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ON TONIGHT'S MENU: TOASTED CORNBREAD WITH FIREFLY GENES?¹ ADAPTING FOOD LABELING LAW TO CONSUMER PROTECTION NEEDS IN THE BIOTECH CENTURY

We face a new situation in history. Ingenuity, striking hands with cunning trickery, compounds a substance to counterfeit an article of food. It is made to look like something it is not; to taste and smell like something it is not; to sell like something it is not, and so deceive the purchaser.²

Robert M. LaFollette

I. INTRODUCTION

Although it seems an exclusively contemporary concern, the effect of manufacturing processes on the food supply began a fierce debate over food quality and safety well over a century ago.³ This "pure food" movement generated harsh opposition to "false" foods such as glucose and oleomargarine, to the deceptive sale of oils and animal fats disguised as butter, and to the sale of cartons of milk and other foodstuffs whose contents were frequently substandard or rancid. The unsanitary and often revolting conditions of food handling, storage, and distribution at the turn of the century evinced a need for legal standards in regulating food quality and preventing "adulteration . . . of food and drink."⁴ These goals, aimed at ensuring consumer safety and informed

1. In a complaint filed last year against the FDA, consumer plaintiffs created a menu of currently marketed bio-engineered foods that are not being labeled as such. *Alliance For Bio-Integrity v. Shalala*, No. 98-1300 (D. D.C. filed May 27, 1998); see also Jeffrey Kluger, *Food Fight: The Battle Heats Up Between the U.S. and Europe Over Genetically Engineered Crops*, TIME, September 13, 1999.

2. JAMES HARVEY YOUNG, PURE FOOD 66 (1889) (quoting Cong. Rec., 49 Cong. I ses., 1886).

3. Food quality has always been subject to legal regulation. For example, from 1266 the Assize of Bread was involved in pricing and marketing of bread in England, setting standards for different varieties of product and levels of quality. For an overview, see Peter Barton Hutt, *A History of Government Regulation of Adulteration and Misbranding of Food*, 39 FOOD DRUG & COSM. L.J. 2, 15, n. 108 (1984). In colonial Virginia, a significant problem with adulteration of wine led to legally imposed penalties. See *id.* at 37.

4. Frederick H. Degnan, *The Regulation of Food Safety*, in 1 FUNDAMENTALS OF LAW AND REGULATION 162 (Robert P. Brady et al. eds., 1997).

purchasing, culminated in the Food and Drugs Act of 1906.⁵ The Act's provisions were broadly defined by the U.S. Supreme Court, which made it a useful tool for addressing the widespread problem of food adulteration.⁶ This success led to the passage of several subsequent food quality measures by Congress,⁷ including the Food, Drug, and Cosmetic Act of 1938 (the "FDCA"), which serves as the cornerstone for food labeling requirements.⁸

The primary emphasis of the FDCA is to penalize deceptive marketing practices and compel disclosure of pertinent information regarding food purchases. Through the FDCA, the government is vested with the power to take action against foods rendered unfit by filth, microbiological contamination, and other forms of spoilage.⁹ Additionally, "adulteration and misbranding"¹⁰ of food carries penalties including criminal prosecution and seizure or condemnation of the offending food product.¹¹

Despite the pervasiveness of their efforts, turn of the century lawmakers could not create legislation encompassing the dramatic changes in food production and distribution that are occurring in modern food markets because of biotechnology. The ability to make informed food purchases involving complex processes continue to be a

5. Pub. L. No. 59-384 § 7, 34 U.S. Stat. 768, 769 (1906). In fact, "... the battle of butter versus oleomargarine engrossed House members through nine straight days of debate, the first major consideration given by either House of Congress to a pure-food issue." See YOUNG, *supra* note 2, at 76.

6. See, e.g., *United States v. Lexington Mill & Elevator Co.*, 232 U.S. 399 (1914) (defining when an added ingredient renders food "injurious to health"); *United States v. Coca Cola Co. of Atlanta*, 241 U.S. 265, 284 (1916) (defining broadly the scope of "added ingredient").

7. See Food, Drug, and Cosmetic Act, § 406, 21 U.S.C. 346 (1938) (establishing *per se* rule against all unnecessary and avoidable poisonous and deleterious substances added to food); Pesticide Residues Amendment, 21 U.S.C. 364(a) (1954) (adding § 408 to regulate pesticide tolerance levels); Food Additives Amendment, 21 U.S.C. §§ 321s, 348 (1958) (defining "food additives" and providing for premarket approval except for GRAS); Color Additives Amendment, 21 U.S.C. §§ 321(t), 379e (1958) (subjecting all colorants to premarket regulation); Saccharine Study and Labeling Act, 21 U.S.C. §§ 321(z), 343(o) (1977) (moratorium on FDA ban of saccharine; requiring labeling of products); Dietary Supplement Health and Education Act, Pub. L. No. 103-417, 108 Stat. 4325 (1994) (excluding dietary supplements from definition of "food additive"); Nutrition Labeling and Education Act of 1990, Pub. L. No. 101-535, 108 Stat. 4325 (1994) (requiring standard-format nutrition labeling).

8. Food, Drug, and Cosmetic Act, § 406, 21 U.S.C. 346 (1938).

9. See Degnan, *supra* note 4, at 162.

10. *Id.*

11. *Id.*

primary concern despite modern production techniques. The variable factor in the modern age, however, is that the identification of "pure" butter, milk, fruits, and vegetables is no longer as clear as it was to the original "pure food" proponents. Additives, preservatives, novel ingredients, and biotechnology have blurred the pure food definition, a complication that will fuel debate as biotechnology takes a greater role in the food supply.

As the "biotech century" comes in,¹² consumers have already seen their local farmer, milk peddler, and butcher replaced by multinational producers and corporate-controlled agribusinesses.¹³ Over the past several years, these producers have brought whole and processed foods with manipulated genetic characteristics to consumers' tables. Few of these foods are labeled. Many of them have had little or no safety testing. Because of the novelty of biotechnology and the lack of regulation, many feel that these genetically-modified ("GM") foods present unacceptable risks to the consumer. This perspective is accompanied by calls for a complete ban on GM production, stricter testing for GM foods, or, at the very least, labeling of foods derived from GM crops so that consumers will be aware of what they are purchasing.¹⁴ However, current law is largely unresponsive to these calls. Little is done to address the concern over conflicting scientific findings and enable meaningful safety assessment of GM crops. Moreover, this lack of guidance can ultimately thwart independent initiatives to label GM foods.

The lack of a federal labeling scheme for GM foods creates a disjointed, ad hoc approach to their regulation, as legislatures, agencies, and courts struggle to address the complex issues that genetic engineering raises. Indeed, the lack of GM labeling requirements erodes the consumer protection mission of the FDCA by ignoring the question of how accepted food safety standards will evolve as biotechnology enters the marketplace. Additionally, the lack of federal guidance permits a mounting litigious battle in what can amount to little more than a propaganda war between GM corporations and their "organic" counterparts. A regulatory structure that monitors and labels GM foods will enable risk assessment, encourage the best use of this

12. JEREMY RIFKIN, *THE BIOTECH CENTURY: HARNESSING THE GENE AND REMAKING THE WORLD* (1998).

13. Major corporate agribusinesses include Novartis, Monsanto, Ceiba-Gigny, American Cynamid, and Upjohn. *See id.*

14. Frederick H. Degnan, *The Food Label and the Right to Know*, 52 *FOOD & DRUG L.J.* 49 (1997).

new and powerful technology, and ease the current consumer hostility to genetic engineering that threatens to obscure its potential benefits.¹⁵

This Comment argues that a federal labeling scheme for genetically-engineered food is necessary and consistent with the rationale for previous federal food safety measures. Part Two provides an overview of the agricultural applications of biotechnology and describes the genesis of the biotech and organic food markets. Part Three describes the disjointed manner in which courts have responded to biotechnology issues because of the lack of federal guidance. This Part first argues that GM labeling falls within the definition of a substantial state interest. Second, labeling GM foods is a disclosure requirement, and as such should be held to a less strict review under the commercial speech doctrine, which so far has derailed the imposition of mandated labels. Part Four describes the lack of a comprehensive response by regulatory agencies and Congress, which forces ad hoc judgments and safety assessments that erode consumer protection in contravention of established food safety law. Part Five suggests that as a basis for a food labeling program, the Food and Drug Administration ("FDA") should be given explicit authority for testing GM products by adopting a process-based regulatory approach. This approach is best achieved through enlarging the terms "food additive," "materially altered," and "misleading" as defined in the Food, Drug, and Cosmetic Act. This Part also offers suggestions for a more unified approach to GM crop production oversight. In addition to a federal labeling scheme, voluntary labeling efforts for non-GM foods should be encouraged, and the disjointed food supervisory duties of the Food and Drug Administration, Department of Agriculture, and Environmental Protection Agency might best be replaced by one food quality agency.¹⁶ This Comment concludes that accommodating the legitimate safety concerns surrounding biotechnology will promote the most effective use

15. Biotechnology is making an impact in medicine as well. Gene therapy techniques replace genes that are missing or are not functioning correctly with the correct gene. The first successful gene therapy was used in 1990 to treat an immune system defect in children called ADA. Gene therapy trials are currently underway to treat diseases such as brain tumors, cystic fibrosis, and HIV. *See generally* Judith E. Beach, *No "Killer Tomatoes": Easing Federal Regulation of Genetically Engineered Plants*, 53 *FOOD & DRUG L.J.* 181 (1998).

16. One element of this argument is that labeling laws are better focused on protecting consumers from deception not by imposing definitions on "organic," but by recognizing risks posed to the food supply by requiring the labeling of bio-engineered foods. Using regulatory power to clarify the term "organic" has proven to be inefficient and of dubious value to consumers. *See* Kenneth C. Amaditz, *The Organic Foods Production Act of 1990 and its Impending Regulations: A Big Zero for Organic Food?*, 52 *FOOD & DRUG L.J.* 537 (1997).

of the technology.

Underscoring the argument made in this Comment is that the legal legitimacy of GM foods cannot depend on technological expertise alone. Regulatory actions with regard to biotechnology must be based on a reasoned risk assessment that satisfies public protection concerns and not solely narrow commercial interests.¹⁷

II. THE EMERGENCE OF BIOTECHNOLOGY IN AGRICULTURE

This Part describes the process of genetic engineering, the controversy surrounding its appearance in food products, and the consumer opposition that impedes its acceptance in the market. It shows that regulation of GM foods through labeling will prevent the perpetuation of the environmental and economic risks that fuel consumer distrust of the GM industry.

Although the use of biological organisms in food is in itself not a new development,¹⁸ the use of DNA in a commercial context is a relatively recent occurrence. Genetic engineering refers to the process of transferring DNA from one organism to another.¹⁹ Genetic traits that code in naturally produced proteins are located, removed, isolated, and spliced into the genetic material of a different organism. This induces the host to produce the desired trait, and the new genes may be grown in commercial quantities. Because genetic change to the individual organism is immediate, genetic engineering is less time-consuming than the traditional method of cross-breeding species for producing desired traits. A plant or animal that is modified in this way is called *transgenic*.²⁰

The prevailing opinion is that the social and commercial effects of transgenic species will be more far-reaching than anything seen in the industrial revolution or the computer age. Genes, it seems, "are the raw

17. SHEILA JANSANOFF, *SCIENCE AT THE BAR: LAW, SCIENCE, AND TECHNOLOGY IN AMERICA* 153-54 (1995).

18. Adding bacteria to convert milk to yogurt is a common example.

19. Also known as recombinant DNA technology, it allows direct injection or immersion of genetic material into the DNA of another organism; such as splicing a gene from a silk moth into the DNA of a potato in order to increase resistance to disease. See Dan L. Burk, *The Milk Free Zone: Federal and Local Interests in Regulating Recombinant BST*, 22 COLUM. J. ENVTL. L. 227, 231 (1997).

20. Although this Comment focuses on GM applications to food products, controversy also surrounds the application of the technology to humans and animals. See generally RIFKIN, *supra* note 12.

resource of the new economic epoch."²¹ Although biotechnology appears to be an awesome new science with limitless possibilities, a major controversy is the propriety of using genetic material as an economic commodity. Observers criticize the practice of searching the planet for species of microbes, plants, animals, and humans with rare genetic traits that may have market potential in another organism. Perhaps the most controversial practice, however, is that after modifying a gene, companies seek patent protection for their new "invention."²²

Criticisms of commercial biotechnology come from a variety of moral, religious, and economic philosophies. Foreboding predictions of an already shrinking gene pool becoming a source of monetary value abound. But whether we can turn the clock back and avoid the manipulation of DNA seems to be a moot question. The choice is no longer whether we should use biotech, but what kinds of biotech applications we will choose.²³

Mysteriously, the great public concern over food derived from GM crops is often dismissed and even ignored.²⁴ By defining the controversy as a "socioscientific dispute,"²⁵ proponents of GM dismiss consumer opposition as "ultimately [a question of] policy, not questions of science."²⁶ The rationale is that since genetic engineering is "complex enough to elude the understanding of the average citizen," the controversy must therefore be centered around "societal preference."²⁷ Yet the well-documented studies show that the safety of genetic engineering is not completely understood.²⁸ Moreover, consumers in

21. Jeremy Rifkin, *Genetic Blueprints Aren't Mere Utilities*, L.A. TIMES, July 8, 1998, at B7. Biotech is being used in a variety of fields: animal husbandry, energy, construction materials, pharmaceuticals, and foods. *See id.*

22. *See id.* The patent issue will likely become a controversial question in biotech. "It is expected that in less than eight years, nearly all of the sixty thousand or so genes that make up the genetic blueprints of the human race will have been identified and become the intellectual property of trans-national life science companies." *Id.*

23. *See id.*

24. Recent polls show eighty to ninety percent of consumers in the U.S. and Europe demand labeling of GM foods, primarily so that they can avoid buying them. Fully ninety-three percent of Americans feel that GE foods should be labeled, and fifty-four percent wanted to see agriculture move toward organic production methods. *See* Campaign for Food Safety press release, FOOD BYTES #13, "News and Analysis on Genetic Engineering & Factory Farming," (Oct. 31, 1998) (on file with the author).

25. *See* Burk, *supra* note 19, at 229 (quoting MILTON R. WESSEL, SCIENCE AND CONSCIENCE 4-5 (1980)).

26. *Id.* at 229.

27. *Id.*

28. *See, e.g.,* Mikkelsen, T.R., *The Risk of Crop Transgene Spread*, 380 NATURE 31

general are well-informed about the risks. Yet neither the GM industry nor regulators offer any information to assuage these legitimate concerns. The negative consumer reaction has led GM companies to oppose GM information being given to consumers, even at the cost of litigation.²⁹

A. *Balancing Biotech Benefits and Risks*

Despite the variety of perceived risks in GM foods, the general observation is that "[b]iotechnology appears to be leading the race as the primary tool of agriculture for the twenty-first century."³⁰ Most agricultural biotech research has created improved crop strains that are herbicide-tolerant and virus-resistant. However, the great benefits of these crops also pose serious potential risks to economy, biodiversity, and human health.

1. Economic Risks

GM advocates often describe voluntary GM labeling initiatives as being "suspiciously concentrated in small-farm . . . states."³¹ Yet there is evidence that many GM production methods have catastrophic ripple effects on small farms. First, family farms that cannot afford large-scale production often see their prices forced down by the prolific output of farms that use GM methods, which can afford greater economies of scale and lower labor costs. An example of this effect can be seen in the use of the bovine growth hormone BGH.³²

Second, GM companies exert vigorous economic control over a farmer's planting. For example, the Monsanto corporation has received criticism for prosecuting farmers who save its herbicide-resistant

(1996); Skogsmyr, *Gene Dispersal From Transgenic Potatoes to Conspicifics: A Field Trial*, 88 THEOR. APPL. GENET., 770-74 (1994). See *infra* note 53 and accompanying text.

29. Monsanto, a frequent intervenor in labeling suits, independently sued several dairies for labeling their products "non-BGH." These companies included Swiss Valley Farms in Iowa and The Pure Milk and Ice Cream Company in Waco, Texas. See Wesley J. Smith, 'Scorched-Earth' Litigation Corrupts Judicial Process, DAYTON DAILY NEWS, January 9, 1997, at 11A; *Growth Hormone for Cows Raises Health Questions*, BUFFALO NEWS, April 30, 1996, at B2; Robert Steyer, *Monsanto, Texas Dairy Settle Suit*, ST. LOUIS POST-DISPATCH, July 3, 1995, at 14.

30. Sara M. Dunn, *From Flav'r Sav'r to Environmental Saver? Biotechnology and the Future of Agriculture, International Trade, and the Environment*, 9 COLO. J. INT'L ENVTL. L & POL'Y 145, 146 (1998).

31. See Burk, *supra* note 19, at 296.

32. See discussion Part III, *infra*.

"Roundup Ready" soybean seeds.³³ Seed-saving is a traditional farming practice, but since GM seeds are intellectual property, Monsanto and others can contractually limit use of the seeds to one season, guaranteeing future sales since farmers must now purchase additional seed each growing season. Additionally, the farmers must then purchase their herbicide from Monsanto, since the Roundup Ready soybeans are specifically altered to withstand Monsanto's own brand of herbicide. However, since a patent for "Terminator Technology" was granted last year, the need for prosecuting seed-saving farmers has become obsolete. The "terminator" gene is a complex of genes that, when spliced into a crop plane like Roundup Ready soybeans, will render the seeds sterile after a certain amount of time. This practice ensures that farmers must return to the company each year for new seed.³⁴ The legality of this practice is currently being challenged in federal court.³⁵

Finally, there is evidence that GM crops could destroy the biological basis of alternative farming methods due to pest and weed resistance. This is due to the genetic manipulation of bacillus thuringiensis, a natural pesticide commonly known as "Bt." Bt occurs naturally in the soil and is relied on heavily by organic farmers. Until now, resistance has not been a concern because Bt breaks down quickly in sunlight and organic farmers use it only sparingly. But the splicing of Bt into crops by GM companies creates a plant that is, throughout its life, deadly to the pests that eat it.³⁶ While a novel product like this might be an advantage to GM companies, the widespread and ever-present use of Bt in plants is likely to lead to insect resistance, thus robbing organic growers of the safest pesticide available and in effect destroying the sustainable agriculture that stands in opposition to GM production.³⁷

33. See FOOD BYTES, *supra* note 23.

34. The "Terminator" patent has attracted unprecedented opposition from farmer's organizations and environmental groups. Over 1,800 individuals from 54 countries have written personal protests demanding that the technology be banned by the USDA. See *id.*

35. See, e.g., Rick Weiss, *Food War Claims Its Casualties; High-Tech Crop Fight Victimizes Farmers*, WASHINGTON POST, September 12, 1999, at A1. (Reporting that antitrust lawsuits are planned for late 1999 against major GM agribusinesses; eight major law firms have signed on to represent plaintiff farmers with what may be the largest antitrust suit in history).

36. Maine is the only state that prohibits the use of Bt corn seeds, banned in 1998. See Sharon Mack, *Farmers Hear About Bio-Engineering*, BANGOR DAILY NEWS, January 13, 1999. Some strains of Bt produce proteins that are lethal to certain insects with alkaline digestive tracts. *Id.*

37. A Cornell University study showed that cross-pollination of Bt from corn plants into milkweed kills Monarch butterflies. See 399 NATURE 6733 (1999).

Economic difficulties are not borne solely by farmers. Businesses face their own problems with GM foods. The lack of any means for identifying GM foods from their natural counterparts makes it difficult to source out desired goods for consumers. This sourcing problem compelled several restaurants to join the current lawsuit against the FDA.³⁸ As one nationally recognized chef says:

People come to [my restaurant] because they trust me [and] know I'm going to source out the highest quality ingredients in the market for their dining experience. By not requiring mandatory labeling and safety testing of all genetically engineered foods, the government is taking away my ability to assure customers of the purity of the food they eat at my restaurants.³⁹

2. Environmental Risks

Many fear that GM crops will cause serious genetic pollution and biosphere damage.⁴⁰ Examples of environmental problems can be seen where a single genetic mutation occurs in an organism, even where it occurs for natural reasons. Recent genetic problems of this sort include the appearance of citrus canker, chemical resistance, and transformations of benign bugs into pests.⁴¹ As for genetically-engineered mutations, no one knows if they will cause "gene flow," a phenomenon where genes are transferred to weedy relatives through cross-pollination. Gene flow may conceivably create resistance in other plants, producing strains of "super" weeds or "super" viruses. Cross-pollination of gene traits may also compound the problem of antibiotic resistance.

A basic knowledge of biology lends skepticism to biotech companies' claim that these environmental problems are but a remote

38. See *Alliance for Bio-Integrity v. Shalala*, No. 98-1300 (D. D.C. filed May 27, 1998).

39. *Id.*

40. See *id.* Not all uses of genetic engineering are so ominous. In the alternative, many researchers are using biotechnology in an effort to understand genetic expression, knowledge of which even now is limited. This knowledge is used to create a sophisticated, organic-based approach to agriculture, relying on integrated pest management, crop rotation, natural fertilization, and other sustainable methods. *Id.*

41. See Scott D. Deatherage, *Scientific Uncertainty in Regulating Deliberate Release of Genetically Engineered Organisms: Substantive Judicial Review and Institutional Alternatives*, 11 HARV. ENVTL. L. REV. 203, 207-08 (1987) (describing economic consequences of single genetic mutations of the Florida citrus canker, apple maggot, rice brown planthopper, corn leaf blight, gypsy moth, kudzu vine, and Dutch elm disease).

possibility. Unlike typical food additives, genetic organisms grow, change, and adapt to new environments and hosts. Genes may replicate indefinitely. They have the ability to mutate over time, making it difficult to investigate, control, and prevent unwanted outcomes. This difficulty is evidenced by the fact that microbiological contamination of food continues to be a problem despite modern manufacturing processes.⁴² Moreover, biotech product research and development operates from the faulty assumption that a controlled input going into a biological organism will lead to predictable results. Yet it is clear that the consequences of introducing GM plants into the food chain cannot be completely understood at this stage in scientific understanding of gene expression. Since gene mutations could have devastating effects on biodiversity, it is critical that regulatory agencies engage in a complete risk assessment, both in the environmental impact and the final product.⁴³

3. Human Health and Safety Risks

Derivative from the risks in GM crop production are those associated with foods that actually end up in the grocery cart. These risks are highlighted by the experience with GM foods that are already for sale. The first genetically-engineered crop for sale in the U.S. was the Flav'r Sav'r Tomato, marketed in 1994.⁴⁴ Another widely used "whole food" is the New Leaf Superior potato, designed with genes of the Bt pesticide. This crop is among the 45 million acres of corn and soybeans designed to produce their own pesticides or withstand herbicides.⁴⁵ These potatoes can be found in store products, fast-food

42. See *infra* note 71 and accompanying text.

43. It has been suggested that liability is the 'Achilles Heel' of the biotech industry. Not only will insurance companies be unwilling to insure corporations against unknown risks, the likelihood of gene flow will cause damages to gardeners and farmers unable to sell their crops. To establish damages, an unwanted gene just needs to show up. See Rick Weiss, *Next Food Fight Brewing Is Over Listing Genes on Labels*, WASHINGTON POST, August 15, 1999, at A1 (Testers found traces of genetically engineered corn in organic corn chips made by Wisconsin company Prima Terra Inc. Corn supplied to the company was tainted through cross pollination by gene-altered corn. Prima Terra Inc. was forced to recall 87,000 bags of chips valued at \$147,000). *Id.*

44. Flav'r Sav'r, owned by Calgene, was engineered with flounder genes to withstand freezing, have longer shelf life, and taste better than "traditional" tomatoes. See Dunn, *supra* note 30, at 146. By 1997 the FDA had approved 22 other foods developed with biotechnology. See *id.*

45. Michael Pollan, *Playing God in the Garden*, NEW YORK TIMES SUNDAY MAGAZINE, October 25, 1998.

outlets, and produce sections across the country.⁴⁶

The GM product that has received the most attention from consumers, government, and the media is Posilac, the trade name for what is commonly called recombinant bovine somatotrophin (rBST) or bovine growth hormone (BGH).⁴⁷ The public dispute over BGH hints at the consumer hostility that may develop over future biotechnology products because of the conflicting evidence as to its health risks.

BGH was approved by the FDA in 1993,⁴⁸ and is administered to about three million dairy cows twice a month in order to increase their milk production.⁴⁹ Producers claim it is completely safe because there is no discernible difference between "regular" milk and milk from BGH-treated cows.⁵⁰ This was the basis for the FDA decision not to provide for special labeling. As such, it is impossible for consumers to know if they are purchasing BGH-treated milk.

There has been much controversy over use of this hormone since its introduction, both for human health reasons as well as economic ones. First, there is conflicting evidence as to the safety of BGH.⁵¹ Paramount are concerns about the high levels of growth hormone, IGH-1, that are found in milk from cows treated with BGH. IGH-1 has been linked to

46. McDonald's has come under fire for its use of GM food sources, and has been a symbol for the international dispute of U.S. export of GM corn and soybeans. See NEWSWEEK, September 13, 1999, at 33. However, one supplier, Archer Daniels Midland, has responded by announcing it will separate its GM and non-GM soybeans and corn. *Id.*

47. This Comment refers to the hormone as "BGH". Manufactured by Genetech and owned by Monsanto corporation, BGH is a synthetic formulation of a naturally occurring growth hormone in cows. See *FDA Charged With Ignoring BGH Hazards*, CHEMICAL MARKET REPORTER, Jan. 4, 1999, at 6(1).

48. *See id.*

49. *See id.*

50. Just what is in "regular" milk is an interesting question, since most cows are treated with antibiotics and hormones whose residues end up in dairy products. There is controversy over whether these "ordinary" drugs are within levels acceptable to human health: these include pituitary and steroid hormones, thyroid and hypothalamic hormones, gastrointestinal peptides and growth factors like IGF-1. Organic milk does not use these treatments. *See infra* note 51.

51. Studies have shown rBST increases the levels of insulin-like growth factor 1 (IGF-1) in milk, which passes into the blood stream of milk consumers. While ingested IGF-1 would ordinarily be broken down in the stomach, the presence of caesin in milk prevents its absorption. Furthermore, high levels of IGF-1 are linked to increased incidence of breast and prostate cancers. See, e.g., Susan E. Hankinson et. al., *Circulating Concentrations of Insulin-Like Growth Factor I and Risk of Breast Cancer*, 351 LANCET 1393 (1998); June M. Chan et. al., *Plasma Insulin-Like Growth Factor-I and Prostate Cancer Risk: A Prospective Study*, 279 SCIENCE 563 (January 23, 1998); P.V. Malvern et. al., *Periparturient Changes in Secretion and Mammary Uptake of Insulin and in Concentrations of Insulin and Insulin-Like Growth Factors in Milk of Dairy Cows*, 70 J. DAIRY SCIENCE 2254 (1987).

several forms of cancer. There is evidence that the IGH-1 is more potent in BGH-treated milk than in regular milk because it is bound less firmly to accompanying proteins.⁵² However, researchers disagree about a critical factor: whether the hormone is broken down in the digestive tract or whether it can enter the blood stream by passing through the intestinal wall and promote cancers. The National Institutes of Health observed that it is inconclusive whether the IGF-1 in BGH-treated milk can affect the esophagus, stomach, or intestines.⁵³ Despite these statements, proponents of GM have boldly asserted that the "scientific literature overwhelmingly supports the safety of [BGH],"⁵⁴ and that studies from "around the world have failed to unearth any cognizable threat to human health from [BGH] usage."⁵⁵

The lack of a regulatory response to this controversy is even more incredible when international views on agricultural biotechnology are considered.⁵⁶ For example, after nine years of review, Canada banned the use of BGH after researchers uncovered evidence that U.S. officials overlooked data about potential health risks that indicated a need for additional testing.⁵⁷ In response to the Canadian findings, several U.S. consumer groups have asked the federal government to pull BGH off the American market and re-evaluate the research used to prove its safety to the FDA in 1993.

American biotech companies continue to fight diligently to prevent such a ban from occurring in the U.S. For example, BGH producers bring lawsuits against state legislatures and private companies who disclose the presence of BGH on labels.⁵⁸ This is an understandable

52. See Chan, *supra* note 51.

53. See NIH technical assessment confirmation statement on bovine somatotrophin. 265 JAMA 1423, 1424-25 (1991); R.J. Playford, et. al., *Effect of Luminal Growth Factor Preservation on Intestinal Growth*, 341 THE LANCET 843-48 (April 3, 1993); Judith Juskevich, *Bovine Growth Hormone: Human Food Safety Evaluation*, SCIENCE, August 24, 1990, at 875, available in 1990 WL 3304311.

54. See Burk, *supra* note 19, at 238.

55. *Id.*

56. Mounting public opposition to rBST and GE crops in general forced European Commission officials to consider a three to five year moratorium on planting GM crops. Across Europe, fields of "frankenplants" are uprooted and burned by protestors, and supermarket chains are attempting to source out non-GE products. See FOOD BYTES, *supra* note 24.

57. *Canada Rejects Hormone Use*, AP ONLINE, January 15, 1999, available in 1999 WL 2231912. The Health Protection Branch of the Canadian government shows 20 to 30 percent of rats in a study absorbed rBST into their blood streams and prostate gland; some developed cysts in the thyroid. See CHEMICAL MARKET REPORTER, *supra* note 47.

58. See Dunn, *supra* note 30.

strategy, given the acknowledgment by one biotech executive that labeling a product derived from the use of BGH would be "like putting a skull and crossbones on it."⁵⁹ BGH producers have also steadfastly opposed any labeling by manufacturers who do *not* use rBST: When dairy manufacturers began using non-BGH labels soon after the drug's approval, one GM company brought several lawsuits, alleging libel, false advertising, and commercial disparagement through the use of these labels.⁶⁰

The primary problem with GM manufacturers calling public fear of their product "unfounded" is that there is little information offered to address the likelihood of damages by the food. This silence, coupled with a litigious strategy to prevent GM labeling of any kind, produces great distrust, both of the GM companies and their products. Consumers and courts alike⁶¹ perceive a covert strategy to suppress information about BGH, based on the reasoning that consumers' lack of scientific sophistication ought not be permitted to affect the burgeoning biotech food business. The absence of GM labeling information has been called "paternalistic manipulation" of information.⁶² Yet in most states, consumers continue to buy rBST treated milk and other GM products unknowingly, because of suppressing labels despite their desire to know, and despite evidence that many consumers are still willing to purchase milk from BGH-treated cows.⁶³

B. The Organic Movement

The greatest testament to consumer distrust of GM foods (and processed foods in general)⁶⁴ is the spectacular growth of the organic foods industry. Consumers of organic food and dairy products prefer to avoid the effects of modern industrial farming, the increased yields of

59. See FOOD BYTES, *supra* note 23.

60. See Ben & Jerry's Homemade, Inc., v. Lumpkin, *available in* No. 96 C 2748, 1996 WL 495554 (N.D. Ill. Aug. 28, 1996).

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

62. *Id.* at 80.

63. Many states such as Wisconsin have approved voluntary labeling schemes for milk from untreated cows, "Farmer Certified BGH-Free." See WIS. STAT. ANN. § 97.25(3) (West 1998) (authorizing dairy plants, retail food stores, and restaurants to place certification on dairy label).

64. Although the average consumer does not have information about particular processing methods, the Nutritional Labeling Act provided information about processed ingredients: a consumer with average sophistication can discern highly processed foods from other food; a list of ingredients such as "hydrogenated," "partially hydrogenated," "alkali," etc. See Nutritional Labeling and Education Act, 21 U.S.C. 343(r) (1991).

which require enormous amounts of capital-sensitive inputs such as fertilizer, hormones, antibiotics, pesticides and herbicides, machinery, and fuel.⁶⁵ Although sometimes portrayed as "health nuts and Luddites,"⁶⁶ the modern organic consumer is no longer the stereotypical blueberry-growing hippie. Organic agriculture, while only a fraction of the size of conventional farming, has become a \$4.2 billion a year market with a growth rate of twenty percent per year since 1990.⁶⁷ While organic⁶⁸ food products could once be found only at your local health food store or co-op, even mainstream retail food chains are now making shelf space to offer these "pure" foods. As a result of this growth, consumers are presented with a variety of independent labels to guide their choices, such as "organically produced,"⁶⁹ "ecologically grown," "natural," "wild," "residue-free," as well as a variety of third party certifications.⁷⁰

The concern over the modern food production methods is based upon several factors: First, factory farming has increased the spread of disease among animals and necessitated widespread use of antibiotics and pesticides. Producing ever-increasing yields of milk, eggs, and meat requires use of growth hormones. Second, foods are shipped much greater distances than they were twenty years ago, even across national borders. Globalization of the food supply has introduced bacteria and other organisms into the U.S. with sometimes-disastrous results. Well-publicized incidents of food scares, food-poisoning epidemics, and mad

65. See Pollan, *supra* note 45. Typical organic farming methods include complex crop rotations to prevent buildup of specific pests, planting strips of flowering crops to attract beneficial insects like ladybugs that eat beetle larvae and aphids, and planting several varieties. The approach is the antithesis of GE farming in that it focuses on process rather than end product.

66. Christopher Palmeri, *New Age Moo Juice: There's No Scientific Evidence That Says It's Better For You—And It Costs A Buck More Per Gallon. But Horizon's Organic Milk is Flying Off the Shelves*, FORBES, October 19, 1998 at 122.

67. See Ben Lilliston, *Organic v. "organic": The Corruption of a Label*, THE ECOLOGIST, July 17, 1998, available in 1998 WL 12575422.

68. Proponents of a "USDA Organic" certification program allege that 'organic' has no real meaning and is confusing for consumers. The term generally refers to foods that are as whole as possible, and either raised without hormones, antibiotics, and natural surroundings, or grown with natural pesticide methods in a sustainable manner.

69. Stonyfield Farms Yogurt, for example, claims it is "All Natural," and has two of these independent organic certifications: "Vermont Certified Organic Processor," and "Organically Produced in Accordance With the California Organic Foods Act of 1990. See CAL. FOOD & AGRIC. CODE § 46000 (West 1999).

70. A successful independent labeling scheme can be found in the California Organic Certification Act, the labels of which are used nationwide and widely recognized. See *id.*

cow disease⁷¹ have "profoundly affected consumer consciousness and altered market conditions."⁷² Moreover, despite assurances that the U.S. has one of the safest food supplies in the world, Americans suffer from a "literal epidemic" of food poisoning, estimated at over 80 million cases per year.⁷³ Americans also suffer from high rates of immune and reproductive disorders, obesity, heart disease, and food-and-water-related cancers and diseases.⁷⁴ The hazards presented by pesticides on fruits and vegetables, hormone and antibiotic residues, fecal or bacterial contamination of fruits, and meat transported great distances lead many consumers to seek out organic products.⁷⁵ Although GM science seeks to solve some of these problems, the flight of consumers is not likely to be abated in GM's current state.

III. THE JUDICIAL RESPONSE TO GENETIC ENGINEERING

Consumer distrust is aggravated by the fact that adjudication of GM labeling disputes often turns in favor of keeping information from the consumer.⁷⁶ This section first describes the confused judicial response to

71. For recent news highlights regarding food scares and poisoning incidents, see generally Lawrence K. Altman, *Outbreak of Cyclospora Surprises Health Officials*, CINCINNATI ENQUIRER, June 30, 1996, at A22; Tom Daykin, *Oscar Mayer Recalls Two Lunch Meat Products For Fear of Bacteria: Kansas City Illness Led To Testing That Revealed Presence of Listeria*, MILWAUKEE J.-SENTINEL, January 16, 1999, at 3; Tom Paulson, *Odwalla Juice is E.Coli Source*, SEATTLE POST-INTELLIGENCER, October 31, 1996, at A1; Lisa Singhania, *Tainted Hot Dogs Traced to Zealand Meat Processor: Bacteria in Packages Killed Four, Sickened Scores Across Nation*, DETROIT NEWS, January 1, 1999, at A13; Mary Beth Sheridan, *Health Scare Puts Mexico's Strawberry Harvest on Hold*, L.A. TIMES, April 9, 1997, at A1; Mark Skeptic, *Small Cartons of Land O'Lakes Milk Recalled*, CHICAGO SUN-TIMES, February 4, 1999, at 3; Sara Lee Says Tests May Tie Bacteria to Its Food, L.A. TIMES, January 2, 1999, at C2; *Strawberries at Lunch Leave Youths Exposed to Hepatitis A*, SUN-SENTINEL (Ft. Lauderdale), April 4, 1997.

72. Lilliston, *supra* note 67.

73. *See Id.*

74. *See id.*

75. *See id.* In addition to contamination concerns, many consumers look to organic foods for the preferred effects of the small-scale production typically associated with organic farming: survival of small family farms, protecting the rural environment, the humane treatment of livestock, and locally-grown food. "Our customers have come to recognize our trade name, Organic Valley: A Family of Farms, as not just a line of quality products, but also as a philosophical approach to agriculture worth of support. That unusual level of customer loyalty has become the envy of agribusiness." See press release at Organic Valley Website, <http://www.organicvalley.com> (visited February 15, 1999).

76. Many consumers are demanding that they be given information on the GM crops already for sale. The FDA is being taken to court by consumer groups who challenge the marketing of thirty-three genetically engineered whole foods that are being sold without labeling or safety testing. *Alliance for Bio-Integrity v. Shalala*, No. 98-1300 (D. D.C. filed May 27, 1998). These foods are used as ingredients in processed foods such as soy-based baby

the issues raised by the two types of GM labeling schemes. In a criticism of the Second Circuit's decision in *International Dairy Foods v. Amestoy*, this section argues that consumer concern presents a substantial state interest, trumping any First Amendment rights a GM company may assert. Next, this section sets forth a legal foundation for federal labeling of GM foods by arguing that a state-compelled labeling scheme is properly considered a disclosure requirement, and as such should be held to a less strict review than other compelled commercial speech.

A. *Ad Hoc Judicial Reactions-The Amestoy Case*

Courts traditionally act as a forum for addressing conflicting public expectations. However, it is worthwhile to recognize that the judiciary has another tradition of looking favorably on science and industry and acting as vehicles for securing public acceptance of new technology.⁷⁷ This posture can be seen from the first time the Supreme Court addressed a biotechnology issue in *Diamond v. Chakrabarty*,⁷⁸ a 1980 case concerning the marketing of DNA research. The subject of the patent application was an oil-eating bacterium.⁷⁹ Although not a product of bio-engineering, the bacterium was rejected by the patent examiner because it had never existed before in nature, and because living things were considered not patentable.⁸⁰ The Court held that a live but human-made organism is patentable subject matter within the meaning of the patent statute, which provides issuance of patents for any "manufacture" or "composition of matter."⁸¹ By enlarging these meanings, the Court created the potential for similar "inventions," including those produced by genetic engineering, to be granted legal protection.

Courts are presented with one of two possible methods for GM labeling schemes, each of which present their own legal issues. The first of these is the state-compelled labeling requirement, usually mandated by the government on behalf of consumers. Typically, this mandate is in the form of a disclosure requirement, which compels manufacturers to

formula and popular brands of corn chips. A central issue in this case is the consumer's right to know about genetic material being engineered into foods.

77. See SHEILA JANSANOFF, *SCIENCE AT THE BAR: LAW, SCIENCE, AND TECHNOLOGY IN AMERICA* 140 (1995).

78. 447 U.S. 303 (1980).

79. See *id.* at 305.

80. See *id.* at 306.

81. 447 U.S. at 307.

reveal product information on which they would ordinarily prefer to remain silent.⁸² The most common legal defense for a GM company challenging such a state-imposed requirement would be to appeal to their First Amendment right "not to speak."⁸³ Under current constitutional adjudication, the state would then have to show that its interest trumps that of the manufacturer. Another "negative" type of state regulation is a complete ban on speech, where a state might forbid the labeling of accurate product information in the interest of serving a "substantial" state interest.⁸⁴

The second type of labeling scheme, which could be deemed "positive," is based on the right of an individual manufacturer to make voluntary disclosures about their product. For example, food producers desiring to characterize their product as "non-GM," "BGH-free," or "organically grown" find these labels a useful tool for establishing brand recognition in a GM-wary marketplace. The most problematic legal issues for voluntary labeling is that the "non-GM" label is often challenged as being "misleading" under the FDCA,⁸⁵ since GM producers feel it may imply inferiority of their product.

*International Dairy Foods Association v. Amestoy*⁸⁶ is the primary case in which a federal court has dealt with a state initiative to compel labeling of a GM product. In *Amestoy*, the Second Circuit Court of Appeals was presented with a challenge to a Vermont statute that compelled disclosure of dairy products produced with the hormone rBST ("BGH").⁸⁷ Acknowledging citizens' petitions and a lack of federal guidance on the matter, the Vermont legislature enacted a BGH labeling scheme, which involved posting a BGH-information sign in retail outlets accompanied by a blue rectangle affixed to BGH-produced products.⁸⁸ In finding for the challenging dairy processors, the court first

82. For a discussion of compulsory labels for rBST on a state level, see Kathleen Lennon, Note, *Government's Udder Disregard For A Consumer's Right to Information on rBST: Mandatory Labeling of Milk Products Should Be Allowed*, 22 VT. L. REV. 433 (1997).

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

84. Nicole B. Casarez, *Don't Tell Me What to Say: Compelled Commercial Speech and the First Amendment*, 63 MO. L. REV. 929 (1998).

85. *Ben & Jerry's Homemade, Inc. v. Lumpkin*, available in No. 96 C 2748, 1996 WL 495554 (N.D. Ill Aug. 28, 1996).

86. 92 F.3d 67 (2d Cir. 1996).

87. The Vermont statute read: "[i]f rBST has been used in the production of milk or a milk product for retail sale in this state, the retail milk or milk product shall be labeled as such." *Id.* at 69.

88. "rBST Information. THE PRODUCTS IN THIS CASE THAT CONTAIN OR MAY CONTAIN MILK FROM rBST-TREATED COWS EITHER (1) STATE ON THE

found that they had demonstrated irreparable harm to their First Amendment rights because they were required to make an "involuntary statement"⁸⁹ when offering their products for sale. The court observed that "[o]rdinarily, it is the purposeful *suppression* of speech which constitutes irreparable harm."⁹⁰ But here, the dairy producers were compelled to make a disclosure about BGH; the implications of which they disagreed. The dairy manufacturers argued that for this reason they deserved more protection from a compelled disclosure than commercial speech doctrine would ordinarily allow.⁹¹ Although the court did not address this argument directly, they nevertheless applied the *Central Hudson* test to determine that Vermont presented no cognizable harms the statute would prevent; thus, its interest was not substantial.⁹² The court held that "consumer curiosity" alone is never a substantial enough interest to compel even an accurate statement about a product.⁹³ Relying exclusively on FDA safety findings, the court held that "it is thus plain that Vermont could not justify the statute on the basis of "real" harms . . . [i]t is undisputed that dairy products derived from herds treated with rBST are indistinguishable from products derived from untreated herds; consequently, the FDA declined to require the labeling of [rBST products]."⁹⁴ From this basis, the court jumped to the conclusion that "strong consumer interest and the public's 'right to know'" was insufficient.⁹⁵ The court further noted:

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

PACKAGE THAT rBST HAS BEEN OR MAY HAVE BEEN USED, OR (2) ARE IDENTIFIED BY A BLUE SHELF LABEL LIKE THIS: [BLUE RECTANGLE] OR (3) A BLUE STICKER ON THE PACKAGE LIKE THIS. [BLUE DOT]. The United States Food and Drug Administration has determined that there is no significant difference between milk from treated and untreated cows. It is the law of Vermont that products made from the milk of rBST treated cows be labeled to help consumers make informed shopping decisions." *Id.* at 70.

89. *Id.* at 71.

90. *Id.* (emphasis added).

91. The district court found that "despite the current public debate, the labels required by [the statute] relate to commercial transactions and are therefore commercial speech." *Int'l Dairy Foods Ass'n v. Amestoy*, 898 F. Supp. 246, 252 (D. Vt. 1995).

92. See *Amestoy*, 92 F.3d 67, 71 (2d Cir. 1996).

93. *Id.* at 74.

94. *Id.* at 69.

95. *Id.* at 73.

treated, or the age at which they were slaughtered. Absent, however, some indication that this information bears on a reasonable concern for human health or safety or some other sufficiently substantial government concern, the manufacturers cannot be compelled to disclose it. Instead, those consumers interested in such information should exercise the power of their purses by buying products from manufacturers who voluntarily reveal it.⁹⁶

The court's "slippery slope" reasoning seems heavily influenced by a sort of technological determinism. Its decision acknowledged only the FDA position on the safety of BGH and completely sidestepped not only the consumer demand in avoiding BGH, but also the mass of conflicting scientific evidence presented to the district court as to BGH's safety.

The vigorous dissent by Judge Leval in *Amestoy* is a well-reasoned approach to the "consumer interest" issues that will continue to arise in the GM debate. Leval observed that a First Amendment benefit for commercial speech has never been used for the purpose of withholding truthful information from consumers, and in effect "stands the Amendment on its ear."⁹⁷ Leval's rationale was that the overall policy of the Amendment is to promote the flow of "accurate, relevant information."⁹⁸ In his view, the most important facts of *Amestoy* were omitted from the majority opinion.⁹⁹ The "consumer curiosity" was a trite characterization of a complex set of issues based on evidence regarding human health, cow health,¹⁰⁰ and farm survival.¹⁰¹ By ignoring the legislature's position on the issue in deference to the FDA's position, Leval criticized the majority approach as "paternalistic social

96. *Id.*

97. *Id.* at 74 (J. Leval, dissenting).

98. *Id.*

99. These facts emerged from surveys, from the state of Vermont and the entire country, which revealed consumer desire for the labeling of rBST milk and overwhelmingly negative reactions to its use. Citizen reaction was well-documented in the press, in surveys, and in comments made to legislative committees and the Department of Agriculture. *See id.* at 75.

100. Curiously, the drug Posilac (rBST), when sold to the farmer, is required to carry a warning label regarding its effects on the cow. It "states that cows injected with the product are at increased risk for: various reproductive disorders, 'clinical mastitis [udder infections] (visibly abnormal milk), digestive disorders such as indigestion, bloat, and diarrhea, enlarged hocks and lesions, and swellings that may be permanent." *Id.* at 78.

101. *See Int'l Dairy Foods Ass'n v. Amestoy*, 898 F. Supp. 246, 251 (D. Vt. 1995) (noting various local interests and concluding that "[s]tates have traditionally acted to protect consumers by regulating foods produced and/or marketed within their borders") (quoting *Grocery Mfrs. v. Gerace*, 755 F.2d 993, 1003 (2d. Cir. 1985)).

engineering."

Judge Leval found "alarming and dangerous" the fact that the majority relied exclusively on the FDA position on rBST in finding that consumer concern could not be considered "real" or "cognizable."¹⁰² Although the dairy processors argued that health concerns are "hypothetical" since there is no conclusive study on health risk in rBST, given that genetic manipulation of food is new and controversial, FDA tests could not possibly cover long-term effects on human health.¹⁰³ Furthermore, the judge observed that many factors inhibit government agencies from adequate risk assessment, including inadequate time, budget, sampling errors, and industry pressure.¹⁰⁴ "To suggest that a government agency's failure to find a health risk in a short-term study of a new genetic technology should bar a state from requiring simple disclosure of the use of that technology where its citizens are concerned about health risks would be unreasonable and dangerous."¹⁰⁵

Finally, Leval directly addressed the commercial speech issue that the majority ignored. Because they were compelled to make statements about rBST beyond merely stating that the milk contained it, the dairy producers claimed they were entitled to First Amendment protection paralleling that of political speech.¹⁰⁶ Here, Leval reasoned that the speech could not reasonably be attributed to the producers because the retailers were the ones displaying the actual sign.¹⁰⁷ Moreover, the label on the sign conveyed the FDA's position on safety and that the State of Vermont was the party communicating the information.¹⁰⁸ Therefore, a consumer could not reasonably conclude that the "speech" was that of the dairy manufacturer.¹⁰⁹ While this is an accurate observation, Leval suggests that a GM label's conformity to First Amendment law is based on this factor.¹¹⁰

B. Labeling GM Foods Reflects a Substantial State Interest.

The *Amestoy* decision is curious in light of contemporary commercial speech jurisprudence, including those cases applying the

102. *Amestoy*, 92 F.3d at 76.

103. *See id.* at 78.

104. *See id.* at 77.

105. *Id.* at 77.

106. *See id.* at 79.

107. *See id.*

108. *See id.*

109. *See id.* at 80.

110. *See id.*

Central Hudson test.¹¹¹ First, observers have noted that the Supreme Court appears to be taking a new approach to commercial speech, showing a "growing acceptance of 'the preservation of a fair bargaining process' as the rationale for commercial speech regulation."¹¹² In most instances where a court recognizes a state interest in informed consumers, it has been an interest in informing them of a difference in product characteristics and preventing the suppression of accurate information. Second, the policy of providing information to consumers has always been a primary concern in commercial speech and disclosure cases and has overcome even the higher standard of review applied to complete bans on speech.

In *Virginia Board of Pharmacy v. Virginia Consumers Council*,¹¹³ the Supreme Court found that paternalistic assumptions by courts that the public will use truthful, nonmisleading commercial information unwisely cannot justify a decision to suppress that information.¹¹⁴ Here, the state of Virginia had banned the advertising of drug prices.¹¹⁵ The Court stated that an alternative to suppressing information is "to assume that this information is not in itself harmful, that people will perceive their own best interests if only they are well enough informed . . ."¹¹⁶ Additionally, "the proper allocation of resources" requires that consumer decisions be "intelligent and well-informed."¹¹⁷

*44 Liquormart v. Rhode Island*¹¹⁸ considered a challenge to a state statute prohibiting liquor price advertising. The Court made several important observations in finding that the statutory ban did not bear a reasonable relation to a state interest in promoting "temperance."¹¹⁹ First, the ban was against truthful, nonmisleading speech about a lawful

111. See *Central Hudson Gas & Elec. Corp. v. Public Serv. Comm'n*, 447 U.S. 557 (1980). In *Central Hudson*, the test set forth to determine if government restriction of commercial speech is permissible rests on four factors: 1) whether the expression concerns lawful activity and is not misleading, 2) whether the government's interest is substantial, 3) whether the restriction directly serves the asserted interest, and 4) whether the restriction is no more extensive than necessary. The last two factors look for a "close fit" between the state interest and the restriction. See *id.*

112. Nicole B. Casarez, *Don't Tell Me What to Say: Compelled Commercial Speech and the First Amendment*, 63 MO. L. REV. 929, 946 (1998) (quoting *City of Cincinnati v. Discovery Network, Inc.*, 507 U.S. 410, 426 (1993)).

113. 425 U.S. 748 (1976).

114. See *id.*

115. See *id.* at 749-50.

116. *Id.* at 770.

117. *Id.* at 765.

118. 517 U.S. 484 (1996).

119. *Id.* at 490.

product and did not concern any interest in consumer protection. "The First Amendment directs us to be especially skeptical of regulations that seek to keep people in the dark for what government perceives to be their own good. That teaching applies equally to state attempts to deprive consumers of accurate information about their chosen products" ¹²⁰ Moreover, a state interest "to keep legal users of a product . . . ignorant in order to manipulate their choices in the marketplace . . . is *per se* illegitimate" ¹²¹

The Court came to a similar conclusion in *Rubin v. Coors Brewing Company*. ¹²² This case dealt with a federal prohibition against revealing the alcoholic percentage content of malt beverages on product labels. In applying the *Central Hudson* test, the goal of preventing brewers from attracting customers based on the alcoholic content of the beer was rejected as a substantial state interest. ¹²³ The government's rationale on suppressing the alcohol content information was that restricting disclosure of information about a product characteristic would "decrease the extent to which consumers will select the product on the basis of that characteristic." ¹²⁴

In each of these commercial speech cases, a strict review is required because the state had imposed a complete ban on speech. The *Central Hudson* test is a tough yardstick, but one that the facts of *Amestoy* would pass over. There are legitimate state interests in compelling disclosure of the process by which certain products were manufactured that may be questionable bases on which to rest a state interest in restricting speech. For example, millions of consumers refrain from genetically engineered foods because of ethical and religious principles. For example, many Jews and Muslims need to avoid foods with substances from specific animals. ¹²⁵ Vegetarians need to avoid animal-derived substances. There are moral beliefs that genetically manipulated food is incompatible with the integrity of nature. GM proponents dismiss these concerns. In the case of BGH, they discredit the clear preference of consumers by stating "[m]ost Americans appear firmly committed to eating, wearing, and drinking a variety of products

120. *Id.* at 503.

121. *Id.* at 487.

122. 514 U.S. 476 (1995).

123. *See id.*

124. *Id.* at 484.

125. These regulations of "kosher" or "organic," however, merely specify standards a product must meet for a manufacturer to hold its product out as having that process. *See* Burk, *supra* note 19, at 308.

obtained at the expense of cattle, and are unlikely to become overly concerned if the animals are further exploited for their benefit."¹²⁶ Yet surveys, like the one in *Amestoy*, confirm that these concerns are indeed widespread.¹²⁷ Protecting the health and welfare of citizens against unknown risks of genetic engineering would seem to be a legitimate state interest. Even if it were not so, the *Amestoy* court erred in placing a strict standard on what was a disclosure requirement.

C. State-Compelled GM Labeling is a Disclosure Requirement.

First Amendment rights have long recognized not only the right to speak, but also the right to silence. When speech is related to political, religious, or other ideological content, full scope of First Amendment rights apply. However, commercial speech has a somewhat lower constitutional status in recent jurisprudence. Disclosure requirements are typically relegated to this status, and courts therefore consider them to be within a state's legitimate power. Package labeling is considered advertising. As such, it ought to be considered with a less strict review since it does not merit the high standards of full First Amendment rights. These applications can be found in decisions that deal with disclosure requirements rather than outright bans on commercial forms of speech.

In *Riley v. National Federation of the Blind of North Carolina, Inc.*, the Supreme Court held that professional fund-raisers could not be compelled to disclose to potential charitable donors the percentage of funds going to costs and fees as opposed to charity.¹²⁸ The decision indicated that when speech is fully protected, the law compelling that speech is subject to the same constitutional test as a law that restricts it.¹²⁹ Although at the time of the *Riley* decision commercial speech was generally seen as an inferior category of expression, it nevertheless suggests that if First Amendment scrutiny is weak for a ban on information that increases information to consumers, then commercial disclosure requirements should also be subject to a lower First Amendment standard for the same reason: to promote a fair bargaining process.

Several attorney advertising cases speak to this issue. In *Zauderer v.*

126. Burk, *supra* note 19, at 229.

127. *Amestoy*, 92 F.3d 67 (2d. Cir. 1996).

128. 487 U.S. 781, 800 (1988).

129. *See id.*

Office of Disciplinary Counsel,¹³⁰ the Court pointed out the "material differences between disclosure requirements and outright prohibitions on speech."¹³¹ It found that "disclosure requirements trench much more narrowly on an advertiser's interests than do flat prohibitions on speech"¹³² *Zauderer* made this distinction by refusing to apply the full *Central Hudson* test to a disclosure requirement; the test was watered down by eliminating the "least restrictive means" prong of the test.¹³³

Zauderer suggests that disclosure requirements need only be reasonably related to a state interest in consumer protection in order to pass constitutional muster.¹³⁴ Some critics believe that disclosure requirements ought to be taken out of commercial speech category completely and afforded no First Amendment protection whatsoever. Their argument is based on a dual premise that consumer interest cannot be subordinated to commercial loss and that a legislature ought to be given deference to protect consumers' right to informed decision-making.

Finally, in *Bates v. State Bar of Arizona*,¹³⁵ the Court again displayed anti-paternalism in establishing that attorneys have the right to advertise their services and fees. The state law which restricted attorney advertising was found to "inhibit the free flow of commercial information and to keep the public in ignorance."¹³⁶ The Court also noted that consumer protection was the only interest that could justify the state's requirement for advertisers to provide additional information about their products.¹³⁷

The commercial speech cases suggest that consumer curiosity, when appropriately characterized as a prophylactic measure against consumer deception, seems to demand a GM disclosure requirement, especially in an environment of substantial consumer petitioning of the state as in *Amestoy*.¹³⁸ They imply that the consumer is in the best position to determine the materiality of information to their decision-making as to food products. Given the uncertainty as to the safety of GM products, a

130. 471 U.S. 626 (1985).

131. *Id.* at 650.

132. *Id.* at 651.

133. *See id.*

134. *See id.*

135. 443 U.S. 350 (1977).

136. *Id.* at 365.

137. *See id.* at 384.

138. *See Amestoy*, 92 F.3d at 67 (2d. Cir. 1996).

legislature seems well within its legitimate power to compel disclosure of their use in the food supply.

D. The FDCA Challenge

Even after passing over First Amendment hurdles, any state-compelled GM labeling scheme must still overcome challenges of violating the FDCA. However, as evidenced in the *Amestoy* decision, the FDCA offers little practical guidance for analyzing GM issues. At least one court has recognized the difficulty this imposes on judicial decision-making. In *Stauber v. Shalala*,¹³⁹ plaintiffs challenged the FDA's decision not to require labeling of rBGH-treated milk under the FDCA. The district court was presented with evidence roughly similar to that in *Amestoy*: frightened consumers and concerns about the safety testing on BGH-treated milk.¹⁴⁰ The FDA's approval of the drug was challenged as "arbitrary and capricious"¹⁴¹ under the Administrative Procedure Act.¹⁴² The District Court for the Western District of Wisconsin observed:

If there is a difference, and consumers would likely want to know about the difference, then labeling is appropriate. If, however, the product does not differ in any significant way from what it purports to be, then it would be misbranding to label the product as different, even if consumers misperceive the product as different. In the absence of evidence of a material difference between rBST-derived milk and ordinary milk, the use of consumer demand as the rationale for labeling would violate [the FDCA].¹⁴³

As in *Amestoy*, the court ultimately deferred to the FDA.¹⁴⁴ Yet as one observer has noted, "[a]bsent statutory command, courts are understandably reluctant to overturn complex scientific conclusions on the merits."¹⁴⁵ But as one critic of the *Stauber* decision has pointed out, by "[u]sing the precedent that disallows courts to consider any evidence that is not part of the FDA record, the court declined to consider any of the plaintiffs' complaints . . . [in order to] bar consideration of any kind

139. 895 F. Supp. 1178 (W.D. Wis. 1995).

140. *See id.*

141. *Id.* at 1191.

142. 5 U.S.C.A. § 706(2)(a).

143. *Stauber*, 895 F. Supp. at 1193.

144. *See id.* at 1197.

145. Deatherage, *supra* note 41, at 236.

of nonagency reviewed data, whether or not it could have been part of the agency record."¹⁴⁶

The district court recognized that it is unrealistic for the judiciary to defer exclusively to scientific studies that, due to limited safety testing, cannot completely address the issues presented at bar.¹⁴⁷ It is argued that courts should use a more encompassing standard of scrutiny than the "substantial evidence" standard.¹⁴⁸ *Staubert* specifically suggested that "in the future it would be helpful to reviewing courts for the FDA to set out the factors it looks at in determining whether a particular risk is a manageable one."¹⁴⁹ *Staubert's* criticism suggests that to legitimately presume the propriety of an FDA position, the agency needs to provide more guidance and an explicit basis for its determination. Until such guidance with respect to genetically engineered ingredients is developed, courts will continue to rely on the FDA in neglect of consumer demand for information as well as any state legislative initiatives designed to compensate for the lack of federal guidance.

IV. REGULATORY AND CONGRESSIONAL RESPONSES TO GENETIC ENGINEERING

The response of agencies and Congress to the food safety issues presented by genetic engineering has been ineffective. First, as commercial biotechnology emerged over the last few decades, its unique issues were merely absorbed into the current regulatory structure for food, drugs, environmental issues, and agricultural production. This failure to adopt a comprehensive approach has resulted in system loopholes, inadequate definitions, and insufficient risk assessment of GM food products. Second, Congressional efforts to create labels for "organic" food instead of GM food is misguided. The FDA and Congress should revise and coordinate their efforts to regulate GM food safety.

There is no comprehensive regulatory scheme for food produced through GM methods. The FDA itself has not sought any additional statutory authority to deal with GM food products.¹⁵⁰ The FDA, as well as other agencies involved in food oversight, contend that existing

146. Emily Marden, *Recombinant Bovine Growth Hormone and the Courts: In Search of Justice*, 46 *DRAKE L. REV.* 617, 634 (1998).

147. *See id.*

148. *Id.*

149. *Staubert*, 895 F.Supp. at 1192.

150. *See Degnan, supra* note 4, at 199.

authority is sufficient to ensure that genetically-engineered food is safe for consumers.¹⁵¹

The federal agencies that oversee food production are the Food and Drug Administration (FDA), the U.S. Department of Agriculture (USDA), and to a limited extent, the Environmental Protection Agency (EPA) and the Federal Trade Commission (FTC). Although the agency functions appear discrete, the complexity of biotechnology creates significant jurisdictional overlap. In the Final Policy Statement for Research and Regulation of Biotechnology Processes and Products, the USDA observed that the largest number of negative comments addressed the potential for overlapping jurisdiction between agencies.¹⁵² These criticisms included the competing claims of both USDA and EPA to regulate agricultural micro-organisms, the potential for delays in regulatory decisions because of jurisdictional disputes, and the possibility for states acting independently because of the lack of federal oversight.¹⁵³ The USDA agreed that "there is the potential for overlapping jurisdiction among the Federal agencies involved in regulating biotechnology products."¹⁵⁴

The USDA regulates genetically-engineered plants through a division called the Animal and Plant Health Inspection Service (APHIS). APHIS is authorized to regulate "organisms and products altered or produced through genetic engineering which are plant pests or which there is reason to believe are plant pests."¹⁵⁵ This agency must regulate GM environmental assessments and field tests, but exempts corn, soybeans, cotton, potatoes, tomatoes, and tobacco. Curiously, all of these products are widely planted GM crops at this time, yet their producers are required only to notify USDA that field tests will occur. However, field tests require extensive precautions to avoid contamination of nearby wildlife. These precautions involve transporting plants to the site in closed containers, thoroughly cleaning the test plot equipment before and after use, and depending on the plant, blocking cross-pollination by bagging flowers, keeping insects from carrying pollen out by putting up cages, removing the plant's reproductive structures, and isolating the plants from other crops.

151. See Statement of Policy for Regulating Products of Biotechnology, 51 Fed. Reg. 23,309 (June 26, 1986).

152. See 51 Fed. Reg. 23,336, 23,346 (1986).

153. See *id.*

154. *Id.*

155. 58 Fed. Reg. 17056 (1993) (to be codified at 7 C.F.R. pt. 340).

The EPA also has regulatory oversight over genetically-engineered plants—a power derived from two Congressional acts. First, the Federal Insecticide, Fungicide, Rodenticide Act (FIFRA) gives the agency responsibility for pesticides. FIFRA authorizes EPA to set tolerances or establish exemptions from tolerance levels of pesticide residues on or in food crops. Since many GM plants are engineered to resist pests, the EPA is involved in regulating pesticide levels in the plant, but has no responsibility for the final product sold to the consumer.

It is important to remember that most commercial biotech applications presently involve only the transfer of one gene to convey one trait. Yet technology is quickly approaching which permits multiple gene transfers for multiple modifications. Without a comprehensive approach to regulate these changes, a best-case scenario will have the administrative process facing increasing demands and costs to catch up. In the worst case, GM foods will slip through the regulatory system in increasing numbers, eventually flooding the food supply with unlabeled, genetically-manipulated foods.

A. FDA Regulatory Authority is Insufficient to Assess GM Safety

The FDA has the primary responsibility for regulating food additives and new foods.¹⁵⁶ "The mission of [FDA] is to ensure that (1) food is safe, pure, and wholesome . . . [u]nder the foods program, FDA sets food standards; evaluates food additives and packaging for potential health hazards; conducts research to reduce food borne disease . . ." ¹⁵⁷ The primary tool for accomplishing this mission is the food label. The FDCA and the Fair Packaging and Labeling Act establish the requirements for a food label,¹⁵⁸ whose fundamental purpose is to meaningfully inform, warn, and instruct.¹⁵⁹

Although the FDA is not explicitly authorized to require label warnings, they have nevertheless published several labeling requirements in the past: warnings against dangerous uses of a product, special dietary uses, nutritional quality guidelines, and for particular food additives such as salt, aspartame, saccharine, and fruit juice

156. FDA is required to determine the safety of animal drugs. Food, Drug, and Cosmetic Act, § 406, 21 U.S.C. 346 (1938).

157. PETER BARTON HUTT & RICHARD A. MERRILL, FOOD AND DRUG LAW 21 (1991).

158. There are four main components of a food label as defined by the FDCA: the common name or identity of the item, the quantity, name and location of manufacturer, and ingredient and nutrition information. See 21 U.S.C.A § 348 (West Supp. 1999).

159. See 21 U.S.C.A. § 343 (West Supp. 1999).

products.¹⁶⁰

In May of 1992, the FDA determined that foods derived from GM plant varieties would be regulated no differently unless "special circumstances" apply.¹⁶¹ This policy ignores a large problem inherent in the FDA guidelines for a food label defining these special circumstances. The labeling element most likely to become outdated with the approach of GM crops is the "common name" or "identity" of a product. The "common name" implication is that although the end product is considered a "potato," it may be "altered so that its usual name no longer accurately describes its basic nature or characterizing properties,"¹⁶² as when the nutritional value is changed. Genetically-enhanced potatoes would not necessarily be altered in this way. For example, a tomato to which a non-occurring element has been added, such as calcium, would have to disclose this difference. Therefore, the FDA cannot address GM processes due to the statutory language focusing on the qualities of the "final product."¹⁶³ This focus has impeded efforts to allow even voluntary labeling of genetically engineered foods.

1. FDA Regulation of Bovine Growth Hormone

Despite the lack of specific guidelines for GM products in general, the FDA issued interim guidelines for the voluntary labeling of bovine growth hormone in February 1994.¹⁶⁴ Voluntary labeling schemes are well-suited to organic and other producers that wish to distinguish themselves as "non-GM" foods. These guidelines state that labels must be truthful, not misleading, and must include a qualifier that FDA had approved the hormone.¹⁶⁵

Dairy manufacturers in many states followed the voluntary labeling guidelines. A handful of states went a step further, refusing to permit any "anti-rBGH" labeling by manufacturers who wanted to promote their products as not being derived from use of the controversial hormone. Among those states that banned "no-BGH" labels was

160. FOOD & DRUG LAW INSTITUTE, RICHARD M. COOPER, ED., FOOD AND DRUG LAW (1991).

161. 57 Fed. Reg. 22,984 (1992). These circumstances are unexpected genetic effects, known toxicant levels, altered nutrient level, significantly different composition, allergenicity, antibiotic resistance potential, and issues specific to animal feeds. *Id.*

162. Burk, *supra* note 19, at 254.

163. 21 U.S.C.A § 343 (West 1999).

164. See Interim Guidance, 59 Fed. Reg. 6280 (1994).

165. *Id.*

Illinois, whose state officials were taken to court in May of 1996 by several dairy product manufacturers.¹⁶⁶ These companies, including Ben & Jerry's, Stonyfield Farm, Whole Foods Market, and Organic Valley, were advised by the Director of Public Health that sales of their products under an "rBGH-free" label would violate provisions of the Illinois Food, Drug and Cosmetic Act.¹⁶⁷ In a press release, plaintiff Ben & Jerry's stated:

We believe our commitment to natural ingredients and to family farming . . . expressed through our products . . . is an important part of our success We believe our business depends in part on our ability to let our customers know that we oppose the use of rBGH; we want to assure them that our milk and cream do not come from cows treated with this laboratory hormone.¹⁶⁸

These producers demonstrated that the restriction on speech was also burdensome on commerce because the logistics involved in interstate food distribution preclude using different packaging for different states.

Although a settlement was eventually reached in favor of permitting "non-BGH" labels such as those used by Ben & Jerry's,¹⁶⁹ the companies still questioned the need for the FDA "qualifier" and whether any government agency has the ability to force a food manufacturer to accept and espouse the FDA position on such a controversial issue.

2. Ensuring Adequate Risk-Assessment

Ideally, the stringency of a regulatory scheme is equivalent to the risk it seeks to prevent. Much of the controversy surrounding the lack of regulation centers on the fact that many of the perceived risks are in dispute or incapable of quantification at this stage of technology. The question is whether it is appropriate to assume genetic manipulation of

166. Ben & Jerry's Homemade, Inc. v. Lumpkin, *available in* No. 96 C 2748, 1996 WL 495554 (N.D. Ill. Aug. 28, 1996).

167. *See id.*

168. Press Release dated May 7, 1996 (on file with the author).

169. Currently, Ben & Jerry's cartons bear labels on the top of the lid and back panel: "WE OPPOSE RECOMBINANT BOVINE GROWTH HORMONE. The family farmers who supply our milk and cream pledge not to treat their cows with rBGH. The FDA has said no significant difference has been shown and no test can now distinguish between milk from rBGH treated and untreated cows. Not all the suppliers of our other ingredients can promise that the milk they use comes from untreated cows." Ben & Jerry's Homemade, Inc. v. Lumpkin, *available in* No. 96 C 2748, 1996 WL 495554 (N.D. Ill. Aug. 28, 1996).

foods to be safe for human health and the environment until it is conclusively proven otherwise, at which point it may be too late to impose controls.

The FDA says it is succeeding in adapting to the new science. Yet the example it gives of their "successful adaptation" to GM foods is pulling them into the current categorical structure.¹⁷⁰ Under the current reasoning, because moth genes are in themselves safe, their genetic presence within an edible item such as a potato must also be safe. This reasoning seems incongruous with the traditional approach to risk-assessment, where data accumulates on a product, experience with it grows, and the tendency toward strict regulation relaxes. Inexplicably, that is not the stance the law has taken with GM products and their introduction into the food supply.

Author Robert Bohrer describes this typical regulatory life cycle of a new technology: the first stage occurs where there is an absence of data concerning the variety of possible risks involved in the new process.¹⁷¹ Typically, this yields a stringent regulatory framework.¹⁷² As data accumulates, experience enables a better assessment of risk.¹⁷³ Technology progresses, more data becomes available, and the regulatory approach is reassessed and relaxed when appropriate.¹⁷⁴ The open question, however, is how to know when it is "appropriate" to loosen regulation. Clearly, an appropriate regulatory structure can be developed only after a meaningful attempt at qualitative risk assessment.

An appropriate assessment of biotech products would include the market nature of the risk, the complexity of genetic manipulation and its potential results.¹⁷⁵ An example of this standard of risk assessment can be found in EPA environmental requirements, which are, for the most part, a stringent regulatory scheme.¹⁷⁶

With respect to biotechnology, current FDA regulations are based on simplistic assumptions, which limit the ability to adequately regulate GM products. First, its risk assessment focuses not on the biotech

170. IVER P. COOPER, *BIOTECHNOLOGY AND THE LAW* 1994.

171. See ROBERT A. BOHRER, *FROM RESEARCH TO REVOLUTION: SCIENTIFIC, BUSINESS, AND LEGAL PERSPECTIVES ON THE NEW BIOTECHNOLOGY* 102 (1987).

172. See *id.*

173. See *id.*

174. See *id.*

175. See *id.* at 103-06.

176. See *id.* Bohrer also points out that regulatory frameworks are affected by ups and downs of the economy: during well-off times, there is less regulation, and vice versa. See *id.*

process, but on its end products. This means that the potential for physiological altering of crops to produce desired traits is not viewed as inherently different from whole foods, or from those selectively bred. Second, the need for oversight is disregarded where there is no "known" risk. Those risks that are in dispute, as is the case with most GM products, are considered too remote to expend the cost of their regulation. Third, FDA risk assessment does not analyze social and economic effects that may follow introduction of a GM product, such as effect of BGH on smaller economies of scale. The regulatory approach to biotech should consider the magnitude of the risks instead of the probabilities offered up to the agencies by GM companies seeking permits. Meeting this challenge will require not only additional funds, but also explicit statutory guidance.

B. Congressional (In)action

Before the FDA has the statutory room to perform testing and compel labeling of GM foods, congressional action is required. However, current congressional action in this area is going in the wrong direction. A current proposal would make it impossible to identify "pure food" under an overall scheme that provides no labeling of GM, corrupts the traditional definition of the word "organic," and prevents independent, voluntary labeling. This effectively holds consumers hostage and destroys meaningful choice as well as any viable alternatives to GM food. Rather than devising a long-term solution to adapt to GM foods and processes, Congress has wrongly focused on labeling "non-GM" foods, which is at best a stopgap measure.

In 1990, Congress passed the Organic Foods Production Act to alleviate confusion and create a uniform organic standard in order to facilitate interstate commerce.¹⁷⁷ The result of this initiative, which was passed to the USDA, has been a dismal failure.¹⁷⁸ After eight years, USDA still has not come up with a workable policy for the "USDA Organic" certification. It is not difficult to understand why this delay has occurred, as the scheme has had checkered progress from the start. For example, the USDA has been a traditional promoter of the latest

177. The Organic Foods Production Act of 1990, 7 U.S.C. §§ 6501-6522 (1994).

178. See, e.g. Kenneth Amaditz, *The Organic Foods Production Act of 1990 and Its Impending Regulations: A Big Zero For Organic Food?*, 52 FOOD & DRUG L.J. 537 (1997). For a discussion of scientific publications and their influence on administrative agencies such as the FDA, see Lars Noah, *Sanctifying Scientific Peer Review: Publication as a Proxy for Regulatory Decision Making*, 59 U. PITT. L. REV. 677 (1998).

technologies developed by agribusiness and biotech companies.¹⁷⁹ The official advisory board in charge of making recommendations, the National Organic Standards Board (NOSB), has seen their policy proposals disregarded by the agency at every turn. Under USDA control, the proposals for "organic"¹⁸⁰ standards include not only the use of genetic engineering, but also permit use of nuclear irradiation, pesticides, toxic sewage sludge fertilizer, intensive confinement of farm animals, and other practices.¹⁸¹

More disturbing is the USDA's proposal that it be given the power to regulate or prohibit voluntary "eco-labels" of any kind. Any voluntary labeling information that implies "organic" production would be prohibited. This may include labels that say, for example, "produced without synthetic pesticides," "pesticide-free farm," "[n]o growth stimulants administered," "raised without antibiotics," and "ecologically produced."¹⁸² Additionally, the nation's 11 state and 33 independent certifying agencies¹⁸³ may be prohibited from certification and labeling using standards higher than the USDA minimum. It appears, however, that this proposal would have limited success in light of recent court settlements involving similar issues.¹⁸⁴

Many observers feel that the only thing preventing organic standards from succumbing to the effects of "agency capture" is the hue and cry from those consumers who created the spectacular growth in the organic market.¹⁸⁵ The proposed organic standards were open for public comment until March 1998, but the definitions for "organic" met with vehement opposition, which delayed action until the end of the year.¹⁸⁶

179. See Lilliston, *supra* note 67.

180. The comment period on these definitions was extended to December 30, 1998. The definitions, if approved, will appear on the National List, published in the Federal Regulations.

181. See *id.*

182. *Id.*

183. See press release at Organic Valley website, <http://www.organicvalley.com> (visited February 15, 1998).

184. See *Ben & Jerry's Homemade, Inc. v. Lumpkin*, available in No. 96 C 2748, 1996 WL 495554 (N.D. Ill. Aug. 28, 1996).

185. Under the Agricultural Marketing Act of 1940, producers who wish to participate in the USDA's certification programs must request and pay for the inspections. There could be legal problems with this requirement combined with the compulsory characteristics of the "USDA Organic" program if it prohibits use of the word "organic" or independent labeling schemes. See, e.g., *Glickman v. Wileman Bros. & Elliot, Inc.*, 521 U.S. 457 (1997).

186. See Rick Franzen, *Will GATT Take A Bite Out of the Organic Food Production Act of 1990?*, 7 MINN. J. GLOBAL TRADE 399 (1998) (one proposal would allow beef fed up to twenty percent non-organic food to carry the "USDA Certified Organic" label).

Federal oversight of GM food labeling is preferable for another reason: conflicts will arise to the extent that "local judgments concerning the safety and desirability of biotechnology differ from those of federal authority."¹⁸⁷ GM advocates say that state assistance in furthering an "ideological" crusade can hardly be called a legitimate reason to burden interstate commerce. Yet even with a "legitimate" consumer interest in origin labeling being postulated, state regulation would still face demanding requirements to overcome their burden on commerce. For this reason, federal labeling is appropriate.

V. ENSURING CONSUMER PROTECTION IN THE BIOTECH CENTURY

It would be difficult to conceive of any topic of discussion that could be of greater concern and interest to all Americans than the safety of the food that they eat.

District Court Judge Mary Lou Robinson¹⁸⁸

A rational strategy to label GM foods must be based on sound research and acknowledge the limits to current scientific knowledge about genetic processes. This strategy requires an approach that respects both sides of the GM debate. First, the regulatory structure must be amended to reflect consumer concerns about food safety. Second, a labeling scheme should be based on the need to monitor GM products in the food supply. Moreover, the label should facilitate consumer access to current, credible information about GM safety. Finally, the government should abandon its regulatory efforts for "non-GM" labels. This section concludes by discussing the suggestions for a new food safety agency.

A. Amending the FDCA

Several amendments to the FDCA have been adopted that encompass consumer needs and cover risks.¹⁸⁹ The FDA has relied mainly on Section 403(a)(1) of the Food, Drug, and Cosmetic Act (FDCA) for these amendments and would presumably do so again for guidance on labeling GM foods. Section 403(a)(1) sets forth the criteria for determining "misbranded" or "adulterated" food. However, GM

187. See Burk, *supra* note 19, at 228.

188. Texas Beef Group v. Oprah Winfrey, 11 F. Supp. 2d 858, 862 (N.D. Tex. 1998).

189. For a description of these amendments, see Degnan, *supra* note 4, at 162.

foods escape the reach of this provision, becoming subject to it only if a problem arises post-marketing, when already in the hands of consumers. Additionally, since transferred genetic material is presumed to be Generally Recognized As Safe (GRAS), it is currently exempt from pre-market approval or testing under this section.

1. Section 403 Definitions of "False and Misleading."

The basic prohibition in food labeling is false or misleading labeling, regulated by Section 403(a) of the FDCA. An article of food is misbranded if "its labeling [is] false or misleading in any [way]."¹⁹⁰ Taken together with other guidelines, a label can be misleading not only for what it suggests to the consumer but also for what it fails to disclose. An unresolved question is whether nondisclosure of a genetic engineering production process is "misleading" or "material" information.

Under current regulations, a GM food, such as pesticide-containing New Leaf Superior potatoes, need only be labeled under two conditions. The first condition is if the item contains an ingredient commonly considered an allergenic food. However, this presumption of "misleading" is refutable by the manufacturer. If the manufacturer argues successfully, the item is exempted from the label requirement. The second condition is if the nutritional content of a food is changed. For example, when a tomato is developed that no longer contains its naturally-occurring vitamin C, that fact must be disclosed. GM foods completely elude the "misleading" standard, because the FDA's view is that the method by which a plant is developed by a plant breeder is not "material" information in a legal sense.¹⁹¹ This unworkable premise has already become irrelevant with advances in biotechnology. It overlooks the very stage where risks occur and focuses on the end product where it becomes too late for prevention of catastrophic outcomes.

Judicial decisions show a traditional disposition toward giving section 403 a high level of protection. Though there are no cases directly on point with GM foods, several cases allude to a broad meaning of "false and misleading." In case of *United States v. Ninety-Five Barrels (More or Less) Alleged Apple Cider Vinegar*,¹⁹² the Supreme Court deemed "misbranded" vinegar made from dehydrated rather than fresh apples. The Court observed that "[d]eception may

190. 21 U.S.C. § 343(a) (West Supp. 1999).

191. *Id.*

192. 265 U.S. 438 (1924).

result from the use of statements not technically false or which may be literally true."¹⁹³ Further, the misrepresentation was found to be of the vinegar itself, its substance, and ingredients.¹⁹⁴ The Court observed that the FDCA requires no disclosure concerning production. When considered independently of the product, the method of manufacture is not material. Yet with GM food products, it is illogical to consider the manufacture independently of the product. "Misleading" ought to encompass an absence of information about genetic alteration of food since the end product is materially different from the traditionally bred variety. Indeed, to profit from their products, GM companies are *required* to prove this difference in applying for patent protection. Many other cases show how broadly the Court interprets "misleading" labeling information.¹⁹⁵

2. "Food Additive."

Extensive requirements for premarket safety testing apply to food "additives."¹⁹⁶ The traditional definition of this term is perhaps the biggest obstacle to testing and labeling GM products. Unless an additive is considered GRAS, it is subject to substantial premarket testing and approval. GM foods are considered GRAS and are not subject to the "additive" definition unless it is a "protein, carbohydrate, fat or oil, or other substance that differs significantly in structure, function, or composition from substances currently found in food."¹⁹⁷ For example, genes from virtually any source may be imposed in a soybean. This soybean in turn becomes a food additive when it is used to make bread, chips, or baby formula. However, FDA has rarely ruled on GRAS status of whole foods when used as a component. The agency does not explain how it would become aware of GM foods that may require submission of food additive petitions because of genetic manipulation, since the focus is solely on the final product.

According to the definition of "food additive," whole foods may

193. *Id.* at 443.

194. *See id.* at 445.

195. *See* United States v. An Article of Food . . . Labeled Nuclomin, 482 F.2d 581 (8th Cir. 1973); United States v. An Article of Food . . . "Manischewitz . . . Diet Thins," 377 F. Supp. 746 (E.D.N.Y. 1974); United States v. An Article of Food . . . Containing 432 Cartons, More or Less, Containing 6 Individually Wrapped Candy Lollipops of Various Flavors, 292 F. Supp. 839 (S.D.N.Y. 1968).

196. 21 U.S.C.A. § 343(m) (West Supp. 1999).

197. *See* Statement of Policy: Foods Derived from New Plant Varieties, 57 Fed. Reg. 22,990 (1992).

indeed be "additives when used as components of prepared foods."¹⁹⁸ Congress, however, has never, before now, had a reason to require premarket approval of traditional foods. Because of this language, FDA has never considered it necessary to examine whether potatoes, tomatoes, carrots, or milk are in fact GRAS. A tomato is considered a tomato, whether it is a Beefsteak tomato grown by a California farmer, or a Flav'r Sav'r tomato developed in a lab. If it is found in the after market to be "poisonous or deleterious," it can be excluded from commerce, but only if the FDA can show that the additive "may render" the food injurious.¹⁹⁹ This means that the food needs to cause an allergic or other reaction in a consumer. Yet there is no indication of just how consumers would be able to identify the GM food as the source of their allergies if it is not labeled.

Disturbingly, it is the applicant company that determines whether a new gene protein is GRAS. The GM companies are the ones who decide whether they need to consult with FDA by following "decision trees" that act as a guide. Yet as a Monsanto executive pointed out, "Monsanto should not have to vouchsafe the safety of biotech food, our interest is in selling as much of it as possible. Assuring its safety is the FDA's job."²⁰⁰

The emphasis on "informal, ad hoc assessment [by the FDA] perpetuates uncertainty for innovative companies and may weaken public confidence."²⁰¹ It also creates loopholes through which GM foods, with their novel, genetically-spliced "ingredients," slip into the food supply untested. For example, although one might think the Bt pesticide genes in New Leaf Superior potatoes would qualify as a "novel substance" for a potato, and therefore an "additive," it is not required to be labeled. This is because pesticides themselves are exempt from FDA regulation. The EPA in turn has no authority over food products. It instead works from the assumption that if the original potato is safe, and the Bt protein genes in themselves are considered by the agency to be safe, then the whole New Leaf package is presumed safe.²⁰² This is a logical fallacy. Food "additives" need to include whole foods that are produced by GM methods.

198. Degnan, *supra* note 4.

199. Food Drug & Cosmetic Act of 1938 § 403(a)(1).

200. Phil Angell, *quoted in* Pollan, *supra* note 45.

201. Lars Noah & Richard A. Merrill, *Starting From Scratch? Reinventing the Food Additive Approval Process*, 78 B.U. L. REV. 329, 413 (1998).

202. See Pollan, *supra* note 45.

3. "Economic Adulteration."

An important provision of the 1938 Act was the concept of "economic adulteration" of food. However, since legal action based on this principle has become next to impossible to pursue, the FDA has practically abandoned it. The concept of economic adulteration prohibited economic fraud upon a consumer by a manufacturer who conceals some perceived inferior value of a product, thus misleading the consumer into a purchase under false pretenses. This could be the case with a consumer who buys a potato but is unaware that it produces its own pesticide. If the consumer would have made another choice with this information, the purchase may be considered fraudulent.

An example of this concept can be found in the use of BGH. Whether purchasing this milk unknowingly is fraudulent is in dispute. GM proponents assert that "no consumer who purchases milk from cows treated with rBST has been deceived or defrauded—the milk is precisely what it purports to be, milk."²⁰³ When a consumer makes a food purchase, "there is no telling whether it comes from farms owned by godless communists, is distributed by corporations with objectionable foreign investments . . . or in some other way is associated with some political, economic, or social outcome that the consumer might find distasteful."²⁰⁴ However, because the process has uncertain effects on the milk produced, this argument ignores the very real differences between BGH-treated and regular milk.

With the advent of modern technology, there are countless numbers of substances used in food production: preservatives, emulsifiers, stabilizers, thickeners, and a variety of other enhancements. "Adulteration" no longer has the same meaning as it once did. However, the FDA has pursued a number of cases that allude to the "adulterated" concept.²⁰⁵

In *United States v. 36 Drums of Pop'n Oil*,²⁰⁶ the FDA successfully contended that a mineral oil, colored and flavored to appear as butter, was "adulterated" because its inferiority had been concealed by making it look like butter, although it was truthfully labeled. Although the FDA eventually abandoned these cases, it successfully prosecuted a number of "adulterated" products.²⁰⁷ Although many consumers

203. Burk, *supra* note 19, at 291.

204. *Id.*

205. See HUTT & MERRILL, *supra* note 157, at 63-64.

206. 164 F.2d 250 (5th Cir. 1947).

207. See, e.g., *United States v. 88 Cases More or Less, Containing Birely's Orange*

currently consider GM foods "inferior", there is still the problem of representing to the consumer that these foods are marketed as being in no way different from typical varieties. Additionally, there is substantial evidence that many consumers desire not to purchase GM foods. The concept of "economic adulteration" is well-suited to this particular problem.

4. "Materially altered."

The FDCA mandates the labeling of "materially altered" foods. Of course, there are technical problems in proving that a GM tomato is no longer the "regular" item, although manufacturers' reference to "traditional" tomatoes suggests that they see their new products as separate and different. Certainly, to acquire patent protection for seeds and fruits suggests that GM products are indeed different from their counterparts. Consider the vigilance with which Monsanto protects its intellectual property in seeds. The seed is "different" for patent protection purposes but the "same" for regulatory oversight. To what extent will food have to be genetically altered before it becomes unlike its natural counterpart? For example, the current law would allow a chicken bred with caterpillar genes in order to produce five wings instead of the regular two to go undisclosed to the consumer. Should this be considered "materially altered" if the consumer will never know about the manipulation?

The FDA abandoned its old policy that any resemblance of a "new" food to a traditional one, or reference to one in its name renders it illegal. For example, enriched macaroni with fortified protein does not violate the macaroni standard. Analogous to this is that a tomato with a flounder gene to prevent freezing damage would not be considered as violating a "tomato" standard.

GM proponents point out, for example, that BGH passed through to milk is "probably neither food additives or adulterants under the statute . . . even if it were considered a food 'additive,' it has been shown by scientific procedures to be GRAS."²⁰⁸ Despite the provisions for animal drugs like BGH, a food product such as the Bt potato may escape any testing under the current regulatory structure. Clearly, the FDA must be given explicit statutory authority for the testing and labeling of GM foods. This authority will require expanded definitions to deal with the peculiarities of biotechnology.

Beverage, 187 F.2d 967 (3d. Cir. 1951).

208. See Burk, *supra* note 19, at 254.

B. Create a Federal Labeling Scheme

While calls for a federal labeling initiative have been based on consumer choice, a more appropriate scheme would be based on concern for public health. Ideally, labels should facilitate epidemiological studies to detect any increase in allergies or diseases linked to GM foods.

As described in Part Three, states have a substantial interest in regulating health and safety initiatives within their borders. A state-by-state GM labeling scheme has been advocated as an alternative in light of the lack of federal guidance.²⁰⁹ Yet state regulation, while a viable alternative, offers problems to interstate commerce and would lack the comprehensive approach needed. Disclosures on labels would not need to be characterized as "warning" labels. For whole foods like produce, a display with the product name and information about the modifications and their purpose could be devised. For components of processed foods, the nutrition labeling guidelines already in place might describe the "genetically modified" ingredients and indicate the percentage of GM components used. An alternative approach might be a symbol on the package indicating the presence of genetically engineered additives. Not only would this disclosure provide adequate sourcing information for consumers and businesses, it might also ease the trade problems the U.S. currently has with exporting genetically engineered foods such as soybeans and beef. In addition to amending the FDA guidelines, there have been other suggestions to make the agency more efficient and risk attentive, including contracting out the safety testing of food additives.²¹⁰

C. Encourage Voluntary Labeling Efforts and Regulation on a State Level

Independent labels serve a variety of consumer markets. By developing guidelines targeted to their consumers, they provide more information in the market. For this reason alone, voluntary organic labeling is preferable to any federal pre-emption of the word "organic."²¹¹ There are "eco-labels," which assure that a food has been

209. For the position that mandatory labeling for GM products should be an option for states, see Lennon, *supra* note 82.

210. Noah, *supra* note 178, at 439-41.

211. One important aspect of eco-labeling of any kind, however, is the potential impact on trade and possible challenges as trade barriers, or international task forces like International Standardization Organization (ISO) that seek to ensure labeling schemes can be operated to achieve their objectives without creating unnecessary obstacles to international trade. See generally Marsha A. Echols, *Food Safety Regulation in the European Union and*

produced in accordance with various environmental concerns. These labels include Midwest Organic, California state certified organic, Vermont certified organic, Mother and Others for a Livable Planet for pesticide-free apples, "ECO-OK" coffee beans, and the Rainforest Alliance label for Latin American produce grown only with pesticides legal in the U.S. and Europe. The Smithsonian Migratory Bird Program in Washington is devising a label for "bird-friendly" coffee that is both organic and harvested in areas with a diverse mix of shade trees that migrating songbirds from North America need to survive.²¹² Obviously, each of these labels reaches out to a different segment of the market.

These individualized marketing niches are an effective way for family farms and smaller companies to compete with agribusiness.²¹³ This is because of the suitability of these methods to small-scale farming and because of the higher prices paid for goods such as organic milk and coffee. The natural and organic markets have only started to grow, and these labeling initiatives need time to develop. Any confusion presented by variety is likely to be weeded out by consumer demand. Likewise, biotech needs time to develop its own merits, assess its risks and benefits, and earn consumer acceptance. Unlike voluntary labeling initiatives, however, this is a task best done through regulation rather than market forces.

States too may establish their own voluntary labeling system. These initiatives have a very successful history. California and Vermont have Organic Marketing Acts; Wisconsin has provided for "BGH-free" labels. Often, the dairies themselves will use labels, or provide them to the retail outlet to display by the product, but not on the product itself.²¹⁴

D. Creation of a Food Safety Agency

One often-mentioned reform is creating a food-safety agency with

the United States: Different Cultures, Different Laws, 4 COLUM. J. EUR. L. 525 (1998); Melody Petersen, *Farmers Feel Rejection of Altered Grain: Genetic Engineering Unpopular Overseas*, KANSAS CITY STAR, August 29, 1999 available in 1999 WL 2433254.

212. Abby Scher, *Green Labels: Can They Build A New Marketplace?*, DOLLARS & SENSE, May 15, 1997, at 22.

213. An example of organic marketing success can be seen in Wisconsin's dairy industry. The state lost 35% of its dairy farms between 1985 and 1995. By forming cooperative business associations and creating organic dairy operations, many farms that would otherwise go under are surviving. See Dr. Robert Cropp, et. al., *Cooperative Ownership Compared to Other Business Arrangements for Multi-Family Dairy Operations*, UCC Occasional Paper No. 11, April, 1996 available at <<http://www.wisc.edu/wcc>> (visited February 15, 1999).

214. Telephone Interview with Joan Behr, Golden Guernsey Dairies/Foremost Farms (February 15, 1998).

oversight over production processes, marketing, and labeling. This possibility should be given more consideration as food production becomes more complex. A new agency could pull together the disjointed food supervisory responsibilities of the EPA, USDA, and FDA. Unlike those agencies, a new food safety agency could avoid conflicts by not being vested with responsibilities that compromise its mission, like working with companies to bring products to market. This would ease application procedures for businesses, regulate risk assessment more carefully, and could possibly phase out GM labels upon proof of risks and benefits.

VI. CONCLUSION

Proponents of recombinant DNA technology point out that "biotechnology has been repeatedly identified as a 'critical' or 'generic' industry that is important to national competitiveness."²¹⁵ However, because of the conflicting evidence as to the safety of GM crop production, it is important to acknowledge risk and create a controlled environment in which it may develop. In order to remedy the legislative and judicial confusion that exists because of the lack of federal guidance on GM foods, this Comment has suggested a number of statutory definitions that might be enlarged. These revisions would allow a federal labeling initiative that facilitates the flow of information to consumers, in conformity with the mission of existing food labeling legislation.

Promoting information flow in the marketplace is important to the success of any industry. Concealment or suppression of GM information at this early stage in biotech development will do more to stunt the growth of the industry than anything else, and consumers will lose out on many of the legitimate benefits of genetic engineering as a result. For these reasons, a federally mandated labeling scheme is essential.

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215. Burk, *supra* note 19, at 273.