third, the cost to producers to keep the foods separated would not be terribly difficult, as is currently demonstrated by organic farmers.[304] Also, this separation of GM foods from non-GM foods would help facilitate systems of tracking GM foods, which some scientists have suggested be created for monitoring purposes, and which the European Union has already implemented for GM products in Europe.[305] This type of system would help detect some of the potential long-term effects that no amounts of immediate testing would be able to provide.[306] Therefore, the additional transactional cost of keeping these foods separated is offset by the omission of the transactional cost that biotech companies should be paying in long-term pre-market testing expenses, but currently are not because they have instead decided to test their products out on the public.[307] The government should at least be able to track these foods so that it can obtain the results from the live testing. Furthermore, the reduction of other transactional costs relating to unimpeded information flow and consumer confidence in government regulation would outweigh any market damage resulting from requirements that companies keep GM foods separate from non-GM foods.[308]

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303 *See supra* text accompanying notes 245-54 (regarding tension between the United States and the EU).

304 McGarity, *supra* note 32, at 501; *see also supra* Part II.C.2 (demonstrating that the FDA gives guidance on voluntary labeling of GM foods, thus assuming that some companies are able to and do label as such).

305 *See* Genetically Engineered Pharmaceutical and Industrial Crop Safety Act of 2003, H.R. 2921, 108th Cong. (2003) (prohibiting the cultivation of genetically engineered pharmaceuticals in the open air and to create a tracking system to regulate pharmaceutical and industrial crops); *supra* text accompanying notes 57-58 (describing a method for facilitating future research on the effects of GM foods through a tracking system); *supra* text accompanying notes 208-14 (describing the EU's requirement that GM food not only be labeled, but also tracked).

306 *See supra* note 131 and accompanying text (describing Judge Leval's point regarding the newness of many biotech techniques). Some people argue that by approving GM foods based on analogy rather than testing, manufacturers treat humans like involuntary guinea pigs. McGarity, *supra* note 32, at 498. If this testing is going to take place, at the very least the products could be carefully monitored so that any future effects can be more clearly understood and remedied.

307 *See supra* note 111 and accompanying text (stating that misleading information has no First Amendment protection).

308 *See supra* note 143-44 and accompanying text (discussing how companies bearing the information burden is most economically efficient).

Finally, labeling would not necessarily impede the progress of biotechnology. On the contrary, labeling would more likely result in increased trust in the FDA and awareness by the public, who would have no reason not to support such efforts if the benefits to them would truly outweigh the risks.[309] If there are substantial risks that biotech companies just do not want to reveal, then the biotech companies' refusal to disclose operates as providing misleading information, which is not protected by the First Amendment in any case.[310]

Lastly, mandatory labeling survives the fourth prong of the *Central Hudson* test because the regulation would be no more extensive than is necessary to serve the government's interests.[311] Mandatory labeling would serve so many different substantial governmental interests that a biotech company would have a difficult time arguing that mandatory labeling is more extensive than necessary to serve all of those interests.[312] Basically, a successful argument would require independent showings that the government could achieve each of its substantial interests in some way besides mandatory labeling.[313]

It is unlikely that the biotech industry would be able to make these independent showings. First, the overall transactional costs would be decreased with mandatory labeling.[314] The only alternative to mandatory disclosure is voluntary disclosure based on market demand.[315] In fact, consumer demand has already resulted in many companies producing foods that are labeled "non-GM."[316] However, when these companies have tried to convey the message to consumers that their food is not GM, biotech companies have muscled lawsuits against them saying the message is misleading because there is no

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[309] People in the United States are generally not opposed to the idea of GM foods, and so unless there really is great danger, people would likely be fine with progress of GM technology. *See supra* text accompanying note 86. On the other hand, not much more damage could be done for the image of biotech companies in Europe, and disclosure would seem to be the first step towards gaining the trust of European people. *See supra* text accompanying notes 82, 254.

[310] *See supra* note 111 and accompanying text (stating that misleading information has no First Amendment protection).

[311] *See supra* text accompanying note 114 (the fourth prong of the *Central Hudson* test).

[312] *See supra* Part III.A.

[313] *See supra* text accompanying note 114 (the fourth prong of the *Central Hudson* test).

[314] *See supra* text accompanying notes 143-44 (discussing how overall it is most economically efficient for companies to bear some of the information burden).

[315] The biotech industry might argue that if enough consumers demand labeling of GM foods, then the market will supply them, as it did for Kosher and organic foods, and thus labels need not be mandated. McGarity, *supra* note 32, at 501.

[316] *See supra* note 88 (listing companies who provide non-GM foods).

difference between GM and non-GM foods.[317] Thus, this less restrictive alternative that is currently in place—allowing the market to dictate the information that companies disclose to the public—not only increases transactional costs, it also hinders the government's substantial interest in disclosing information to the public about which the public is concerned by inviting lawsuits.[318] This less restrictive alternative does not accomplish the government's interests, and thus, is not an alternative at all.

Next, there is no less restrictive way to eliminate trade issues regarding GM foods with Europe.[319] The only other way to eliminate these issues is to receive a decision from the WTO that Europe has to take the GM foods without restriction by labeling.[320] European consumers would still lack faith in U.S. produce and would only be purchasing from the United States out of necessity or lack of information. Even then, European countries could create and enforce place of origin labels and individual European consumers could simply ban *all* U.S. produce.[321] So, even if the WTO were to force Europe to take U.S. GM food products without labels, U.S. food would only be further undermined and the trade issues would not really be solved.

In sum, in applying the *Central Hudson* test to a statute mandating labeling of GM foods, any First Amendment conflict would be minimal at best.[322] The *Central Hudson* test is the most appropriate test to determine the constitutionality of mandatory labeling of GM foods.[323] The first part of *Central Hudson* either does not apply or would result in a favorable ruling for the government if an agricultural company questioned legislation mandating labeling.[324] The government has many substantial interests in requiring the disclosure of GM information,

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317 *See, e.g., supra* note 229 (describing the lawsuit Monsanto brought against Oakhurst Dairy).

318 *See supra* text accompanying notes 236-68 (describing the government's substantial interest in requiring disclosure).

319 *See supra* text accompanying notes 245-54 (regarding tension between the United States and the EU).

320 *See supra* text accompanying notes 247-49 (discussing how a WTO decision for the United States will not necessarily solve the problem).

321 *See supra* text accompanying notes 248-49; s*ee, e.g.,* Tariff Act of 1930, 19 U.S.C. § 1304 (2000).

322 *See infra* text accompanying notes 323-26; *supra* text accompanying notes 106-07.

323 *See supra* text accompanying notes 270-72 (describing how *Zauderer* might be applicable, but using the *Central Hudson* test for this analysis is more comprehensive).

324 *See supra* text accompanying notes 273-80 (discussing application of the first prong of *Central Hudson*).

which are directly and significantly advanced by disclosure.[325] And, the government has no less restrictive way to accomplish all of its goals.[326] Therefore, as long as the labeling mandated by the government is not misleading, it is reasonable to conclude that it would be upheld.

C. The Recently Expired Proposal for Labeling GM Foods

In 2003, the bill GERKA was proposed to the House of Representatives.[327] If enacted, this bill would have required the following additions to the FFDCA:

> (a) IN GENERAL- Section 403 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 343) is amended by adding at the end the following paragraphs:
>
> `(w)(1) If it contains a genetically engineered material, or was produced with a genetically engineered material, unless it bears a label (or labeling, in the case of a raw agricultural commodity, other than the sale of such a commodity at retail) that provides notices in accordance with the following:
>
> `(A) A notice as follows: 'GENETICALLY ENGINEERED.'
>
> `(B) A notice as follows: 'THIS PRODUCT CONTAINS A GENETICALLY ENGINEERED MATERIAL, OR WAS PRODUCED WITH A GENETICALLY ENGINEERED MATERIAL.'
>
> `(C) The notice required in clause (A) immediately precedes the notice required in clause (B) and is not less than twice the size of the notice required in clause (B).
>
> `(D) The notice required in clause (B) is of the same size as would apply if the notice provided nutrition information that is required in paragraph (q)(1).

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325 *See supra* text accompanying notes 281-310 (giving a summary of the government's reasons and accomplishments in requiring disclosure).

326 *See supra* text accompanying notes 311-21 (explaining how mandatory disclosure is the least restrictive way to accomplish the government's goals).

327 Genetically Engineered Right to Know Act, H.R. 2916, 108th Cong. § 2 (2003).

> `(E) The notices required in clauses (A) and (B) are clearly legible and conspicuous.[328]

The following label shows the relative sizes of information that the bill would have required:

GENETICALLY ENGINEERED

THIS PRODUCT CONTAINS A GENETICALLY ENGINEERED MATERIAL, OR WAS PRODUCED WITH A GENETICALLY ENGINEERED MATERIAL

Nutritional Facts

Serving Size ½ cup (31g)

Servings Per Container about 6

In addition to the requirement that foods containing GM products or that were created by GM processes contain this label, the bill provided that foods containing adventitious genetically engineered material would only be considered genetically engineered if it contained over one percent genetically engineered material.[329]

This bill was positive in many ways.[330] First, because the bill requires disclosure, it appropriately would reduce the transactional costs

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328 *Id.* § 3.

329 *Id.* Some other aspects to this bill worth noting include the following: it does not apply to restaurant food, it requires periodic testing of food to determine accuracy of labeling, and the consequence of misbranding is civil penalties. *Id.* Also, if this bill were enacted, it would require changes to the Federal Meat Inspection Act and the Poultry Products Inspection Act to ensure mandatory labeling of meat and poultry food if it contains genetically engineered material or if it was produced with genetically engineered material. *Id.* §§ 4-5.

330 *See infra* texts accompanying notes 331-35.

generated by inconsistent and voluntary labeling.[331] Second, the bill's one percent or less requirement for adventitious GM material is similar to the European Union's system of labeling, and thus is a step towards compliance with the European Union's requirements; however, updating the bill for compliance with European Union would require labeling of products containing 0.9% GMOs or greater.[332] Third, the bill's required disclosure for not only food that contains genetically engineered material but also food produced by genetic engineering, regardless of the presence of GM material, is a positive requirement for two reasons.[333] The European Union requires disclosure of foods produced by genetic engineering, so including similar disclosure in U.S. labeling laws helps make U.S. products comply with the EU requirements.[334] Also, this requirement not only accommodates those people who are opposed to the *presence* of GM material in their food, but also appeals to those people who oppose, for ideological reasons, the *process* itself.[335]

Despite the several advantages of GERKA, the bill did not satisfactorily achieve its main purpose—to accurately and completely inform consumers.[336] First, the bill should require that the label explain the goal of the GM technology used in the product, in accordance with the FDA's point that most people want to know this information.[337] This sort of explanation would more completely accomplish the government's goal of disclosure for those people who want to know more than just whether a product is GM.[338] For example, a label stating, "This product contains high oleic acid soybean oil from soybeans developed using biotechnology to decrease the amount of saturated fat," would inform a

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331 *See supra* text accompanying notes 158-59 (describing reasons for regulating voluntary disclosure).

332 *See supra* text accompanying note 214 (giving the EU percentage requirement).

333 *See* Genetically Engineered Right to Know Act, H.R. 2916, 108th Cong. (2003).

334 *See supra* text accompanying notes 211 (describing EU's disclosure requirement for foods produced using genetic engineering even if the food itself does not contain any GM product).

335 *See supra* notes 69-80 and accompanying text.

336 One aspect to the bill that may need to be changed, though not addressed in this Note, is the terminology used to disclose: "Genetically Engineered" is the proper terminology according to the FDA. *See supra* text accompanying notes 218-29. However, the language used by the European Union, at least in its English translation, uses "genetically modified," so if this bill is to have relevance in conforming U.S. law to that of the EU's, it may need to address this difference in wording if the European Union is as particular as the FDA about the wording. *See* EU, *Q & A, supra* note 202.

337 *See supra* text accompanying note 220 (regarding the FDA pointing out that most people want to know the goal of GM technology).

338 *See supra* Part II.C.1 (explaining the government's reasons for mandating disclosure); text accompanying note 220 (giving an FDA suggestion on how to provide the purpose).

consumer who is primarily concerned that the point of the genetic engineering is only to benefit a company's profits, that the point of the genetic engineering is also to directly benefit the consumer.[339] Furthermore, a person concerned about allergies or other adverse health effects related to GM foods could experiment with avoiding some, but not all, GM foods, based on the assumption that it is a particular modification that is causing an allergic reaction. A requirement that the label disclose contact information or an avenue to obtain more specific information would also help achieve the goal of increasing the amount of information available to consumers.

Furthermore, the bill should not require that "GENETICALLY ENGINEERED" be twice the size of the nutritional information.[340] This size requirement implies that the information is intended to serve as a warning rather than as a general disclosure. Because science is still not conclusive on the effects of GM foods, a warning is just as inappropriate as no disclosure at all.[341] Along the same lines, the bill should include a section requiring that a food producer who wants to label a food to indicate that it does not contain GM material must not suggest that the food is safer, unless validated by science.[342] This change would further clarify that the intent of the bill is not necessarily to serve as a warning.

Because science is not conclusive regarding the safety of GM foods, the purpose of requiring disclosure of GM food should be to provide the public with unbiased information. At this point, unbiased and meaningful disclosure would be the only way to avoid the First Amendment concern of misleading consumers.[343]

IV. MODIFICATIONS TO THE "GENETICALLY ENGINEERED RIGHT TO KNOW ACT"

A modified version of the "Genetically Engineered Right to Know Act" that conforms with the purpose of unbiased disclosure to the public

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339 *See supra* text accompanying 220 (giving an FDA suggestion on how to provide the purpose).

340 *See supra* text accompanying note 329 (stating the bill that would require "GENETICALLY ENGINEERED" be twice the size of nutritional information on the label).

341 *See supra* note 261 (describing Professor Corduan's analysis that care should be given to avoid a logical fallacy).

342 *See supra* text accompanying note 229 (explaining that the FDA does not want to mislead people into thinking that foods that are not GM are better than those foods that are GM).

343 *See supra* note 111 and text accompanying (stating that misleading information has no First Amendment protection).

should be introduced to Congress. Although the following modifications would not necessarily fulfill all the requirements of EU, in particular, it does not address requirements of traceability, it does address the primary labeling discrepancies between the European Union and the United States.[344]

First, a modified version of GERKA should require that the purpose of the modification be included in the disclosure. Second, the bill should require labeling and tracking of foods containing 0.9% GMOs or greater. Third, the bill should require that contact information be included so that consumers have a way to gather more information. Fourth, the bill should require that the disclosure be the same size as nutritional information, not twice as large. Fifth, the bill should include a section describing how manufacturers must label foods if they choose to indicate that they are not GM.

To effect these changes, § 3(a)`(w)(1) of GERKA should be changed to read:

> (a) IN GENERAL- Section 403 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 343) is amended by adding at the end the following paragraphs:
>
> `(w)(1) If it contains a genetically engineered material, or was produced with a genetically engineered material, unless it bears a label (or labeling, in the case of a raw agricultural commodity, other than the sale of such a commodity at retail) that provides notices in accordance with the following:
>
> `(A) A notice as follows: `GENETICALLY ENGINEERED.'
>
> `(B) A notice indicating the purpose of the genetic engineering.
>
> `(C) A notice offering a phone number, a mailing address, an email address, or an internet site through which more information can be obtained regarding the

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[344] *See supra* text accompanying notes 206, 208-14 (describing EU's requirements of traceability); *supra* note 88 (noting a bill parallel to GERKA offered in the House of Representatives in 2003 entitled Air Cultivation of Genetically Engineered Crops, H.R. 2921, 108th Cong. (2003), which would more appropriately address the issue of tracking GM products).

> product labeled, including information regarding the use of genetic engineering on the product.
>
> `*(D)* The notice required in clause (A) immediately precedes the notice required in clause (B) *and is the same size as the notice in (B).*
>
> `*(E)* The notices required in *clauses (A) and (B) are* of the same size as would apply if the notice provided nutrition information that is required in paragraph (q)(1).
>
> `*(F)* The notices required in clauses (A) and (B) are clearly legible and conspicuous.[345]

Commentary

The addition of section (a)`(w)(1)`(B) would accomplish the goal that the purpose of the modification be included in the disclosure. The addition of section (a)`(w)(1)`(C) would ensure that consumers have a way to gather more information. Finally, the modification to sections (a)`(w)(1)`(D) would decrease the size of "GENETICALLY ENGINEERED," so the label does not appear to be a warning. The following illustrates how the label would look with these modifications:

GENETICALLY ENGINEERED
This product contains high oleic acid soybean oil from soybeans developed using genetic engineering to decrease the amount of saturated fat.
For more information call 123-456-7890 or visit our website at www.company.com.

Nutritional Facts
Serving Size ½ cup (31g)
Servings Per Container about 6

[345] The proposed amendments are italicized and are the contribution of the author.

Furthermore, § 3(a)`(w)(6) of GERKA should be changed to read as follows:

> `(6) For purposes of this paragraph and paragraph (x), a food with respect to which a test has been identified under subparagraph (5) shall not be considered to contain a genetically engineered material if, as indicated by such a test--
>
> `(A) the food does not contain any genetically engineered material, or
>
> `(B) the food contains an adventitious genetically engineered material and the amount of the material in the food is *lower than 0.9 percent*, except that a lower percentage designated by the Secretary shall apply for purposes of this subparagraph if the Secretary determines that a test identified under subparagraph (5) can detect a percentage lower than *0.9* percent.
>
> `(x) If it bears a label indicating (within the meaning of paragraph (w)) that it does not contain a genetically engineered material, or that it was not produced with a genetically engineered material, unless the label is in accordance with regulations promulgated by the Secretary. With respect to such regulations:
>
> `(1) The regulations may not require such a label to include any statement indicating that the fact that a food does not contain such material, or was not produced with such material, has no bearing on the safety of the food for human consumption.
>
> `(2) The regulations may not prohibit such a label on the basis that, in the case of the type of food involved, there is no version of the food in commercial distribution that does contain a genetically engineered material.'
>
> `(3) The regulation must require that such a label not include any statement indicating or implying that a food product is more or less safe because it is or is not

> genetically engineered, unless such information can be substantiated by scientific research.[346]

Commentary

First, changing "one percent" to "0.9 percent" in section `(6)`(B) would bring U.S. GM products more closely in line with the EU standards.[347] Moreover, the change to `(x)`(3) would improve section `(x) by accomplishing disclosure of the most reasonable information to consumers based on present scientific information.

Section `(x)`(1) of the original GERKA correctly makes clear that companies who claim, through labeling, that their food is not genetically engineered, must not be required to also make a disclaimer that this has no bearing on the safety of the food. Such a disclaimer would be improper because it would require companies to make a conclusive statement that genetic engineering does not affect the safety of the product, backed only by a lack of scientific information saying otherwise. On the other hand, genetically engineered products are not necessarily unsafe just because science has not positively concluded safety. Therefore, in order to give consumers a more complete and accurate picture of the current status of scientific understanding, which is currently inconclusive but may become less so in the future, it is important that `(x)`(3) be added to prohibit labels from making any statements not substantiated by science.

V. CONCLUSION

Although the United States does not require GM foods to be labeled, it should require labeling of GM foods because doing so would inspire trust in consumers, who have legitimate reasons for desiring to know this information. Mandatory disclosure by the United States would not only provide information to consumers in the most efficient way, it would also create more uniformity with the laws of European countries, improving the United States's foreign trade relations. Although the expired bill, GERKA, correctly requires mandatory labeling of GM foods, its specific requirements insufficiently capture the proper goal of the bill, which is to accurately disclose information to consumers so that they might make educated decisions when purchasing food. However, by changing the size requirement of the information on the label, by

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346 The proposed amendments are italicized and are the contribution of the author.

347 *See supra* note 214 and accompanying text (describing how the EU regulatory laws require labeling and tracing of products with 0.9% GMOs or greater).

requiring the label to disclose the purpose for using particular genetic modifications and how to gain more information, and by prohibiting unsubstantiated assertions on the label, GERKA can be modified to meet this goal of providing consumers with accurate, non-misleading information. Furthermore, by changing the percentage of GMOs required for labeling to apply in order to conform with the European Union's standards, the bill would more completely open trade with the European Union. The proposed amendments are the most reasonable way of accomplishing these changes, and accordingly, would ensure that a congressionally proposed version of GERKA would successfully achieve the goal of educating consumers.

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