



Biotechnology and the Labeling Dilemma

Citation

Biotechnology and the Labeling Dilemma (2001 Third Year Paper)

Permanent link

<http://nrs.harvard.edu/urn-3:HUL.InstRepos:8846803>

Terms of Use

This article was downloaded from Harvard University's DASH repository, and is made available under the terms and conditions applicable to Other Posted Material, as set forth at <http://nrs.harvard.edu/urn-3:HUL.InstRepos:dash.current.terms-of-use#LAA>

Share Your Story

The Harvard community has made this article openly available.
Please share how this access benefits you. [Submit a story](#).

[Accessibility](#)

Biotechnology and the Labeling Dilemma

Adela M. Choi
30508998
Third Year Paper
Harvard Law School
Submitted to: Professor Peter Baron Hutt

Biotechnology proponents deem biotechnology critics “imperialists for opposing a technology that could be used to develop improved crops for poor nations.”¹ Critics of the technology deride genetically engineered products as “frankenfoods.”² Biotechnology companies claim that their products will feed the world,³ while opponents claim that the products will lead to a bio-disaster.⁴ Ironically, while these heated accusations are

¹Andrew Pollack, *Critics of Biotechnology Are Called Imperialists*, N.Y. Times, February 4, 2001, available at <http://www.nytimes.com/2001/02/04/weekinreview/04POLL.html>.

²Matthew Franken, *Fear of Frankenfoods: A Better Labeling Standard for Genetically Modified Foods*, 1 MINN. INTELL. PROP. REV. 153, 153 (2000).

³Michael Pollan, *Playing God in the Garden*, N.Y. TIMES MAG., Oct. 25, 1998, available at 1998 WL 22330020 [hereinafter *Playing God in the Garden*].

⁴See, e.g. <http://www.greepeace.org/ge>.

hurled between consumer activists and biotechnology companies, the public is largely unaware that these products are already being widely sold in American grocery stores.⁵

Genetically engineered foods have already made a significant impact on the American food supply. In 1999, genetically engineered plants were cultivated on approximately 28 million hectares of the world's land, and this number is expected to triple within 5 years.⁶ The United States is one of the world's largest producers of these products; 55% of the soybeans, 50% of the cotton and 40% of the maize grown in the U.S. is derived from genetically engineered seeds.⁷ This major shift in the food supply has already impacted the public diet, with up to two thirds of all processed foods currently sold in U.S. grocery stores containing genetically altered ingredients.⁸ Moreover, the number of genetically engineered products produced in the U.S. is likely to increase dramatically, with at least 50 genetically engineered crops approved as food products,⁹ and many more products in development.¹⁰ One prominent seed producer has predicted that up to 80% of the produce sold in America will soon contain some kind of genetic modification.¹¹

The American public has expressed concern about the implications and risks of this technology.¹² Public anxiety about biotechnology has been driven in part by the contemporary public's distrust of the scientific establishment and scientific evidence. The public has expressed an increased wariness towards science generally, and towards biotechnology in particular.¹³ This shift in the public mind-set has been accompanied by

⁵Food and Drug Administration, Center for Food Safety and Applied Nutrition, *Report on Consumer Focus Groups on Biotechnology*, Oct 20,2000, available at <<http://www.cfsan.fda.gov/~comm/biorpt.html>>. (finding that "virtually all" of the participants indicated a desire for labeling of bioengineered foods.) [hereinafter *Consumer Focus Groups*]

⁶Philip H. Abelson & Pamela J. Hines, *The Plant Revolution*, 285 SCIENCE 367, (July 16, 1999), available at <<http://www.sciencemag.org>>.

⁷*Food For Thought*, ECONOMIST, June 17, 1999, available at 1999 WL 7363490.

⁸Andrew Pollack, *F.D.A. Plans New Scrutiny in Areas of Biotechnology*, NEW YORK TIMES, January 18, 2001, available at <<http://www.nytimes.com/2001/01/18/health/18REGS.html>>.

⁹Philip R. Reilly, *Public Concern About Genetics*, 1 ANN. REV. GENOMICS HUM. GENETICS 485, 499 (2000).

¹⁰*Next Generation Biotech Products Will Face Traditional Labeling Issues in U.S.*, Food Chemical News, July 13, 1998, available at 1998 WL 10981464.

¹¹Scott Kilman & Jonathan Friedland, *Growth Industry: As Geneticists Develop and Appetite for Greens, Mr. Romo Flourishes*, WALL ST. J. EUR., Jan. 28, 1999, available at 1999 WL-WSJE 5506210.

¹²Reilly, *supra* note 9 at 498.

¹³Michael A. Whittaker, *Reevaluating the Food and Drug Administration's Stand on Labeling Genetically Engineered Foods*, 35 SAN DIEGO L. REV. 1215, 1222-3 (1998).

a diluted degree of trust and respect in the opinions of and the scientific establishment.¹⁴ Public concerns have also been raised about the nature of the technology,¹⁵ the speed with which this technology has been introduced,¹⁶ and the rapid commercialization of the genetically engineered products.¹⁷

These anxieties about genetic engineering are further exacerbated by the fact that the focus of this controversy centers on food. People are likely to express special interest and concern about food—an extremely personal and daily part of life.¹⁸ Dennis Kucinich, a member of the House of Representatives representing Ohio, has stated that “there is nothing more personal than food.”¹⁹ Diane Toops, the news and trend editor of a food trade magazine, has noted that people are often especially distrustful of changes in food products, citing the “consumer mantra: don’t muck with my food.”²⁰ Even Fred H. Degnan, a legal commentator supportive of the FDA’s current policies towards agricultural biotechnology, has acknowledged consumers’ heightened level of concern about the health effects of agricultural biotechnology, noting “the unease felt by many about the use of gene technology in foods—the use of technology in a context that touches our lives daily and personally.”²¹ According to Carol Tucker Foreman of Consumer Federation of America:

Food is special. We eat to sustain life and health. Since food is so basic to us both physically and emotionally, it is really not surprising that consumers are extremely averse to any food-related risk, especially if that risk is perceived as imposed by someone else beyond our individual control and without any countervailing benefit. In short, we eat because it is good for us, not because it benefits those who grow, process or sell food.²²

Tied to this elemental conservatism about the application of novel scientific techniques to the food supply is a growing consumer awareness of the connection between diet and health.²³ In fact, the popularity of such

¹⁴Derek Burke, *Time for Voices to be Raised*, 405 NATURE 509 (2000), available at <<<http://www.nature.com>>.

¹⁵Philip R. Reilly, *Public Concern About Genetics*, 1 ANN. REV. GENOMICS & HUM. GENETICS 485, 502 (2000).

¹⁶*Id.* at 502.

¹⁷Paul Smaglik, *Educated US Public Get More Wary of Genetic Engineering*, 405 NATURE 988, 988 (2000).

¹⁸Nevertheless, Americans’ cultural ties to food are less strong than that seen in European countries. See, e.g., *Sticky Labels*, ECONOMIST, April 29, 1999, available at 1999 WL 7362891; Marsha A. Echols, *Food Safety Regulation in the European Union and the United States: Different Cultures, Different Laws*, 4 COLUM. J. EUR. L. 525, 526 (1998).

¹⁹Jeffrey Kluger et al., TIME INTL., Sept. 20, 1999, available at 1999 WL 25725566.

²⁰Marian Burros, *Irradiated Beef: In Markets, Quietly*, N.Y. TIMES, February 28, 2001, available at <<<http://www.nytimes.com/2001/02/28/living/28WELL.html>>>.

²¹Fred H. Degnan, *Biotechnology and the Food Label: A Legal Perspective*, 55 FOOD & DRUG L.J. 301, 301 (2000).

²³Steven B. Steinborn & Kyra A. Todd, *The End of Paternalism: A New Approach to Food Labeling*, 54 FOOD & DRUG L.J.

“functional foods” as margarine containing chemicals designed to lower cholesterol, attest to the fact that “[t]he distinction between food and drugs is increasingly blurred.”²⁴ Sensitized to the relationship between food and health, the public may be especially wary of any unfamiliar food processing method for fear that the processing might pose unknown health risks.

Motivated by these concerns about genetically engineered products, an increasing number of consumer, environmental, and even farming groups have recently been calling for a greater degree of regulation of genetically engineered foods. Some national politicians²⁵ and state legislatures²⁶ have even taken up the cause. One of the main policy changes advocated by these groups is a call for mandatory labeling of genetically engineered whole foods and foods containing genetically engineered ingredients. Mandatory labeling of genetically engineered foods is also widely supported by the public.²⁷ Despite this demonstrated public interest in a mandatory labeling policy, the FDA has consistently resisted calls for mandatory labeling of genetically engineered foods, and foods containing genetically modified ingredients.

This paper will examine the arguments and motivations underlying the FDA stand against mandatory labeling of genetically engineered foods and ingredients. Part I of the paper will describe FDA’s current regulatory policy towards genetically engineered foods. Part II will advance the theoretical basis for the labeling argument. Part III will explore the FDA and industry’s arguments against labeling. Part IV will evaluate those FDA and industry responses. Part V will examine how predictions about public risk perceptions may have shaped the FDA’s labeling stance. Finally, Part VI will examine the realities facing the government and industry that may affect the direction of labeling policy in the future.

401, 401 (1999).

²⁴ *Dysfunctional*, ECONOMIST, Sept. 11, 1999, available at 1999 WL 7364483.

²⁵ Jeffrey Kluger et al., TIME INTL., Sept. 20, 1999, available at 1999 WL 25725566.

²⁶ Andrew Pollack, *Farmers Joining State Efforts Against Bioengineered Crops*, N.Y. TIMES, Mar. 24, 2001, available at <<http://www.nytimes.com>>.

²⁷ Food and Drug Administration, Center for Food Safety and Applied Nutrition, *Report on Consumer Focus Groups on Biotechnology*, Oct 20, 2000, available at <<http://www.cfsan.fda.gov/~comm/biorpt.html>>. (finding that “virtually all” of the participants indicated a desire for labeling of bioengineered foods.) [hereinafter *Consumer Focus Groups*]

I. FDA Regulation of Genetically Engineered Foods

A. Basic Regulatory Posture.

In 1992, the FDA released its first detailed regulatory statement regarding genetically modified foods.²⁸ Under the 1992 policy, the agency committed itself to regulating genetically engineered foods under the same statutory and regulatory framework as conventionally produced foods.²⁹ In so doing, the agency declared that any regulatory inquiry would focus on the final food product rather than at any process involved in the production of that food.³⁰ The agency stated the regulatory status of these foods hinges on the “objective characteristics”³¹ and “intended use[s]”³² of the final food product, and that the scientific techniques used to produce such foods would be relevant only to the extent that the processes would provide insight into the “safety or nutritional characteristics of the finished food.”³³ In indicating that the safety review of bioengineered foods would be limited to the finished food product, the FDA signaled that it did not believe the process of bioengineering itself to merit increased regulatory concern.³⁴

The 1992 policy focused on the similarities between agricultural bioengineering techniques and traditional

²⁸Statement of Policy: Foods Derived from New Plant Varieties, 57 Fed. Reg. 22984 (May 29, 1992) [hereinafter *1992 Policy*]

²⁹*1992 Policy*, 57 Fed. Reg. at 22990.

³⁰*1992 Policy*, 57 Fed. Reg. at 22984.

³¹*1992 Policy*, 57 Fed. Reg. at 22984.

³²*1992 Policy*, 57 Fed. Reg. at 22984.

³³*1992 Policy*, 57 Fed. Reg. at 22984.

³⁴*1992 Policy*, 57 Fed. Reg. at 22984-22985. More recent statements James Maryanski, the FDA’s Biotechnology Coordinator of the Center for Food Safety and Applied Nutrition have indicated that the FDA’s safety evaluations of genetically modified foods involves an examination of both the final food product and the food production techniques. *Statements of James H. Maryanski*, Before the Senate Committee on Agriculture, Nutrition and Forestry, United States Senate (October 7, 1999), available at <<http://www.vf.cfsan.fda.gov/~lrd/st991007.html>> [hereinafter *Maryanski Statement*]. Nevertheless, despite this apparent shift in stated attitude, FDA’s regulatory classification of these foods, or at least its public statements have generally indicated that the FDA does not feel the need for any dramatic intensification in the regulatory scrutiny applied to genetically modified foods. Maryanski elaborated “Although the study of the final product ultimately holds the answer to whether or not a product is safe to eat, knowing the techniques used to create the product helps in understanding what questions to ask in reviewing the product’s safety. That’s the way the FDA regulates both traditional food products and products derived through biotechnology.” *Id.*

plant breeding techniques. The agency described the application of bioengineering techniques to foods as merely part of a continuum of methods of “genetic modification techniques”³⁵ that includes traditional plant breeding techniques.³⁶ FDA characterized agricultural biotechnology techniques as merely “extensions at the molecular level of traditional methods”³⁷ and predicted that these techniques “will be used to achieve the same goals as pursued with traditional plant breeding.”³⁸ It defined those common goals generally as the “development of new plant varieties with enhanced agronomic and quality characteristics.”³⁹ The FDA based this conclusion on findings that (1) genetic engineering is used only to introduce “only a limited number of well-characterized genes” into the food crop,⁴⁰ (2) that the transferred genes produce “common food substances” or substances that produce or alter fatty acids, or carbohydrates,⁴¹ and (3) that those introduced food substances “are well characterized and not known to be toxic and they would be digested to normal metabolites in the same manner that the body handles the thousands of different proteins, fat and carbohydrates that make up our diet today.”⁴²

In basing its regulatory policy on these conclusions, FDA created a regulatory policy premised on predictions about the direction that agricultural biotechnology would take in the future. After all, there was no guarantee that only certain well-characterized genes would be introduced through agricultural biotechnology, nor that such genes would only produce common food substances. The technology imposes no such limitations on the scope of introduced substances.⁴³ Moreover, some of the most prevalent agricultural biotech products on the market today are characterized and marketed not for their affect on common food substances such as

³⁵The FDA uses the term genetically modified food to refer to both the products of agricultural biotechnology, and the products of traditional breeding techniques. The EU generally uses the term genetically modified interchangeably with the term genetically engineered, both of which are used to describe the products of agricultural biotechnology. *Maryanski Statement*, *supra* note 34 at 2.

³⁶57 Fed. Reg. at 22985.

³⁷57 Fed. Reg. at 22991.

³⁸57 Fed. Reg. at 22991.

³⁹57 Fed. Reg. at 22986.

⁴⁰*Maryanski Statement*, *supra* note 34 at 3.

⁴¹*Id.* at 4.

⁴²*Id.* at 4.

⁴³Lara Beth Winn, *Special Labeling Requirements for Genetically Engineered Food: How Sound are the Analytical Frameworks Used by FDA and Food Producers*, 54 FOOD & DRUG L.J. 667, 668 (1999).

proteins and fatty acids, but for their pesticidal or herbicidal effects. Bt corn was engineered for its pesticidal effects,⁴⁴ and Roundup Ready soybeans was developed for its herbicide-tolerance.⁴⁵ Together, in 1999, these two products alone accounted for over 50 million acres of American farmland.⁴⁶

Nevertheless, the 1992 policy consistently emphasized the similarities between genetic engineering and other traditional plant breeding techniques, and assumed that genetic engineering would be used for exactly the same purposes as traditional breeding techniques. For instance, even though the development of agricultural biotechnology was clearly the impetus for the development of the new policy, and the key focus of the document, the words biotechnology and genetic engineering appear nowhere in the title of the notice: “Statement of Policy: Foods Derived from New Plant Varieties.”⁴⁷ The document further stated that the policy set out in the notice was to cover all “foods derived from new plant varieties, including plants developed by recombinant deoxyribonucleic acid (DNA) techniques.”⁴⁸ Maryanski’s recent remarks before the Senate confirm FDA’s continuing commitment to emphasizing the similarity between genetically engineered foods and traditionally produced foods.⁴⁹ The FDA has taken great pains to emphasize that it will not distinguish between genetically engineered foods and traditional foods for regulatory purposes.

Having determined that agricultural biotechnology was not conceptually different from traditional food breeding techniques, the agency also determined that the foods would not require any special regulatory scrutiny. The agency set out its goal as “ensuring that these new products meet the same safety standards as traditional foods.”⁵⁰ This regulatory commitment to treating genetically engineered foods exactly the

⁴⁴Karen A. Goldman, *Labeling of Genetically Modified Foods: Legal and Scientific Issues*, 12 GEO. INT’L. ENVTL. L. REV. 717, 748 (2000)

⁴⁵Karen A. Goldman, *Labeling of Genetically Modified Foods: Legal and Scientific Issues*, 12 GEO. INT’L. ENVTL. L. REV. 717, 751 (2000). In 1999, of the 21.6 million hectares of genetically engineered soybeans were grown, and 11.1 hectares of genetically engineered corn were grown. See Dan Ferber, *Risks and Benefits: GM Crops in the Cross Hairs*, 286 SCIENCE 1662, available at <<http://www.sciencemag.org>>.

⁴⁶Reilly, *supra* note 9 at 498.

⁴⁷57 Fed. Reg. 22984, 22984.

⁴⁸57 Fed. Reg. 22984, at 22984.

⁴⁹*Maryanski Statement*, *supra* note 34 at 2. (“Bioengineered foods and food ingredients (including food additives) must adhere to the same standards of safety under the Act that apply to their conventional counterparts. This means that these products must be as safe as the traditional foods in the market.”)

⁵⁰*Maryanski Statement*, *supra* note 34 at 1.

same as other foods, of course, is the logical endpoint of the FDA's belief that these foods truly are the same. Accordingly, the FDA committed itself to a policy that focused its safety analysis on the final food product rather than the technology used, and that assumed the existing regulatory framework would be sufficient to address any potential safety concerns that might be raised by bioengineered food products. Again, those conclusions were based on an underlying conviction about the fundamental similarity between bioengineered food products and foods derived from more traditional food production techniques. Moreover, despite some recent tinkering with the regulatory requirements set out in the 1992 policy,⁵¹ the FDA's has remained committed to the position set out in 1992 that the legal status of genetically engineered foods remains the same as that of other traditionally derived foods.⁵²

B. Allergenicity

The 1992 policy did acknowledge the possibility that a gene transferred through agricultural biotechnology techniques might cause allergenicity issues for the engineered food. In response to this risk, the FDA noted that producers of foods transferring genes from organisms known to cause allergies should consult with the agency in order to develop a testing protocol for the engineered organism, and suggested that labeling may be warranted if the food contains a "known or suspect allergen."⁵³ However, the FDA admitted that it is "unaware of any practical method to predict or assess the potential for proteins not previously found in food to induce allergenicity."⁵⁴ Thus, with regard to allergenicity testing for transferred genes not previously found in food, the FDA position is ambiguous, simply stating that the "degree of testing these new proteins should be commensurate with any safety concern raised by the objective characteristics of the protein."⁵⁵

Unfortunately, according to Dr. Goldberg of the Environmental Defense Fund, "most proteins added to

⁵¹See 66 Fed. Reg. 4706 and 66 Fed. Reg. at 4839.

⁵²66 Fed. Reg. at 4711.

⁵³57 Fed. Reg at 22987.

⁵⁴David A. Kessler et al., *The Safety of Foods Developed by Biotechnology*, 256 SCIENCE 1747, 1832 (June 26, 1992).

⁵⁵*Id.*

foods via genetic engineering cannot be tested for allergenicity.”⁵⁶

C. Regulation as Additives

In accordance with the FDA’s determination to apply the current regulatory structure to bioengineered foods, the FDA stated that substances added to food through genetic modifications would be regulated as additives if those same substances would be considered additives had they been added through traditional food processing methods.⁵⁷ Food additives are defined in 21 C.F.R. § 170.3(e)(1) to “include all substances . . . the intended use of which results or may reasonably be expected to result, directly or indirectly, either in their becoming a component of food or otherwise affecting the characteristics of food.”⁵⁸ Generally, materials containing food additives will be considered adulterated if their presence in food presents a “‘reasonable possibility’ that consumption of the food will be injurious to health.”⁵⁹ The FDA determined that application of the food additive regulations in the case of genetically engineered foods would involve an analysis of the “transferred genetic material and the intended expression product or products.”⁶⁰

However, the 1992 policy statement indicated that most transferred genetic material would be exempted from the food additive requirements as falling under the “generally recognized as safe” exemption to the food additive provisions⁶¹ and would thus avoid the stringent safety requirements normally applied to food additives.⁶² The FDA argued that because “[n]ucleic acids are present in the cells of every living organism,

⁵⁶ *Biotechnology in the Year 2000 and Beyond*, *supra* note 22 at 61.

⁵⁷ *Maryanski Statement*, *supra* note 34 at 3.

⁵⁸ 21 C.F.R. § 170.3(e)(1).

⁵⁹ 57 Fed. Reg. at 22989, *citing* *United States v. Lexington Mill & Elevator Co.*, 232 U.S. 399 (1914).

⁶⁰ 57 Fed. Reg. at 22990.

⁶¹ 57 Fed. Reg. at 22990.

⁶² Under 21 C.F.R. § 170.3(i) producers of food additives must “demonstrate to a reasonable certainty that no harm will result from the intended use of the additive.” 57 Fed. Reg. at 22989.

including every plant and animal used for food by humans or animals,”⁶³ the transfer of nucleic acids through genetically engineering could be “presumed to be GRAS.”⁶⁴

Interestingly, the 1992 policy acknowledged that the agency has the authority to reevaluate the GRAS and food additive status of a food that has undergone “significant alteration by breeding and selection.”⁶⁵ Although not cited in the 1992 policy, the FDA also has the authority to review the GRAS status of foods “modified by processes first introduced into commercial use after January 1, 1958.”⁶⁶ Genetically engineered foods clearly meet this standard, since genetic modifications clearly were not in commercial use until well after this statutory deadline. Moreover, the FDA also has authority to review the GRAS status of “distillates, isolates, extracts, and concentration of extracts of GRAS substances,”⁶⁷ and of “substances of natural biological origin intended for consumption for other than their nutrient properties.”⁶⁸ Genetically engineered foods also fit both of these criteria. The nucleic acids that the FDA claims GRAS status for are actually “extracts” from foods that the FDA claims are GRAS, and most of the material currently transferred through genetic engineering controls pesticidal or herbicidal effects, not for their “nutrient properties.”

Thus, under 21 C.F.R. § 170.30(f), the FDA has multiple sources of authority to review the GRAS status of genetically engineered foods. In fact, the FDA arguable has committed itself to reviewing the GRAS status of these foods in that regulation.⁶⁹ Nevertheless, rather than invoking this authority, the agency merely cited the historical rarity of GRAS review of plants altered by plant breeding and selection because “these foods have been widely recognized and accepted as safe.”⁷⁰ In essence, the FDA disregarded its authority to review the GRAS status of foods modified by processes introduced into commercial use after the statutory

⁶³57 Fed. Reg. at 22990.

⁶⁴57 Fed. Reg. at 22990.

⁶⁵57 Fed. Reg. at 22990, *citing* 21 C.F.R. pt. 170.30(f)(2).

⁶⁶21 C.F.R. pt. 170.30(f)(1).

⁶⁷21 C.F.R. § 170.30(f)(3).

⁶⁸21 C.F.R. § 170.30(f)(6).

⁶⁹The statute reads: “The status of the following food ingredients *will be reviewed and affirmed as GRAS or determined to be a food additive or prior to a prior sanction.*” 21 C.F.R. § 170.30(f).

⁷⁰57 Fed. Reg. at 22990.

cut-off. Most noteworthy about this analysis is the fact that the FDA deliberately chose to regulate these foods under the GRAS exception rather than as food additives.⁷¹

Although FDA has the authority to regulate genetic material transferred through biotechnology as food additives, it presumed that those foods would fall under the “generally recognized as safe” exception to the food additive regulations. The FDA implicitly acknowledged that it was not exercising its full regulatory authority towards genetically engineered materials when it stated that it “intends to use its food additive authority to the extent necessary to protect public health. . . FDA will. . . require food additive petitions in cases where safety questions exist sufficient to warrant formal premarket review by FDA to ensure public health protection.”⁷² Moreover, the FDA went further to state that “minor variations in molecular structure that do not affect safety would not ordinarily affect the GRAS status of the substance, and thus, would not ordinarily require regulation of the substance as a food additive.”⁷³ The logic of this statement is circuitous; however, since the entire focus of the additive inquiry is whether or not the added substance affects safety. The only way to determine whether “minor variations in molecular structure” do or do not affect safety would be an additive-type analysis. However, the agency insists that the additive analysis is only required in cases in which the safety of the food additive is already in question. This statement clearly signals a FDA intention to use its food additive authority sparingly.

Because the FDA allows genetically engineered foods to elude classification as food additives under the GRAS exception, genetically engineered food producers are exempted from the strict additive safety standards.⁷⁴ The FDA essentially stated that genetically engineered foods will only be held to the food additive standards in certain limited circumstances, particularly when the added genetic material already occurs in foods cur-

⁷¹Perhaps the agency noted this authority in the 1992 in order to give it flexibility and preserve its ability to regulate genetically engineered materials more stringently in the future. Or perhaps the agency was simply asserting the scope of its regulatory power generally.

⁷²57 Fed. Reg. at 22990.

⁷³57 Fed. Reg. at 22990.

⁷⁴Under the food additive provisions, “‘safe’ or ‘safety’ means that there is a reasonable certainty in the minds of competent scientists that the substance is not harmful under the intended conditions of use.” 21 C.F.R. § 170.3(i).

rently sold on the market.⁷⁵ In place of applying the additive standards, the 1992 policy provided a detailed section titled “Guidance to Industry for Foods Derived from New Plant Varieties”⁷⁶ that was designed to “provide[] [manufacturers with] a basis for determining whether new plant varieties are as safe and nutritious as their parental varieties.”⁷⁷ This section outlines a “decision tree” approach⁷⁸ for the industry to guide these safety determinations.

D. Labeling

The FDA determined in 1992 that bioengineered modified foods do not require special labeling, and the agency has adhered to that position ever since. The agency’s labeling authority is derived mainly from section 403 of the act which dealing with misbranded food. Under section 403(i) the food label must bear the common or usual name of the food,⁷⁹ or, alternatively, an “appropriately descriptive term.”⁸⁰ In addition, the “label must reveal all facts that are material in light of representations made or suggested by labeling or with respect to consequences which may result from use.”⁸¹ The FDA has interpreted these statutory provisions as requiring labeling if the genetically engineered food “differs from its traditional counterpart

⁷⁵57 Fed. Reg. at 22990. (“When the substance present in the food is one that is already present at generally comparable or greater levels in currently consumed foods, there is unlikely to be a safety question sufficient to call into question the presumed GRAS status of such naturally occurring substances and thus warrant formal premarket review and approval by FDA.”)

⁷⁶57 Fed. Reg. at 22991.

⁷⁷57 Fed. Reg. at 22992.

⁷⁸57 Fed. Reg. at 22985.

⁷⁹57 Fed. Reg. at 22991, *citing* 21 U.S.C. § 343(i)

⁸⁰57 Fed. Reg. at 22991, *citing* 21 U.S.C. part 101.3.

⁸¹57 Fed. Reg. at 22991, *citing* 21 U.S.C. § 343(a); 21 U.S.C. § 321(n). Under 21 U.S.C. § 343(a), “A food shall be deemed to be misbranded. . . if its labeling is [sic] false or misleading in any particular, or (2) in the case of food to which section 350 of this title applies, its advertising is false or misleading in a material respect or its labeling is in violation of section 350(b)(2) of this title.” 21 U.S.C. § 321(n) states that “in determining whether the labeling or advertising is misleading there shall be taken into account (among other things) not only representations made or suggested by statement, word, device, or any combination thereof, but also the extent to which the labeling or advertising fails to reveal facts material in light of such representations or material with respect to consequences which may result from the use of the article to which the labeling or advertising relates under the conditions of use prescribed in the labeling or advertising thereof or under such conditions of use as are customary or usual.”

such that the common or usual name no longer applies to the new food, or if a safety or usage issue exists to which consumers must be alerted.”⁸²

Because FDA considers biotechnology to be simply an extension of traditional food production techniques, it does not consider the use of these processes to be material information for labeling purposes.⁸³ Thus FDA stated that it would not require labeling for genetically engineered foods because:

The agency is not aware of any information showing that the foods derived by these new methods *differ from other foods in any meaningful or uniform way, or that, as a class, foods developed by the new techniques present any different or greater safety concern* than foods developed by traditional plant breeding. For this reason, the agency does not believe that the method of development of a new plant variety (including the use of new techniques including recombinant DNA techniques) is normally material information within the meaning of 21 U.S.C. § 321(n) and would not usually be required to be disclosed in labeling for the food.”⁸⁴ [italics added]

The FDA argued that genetically engineered foods do not need to be labeled because they are no different and do not pose any different risks than their conventional counterparts. More recently Maryanski has defined the scope of the FDA’s labeling authority extremely narrowly stating that, “Labeling by law, is limited to identifying significant changes in a food’s composition, and it must not mislead consumers.”⁸⁵

Under this narrow construction of its labeling authority, the FDA determined that information regarding genetic engineering techniques would only be “material” for labeling purposes if one of four conditions were met. Labeling would be required only if (1) the bioengineered food were “significantly different from its traditional counterpart such that the common or usual name no longer adequately describes the new food”; (2) “if an issue exist[ed] for the food or a constituent of the food regarding how the food is used or consequences of its use”; (3) “if a bioengineered food has a significantly different nutritional property” than the traditional counterpart; or (4) if it “includes an allergen that consumers would not expect to be present based on the

⁸²57 Fed. Reg. at 22991.

⁸³57 Fed. Reg. at 22984. See also Larry Thompson, *Are Bioengineered Foods Safe?*, FDA Consumer (January February 2000) available at <<http://www.cfsan.fda.gov/~dms/fdbioeng.html>> in which FDA Commissioner Henney states “We are not aware of any information that foods developed through genetic engineering differ as a class in quality safety, or any other attribute from foods developed through conventional means. That’s why there has been no requirement to add a special label saying that they are bioengineered.”

⁸⁵*Maryanski Statement*, *supra* note 34.

name of the food.”⁸⁶ Notably, consumer expectations are only ever mentioned are in the context of food allergens. Furthermore, the agency has explicitly stated that it will “not require disclosure in labeling of information solely on the basis of consumers’ desire to know.”⁸⁷

E.

Recent Developments

In response to public criticism of its policy toward genetically engineered foods, the FDA has recently announced a number of modifications of the 1992 policy. On January 18, 2001, the FDA announced that it was providing the agricultural biotechnology industry with draft guidance entitled “Voluntary Labeling Indicating Whether Foods Have or Have Not Been Developed Using Bioengineering.”⁸⁸ Although the FDA acknowledged most of the labeling comments it has received requested mandatory labeling,⁸⁹ the agency reiterated its opposition to mandatory labeling. The FDA specifically argued that those calling for labeling had not demonstrated that any of the “bioengineered foods already on the market... [have] adverse health effects,”⁹⁰ and characterized the calls for mandatory labeling as merely “expressions of concern about the unknown.”⁹¹ Thus, it concluded that it was “still not aware of any data or other information that would form a basis for concluding that the fact that a food or its ingredients was produced using bioengineering is a material fact.”⁹² Given the agency’s conviction that genetically modified foods are not materially different from conventionally derived foods,⁹³ the FDA appears to shift the burden of proof on the safety issue away

⁸⁶ *Id.*.

⁸⁷ U.S. Food and Drug Administration, Center for Food Safety and Applied Nutrition, *FDA’s Policy for Foods Developed through Biotechnology*, 1995, 7, available at <<http://www.cfsan.fda.gov/~biopolcy.html>>.

⁸⁸ Draft Guidance for Industry: Voluntary Labeling Indicating Whether Foods Have or Have not been Developed Using Bioengineering, 66 Fed. Reg. 4839, 4839 (January 18, 2001). [hereinafter *Draft Guidance*]

⁸⁹ *Draft Guidance*, 66 Fed. Reg. at 4840.

⁹⁰ *Draft Guidance*, 66 Fed. Reg. at 4840.

⁹¹ *Draft Guidance*, 66 Fed. Reg. at 4840.

⁹² *Draft Guidance*, 66 Fed. Reg. 4839, 4840.

⁹³ Larry Thompson, *Are Bioengineered Foods Safe*, FDA Consumer, Jan Feb 2000, Interview with FDA Commissioner Jane

from the food producers and towards advocates mandatory labeling. In addition, the FDA was careful to frame the voluntary labeling standards as aiding manufacturers to satisfy idiosyncratic consumer preferences rather than as aiding consumers in making informed purchasing decisions.⁹⁴ Moreover, in so doing, the FDA reiterated that it does not consider the use of bioengineering to be a material fact.⁹⁵

In addition, the 1992 determination that genetically engineered foods do not merit new regulatory structures notwithstanding, in 1996 the FDA provided the industry with guidelines for a voluntary consultation program with the FDA regarding potential regulatory issues to be addressed before placing genetically engineered foods on the market.⁹⁶ On January 18, 2001, the FDA proposed making the voluntary consultation into a mandatory consultation program.⁹⁷ The proposed rule would “require the submission to the agency of data and information regarding plant-derived bioengineered foods at least 120 days prior to the commercial distribution of such foods.”⁹⁸ This change in policy is especially notable because in 1992, an article in *Science* authored by then Commissioner Kessler and other FDA officials stated that formal pre-market review requirements for genetically modified foods would “waste [FDA] resources and not advance public health.”⁹⁹ Although the proposed “pre-market notification” requirements are probably not as comprehensive or as resource intensive as the “pre-market review” that Commissioner Kessler had in mind,¹⁰⁰ the shift in policy between 1992 and 2001 is notable. These policy changes were effected largely in response to consumer

E. Henney, M.D., available at <<http://www.cfsan.fda.gov/~dms/fdbioeng.html>>.

⁹⁴66 Fed. Reg. 4839, 4840. The FDA stated, “[w]e are providing guidance to assist manufacturers who wish to label their foods voluntarily as being made with or without the use of bioengineered ingredients.”

⁹⁵*Id.*

⁹⁶*Guidance on Consultation Procedures: Foods Derived from New Plant Varieties*, latest version available at <<http://www.cfsan.fda.gov/~lrd/consulpr.html>>.

⁹⁷*Premarket Notice Concerning Bioengineered Foods*, 66 Fed. Reg. 4706 (January 18, 2001).

⁹⁸66 Fed. Reg. 4706, at 4707.

⁹⁹David A. Kessler, Michael R. Taylor, James H. Maryanski, Eric L. Flamm, Linda S. Kahl, *The Safety of Foods Developed by Biotechnology*, 256 *SCIENCE* 1748 (June 26, 1992), available at <<http://www.sciencemag.org>>.

¹⁰⁰61 Fed. Reg. at 4711.

demands for greater transparency of the review process voiced during public hearings held by the FDA.¹⁰¹

II.

The Argument For Mandatory Labeling of Genetically Engineered Foods

A. The Consumer Right to Know

Despite FDA's assurances that genetic engineering is not a material fact, and that genetic engineering is a perfectly safe process, some consumer groups,¹⁰² environmental groups,¹⁰³ national politicians,¹⁰⁴ and even some farming organizations¹⁰⁵ advocate mandatory labeling of foods containing genetically modified ingredients. Arguments for labeling of genetically engineered foods often cite a variety of justifications, including: the possible allergenicity of genetically engineered foods,¹⁰⁶ unknown long term health impacts of bioengineered foods,¹⁰⁷ the potential for environmental damage posed by these foods,¹⁰⁸ and religious considerations¹⁰⁹ as reasons that consumers may need labeling information. These groups contend that labeling is the only way for consumers with these concerns to avoid genetically engineered foods. Consumers

¹⁰¹Press Release, US Department of Health and Human Services, *FDA Announces Proposal and Draft Guidance for Food Developed Through Biotechnology* (January 17, 2001), available at <<http://www.cfsan.fda.gov/~lrd/hhbioen3.html>>.

¹⁰²See Thomas O. McGarity & Patricia I. Hansen, *Breeding Distrust: An Assessment and Recommendations for Improving the Regulation of Plant Derived Genetically Modified Foods, Executive Summary*, January 11, 2001, available at <http://www.biotech-info.net/Breeding_Distrust.html>

¹⁰³See, e.g., <<http://www.greenpeaceusa.org/ge/>>.

¹⁰⁴See, e.g., Sharon Shmickle, *Genetic Engineering of Foodstuffs Sows Debate over Labeling*, STAR TRIBUNE NEWSPAPER OF THE TWIN CITIES, Oct. 18, 1999, available at 1999 WL 7511348 (describing Kucinich's sponsorship of a bill requiring mandatory labeling of genetically engineered foods).

¹⁰⁵Mandatory labeling is supported by the American Corn Growers Association. See *Biotechnology in the Year 2000 and Beyond*, *supra* note 22 at 218. The organization's representative stated, "We recognize that biotechnology companies have made a sizeable investment in the research and development of GMOs. That is not our concern. Our concern is the investment that the American farmer makes in purchasing, planting, nurturing and harvesting of crops that may not have a readily available market." *Id.*

¹⁰⁶See, e.g., Michael Jacobson, *Genetically Modified Food Fight*, 172 WEST. J. MED. 220 (2000), available at <<http://www.ewjm.com/cgi/content/full/172/4/220>>.

¹⁰⁷*Id.*

¹⁰⁸*Id.*

¹⁰⁹*Id.*

themselves note that they have no way of knowing whether or not a food product is bioengineered or contains bioengineered ingredients without labeling, and indicate a strong preference for the labeling of such foods.¹¹⁰ Although all of these consumer concerns stand as independent justifications for labeling, the rhetorical force of these arguments is derived from an even more basic argument: that consumers have a right to know what they are eating. As stated by Representative Dennis Kucinich, a Democrat from Ohio who has actively advocating the labeling of bioengineered foods, “American consumers must have the right to choose what foods they and their families eat.”¹¹¹ Although the call for labeling has been triggered by consumer unease with agricultural biotechnology, this labeling argument draws on basic assumptions about the public’s rights as participants in democracy and as participants in a market economy.

B. The Appeal of the Argument for Labeling.

Agricultural biotechnology has triggered a number of basic societal fears: heightened concerns about the safety of food, distrust of government, distrust of the scientific establishment, and distrust of multinational corporations. Because consumers and consumer groups are likely to be influenced by one or more of those fears when they consider the issue of genetically engineered foods, it is understandable that they would express interest in strengthening applicable regulations. Nevertheless, the calls for labeling of genetically modified foods are qualitatively different from demands for other kinds of government regulation.

Demands for mandatory labeling are premised on key assumptions about the *kind*, not just the degree, of regulation that is appropriate, and about *which actors* should be equipped to make decisions about the growth and development of this technology. FDA’s current policy generally rests on the assumptions that

¹¹⁰ *Consumer Focus Groups*, *supra* note 5 at 4.

¹¹¹ Sharon Schmickle, *Genetic Engineering of Foodstuffs Sows Debate over Labeling*, STAR TRIBUNE NEWSPAPER OF THE TWIN CITIES, Oct. 18, 1999, *available at* 1999 WL 7511348.

agricultural biotechnology does not pose any “unique” risks—that it is merely an extension of traditional breeding techniques, and that information about the application of this process is therefore not material. On an institutional level, FDA’s policy also assumes that the (1) government and industry scientists, not consumers, are best positioned to determine whether or not information is “material” for labeling purposes; (2) consumers should trust government agencies to make rational and responsible decisions about the extent, speed, and nature of the entrance of this technology into the marketplace; and (3) labeling policy decisions should and can be non-political, i.e. based solely on scientific evidence.

The recent calls for labeling represent fundamental challenges to these basic institutional premises. Arguments for labeling represent a fundamentally different understanding of how power and information should be distributed between the agricultural biotechnology industry, the FDA, and consumers. In fact, advocates for labeling would generally posit that (1) only consumers can ultimately determine what information is “material;” (2) consumers should have a right to use their buying power to affect the extent, speed, and nature of the entrance of biotechnology into the marketplace; and perhaps most importantly (3) any decision about labeling policy is political, and science alone cannot determine public policy. These conflicting viewpoints are premised not on different understandings of the technology itself, but on different understandings of proper balance of power between the FDA, consumers and the industry.

C.

Labeling is generally a politically palatable compromise.

Labeling is an extremely palatable regulatory position because it accommodates both public apprehensions about the entrance of this technology into the marketplace, and a growing skepticism about the effectiveness of government agencies and regulations. For consumers nervous about the application of biotechnology to our

food supply, but also distrustful of government agencies, labeling offers an extremely attractive solution because it allows consumers to make decisions for themselves, as opposed to “command and control” regulation regimes in which the government directly interposes itself between the regulated industry and consumers. In the current environment of deep distrust of the adequacy of both unregulated market forces and government regulatory structures to adequately address the public’s needs and concerns,¹¹² informational remedies offer “one of the few weapons available with which people can further their interests.”¹¹³ Such remedies, at least arguably, transfer power from both the regulated industry and the government to the consumer.

Because informational remedies are seen as empowering consumers to make decisions about their exposure to particular risks without directly interposing government regulations between producers and consumers, these remedies have resonance with a broad spectrum of the populace. These remedies are likely to appeal to “equally to conservatives, who applaud ‘market facilitation’ and ‘bootstrapping,’ and to liberals, who favor ‘empowerment and the ‘right to know.’”¹¹⁴ Moreover, these kinds of solutions are likely to appeal particularly to the Baby Boom generation’s sense of “active, informed consumerism.”¹¹⁵

1.

Public Ignorance about Genetic Engineering.

The public’s interest in informational remedies notwithstanding, one of the most disturbing aspects of the move to agricultural biotechnology is the lack of public awareness of this issue. Notably, there is increasing evidence that Americans are not fully aware of the extent to which genetically engineered foods have come to

¹¹²William M. Sage, *Regulating Through Information: Disclosure Laws and American Health Care*, 99 COLUM. L. REV. 1701, 1707 (1999).

¹¹³William M. Sage, *Regulating Through Information: Disclosure Laws and American Health Care*, 99 COLUM. L. REV. 1701, 1707 (1999).

¹¹⁴Sage, *supra* note 112, at 1825-6.

¹¹⁵Sage, *supra* note 112, at 1825-6

be present in a large part of our food supply. In fact, a recently issued report on consumer focus group studies conducted by the FDA confirmed that Americans by and large are unaware of the impact that genetically engineered foods are already having on their diets:

After being presented with a factual account of the extent to which certain grain crops in the US are being produced from bioengineered seed and the extent to which bioengineered ingredients are present in processed foods, most participants expressed great surprise that biotechnology has become so pervasive in the U.S. food supply. Even among participants who considered themselves well-informed about biotechnology, many registered amazement.¹¹⁶

2.

Public Value Based Arguments for Labeling.

Given this public lack of knowledge about the entrance of biotechnology into the marketplace, labeling would serve important societal values and goals. Cass R. Sunstein has developed a case for informational remedies based on liberty considerations, arguing that “[i]f people are unaware of the consequences of their choices, they are, to that extent, less free.”¹¹⁷ This proposition makes intuitive sense: one of the basic assumptions of liberty is the ability to make meaningful personal choices.

Furthermore, Sunstein also points out that providing citizens with information facilitates the functioning of deliberative democracy by allowing citizens to fully “engage in their monitoring and deliberative tasks.”¹¹⁸

He argues that providing citizens with information about both governmental and market activities allow citizens to “oversee government action and also to assess the need for less, more, or different regulation.”¹¹⁹

¹¹⁷Cass R. Sunstein, *Informing America: Risk, Disclosure, and the First Amendment*, 20 FLA. ST. U. L. REV. 653, 655 (1993).

¹¹⁸Cass R. Sunstein, *Informational Regulation and Informational Standing: Akins and Beyond*, 147 U. PENN. L. REV. 613 (1999). Sage makes a similar argument about mandatory disclosure laws when he states, “Mandatory disclosure laws have a role in bringing difficult decisions into the open and providing the deliberative process with the information needed to resolve them. In a representative democracy, citizens often insist that deliberations that affect them be conducted in public view.” William M. Sage, *Regulating through Information: Disclosure Laws and American Health Care*, 99 COLUM L. REV. 1701, 1803-4 (1999). Moreover, Sage quotes March and Olsen in arguing “a democratic polity requires a rich mélange of information and suffers when there is a monopolistic control over information or when an expert community is monolithic in belief or organization.” *Id.* at 1821, citing JAMES G. MARCH & JOHAN P. OLSEN, *DEMOCRATIC GOVERNANCE*, 82-3 (1995).

¹¹⁹Cass R. Sunstein, *Informational Regulation and Informational Standing: Akins and Beyond*, 147 U. PENN. L. REV. 613, 625 (1999).

Indeed, regardless of one's personal view of agricultural biotechnology, one of the key assumptions of an open and free democratic society is that citizens can most effectively govern themselves when they are armed with information about government and marketplace activities directly affecting their lives.¹²⁰

If consumers are not aware of what is contained in the food they are eating, or the food processing techniques that have been applied to those foods, they are not in any position to hold the government or the food producers accountable for the safety of those foods generally, or for the particular regulations that have been applied to those foods. Again, regardless of one's view of the safety of agricultural biotechnology, it is clear that consumers cannot effectively oversee government regulations about biotechnology unless they are aware that this technology is being applied. At this point, it is impossible to measure consumer support for FDA's current regulation of agricultural biotechnology because consumers are simply not aware of the extent to which the products of agricultural biotechnology have already entered their diets.¹²¹

Such public ignorance clearly diminishes the accountability of the FDA. Even if all consumers would approve of FDA's current regulatory stance if fully informed, they cannot express this approval until they are armed with the relevant facts. Information, or a lack thereof, is an essential factor in determining the extent to which citizens can hold government agencies accountable for their regulatory actions. To the extent that the government actors should be accountable to the public in a democracy, consumers should have information about the products that they are consuming daily. The FDA's own data indicate that the market is not providing customers with that information in the absence of mandatory labeling, and thus that the FDA is regulating in a vacuum.

The FDA's focus group findings confirm that citizens do expect to be provided with such information about

¹²⁰Interestingly, those who argue for relaxed labeling standards and federal regulatory oversight with regard to nutritional claims on food packaging are likely to be the same advocates who would argue that manufacturers and other food producers should not be required to label foods containing genetically modified food products. Nevertheless, the basic argument for consumer disclosure in both cases is very similar: Consumers should be allowed to have the most information that will allow them to make informed consumer choices without the interference of government agencies paternalistically deciding how they well they will be able to interpret those labels.

¹²¹*Consumer Focus Groups*, *supra* note 5 at 6.

the application of biotechnology to foods on the market, and that the absence of such information on the market violates their sense of liberty and fairness. Interestingly, when told of the extent to which biotechnology has already affected the food supply, the primary reaction of the study participants was not immediate concern about the health impacts that the unknowing consumption of such food may have had on their health.¹²² Instead their primary reaction was “outrage that such a change in the food supply could happen without them knowing about it.”¹²³ Participants also related being “disturbed by the lack of public information and public input to a major development in the quality of their food supply.”¹²⁴

Participants’ suspicion of this technology also seems to be linked to a fear that the new technology threatened their personal autonomy. Some of the participants indicated that they were being used as “guinea pigs.”¹²⁵ Even more disconcerting is the fact that consumers who expressed acceptance of agricultural biotechnology often also expressed a degree of “technological fatalism, the belief that ordinary people can’t have much influence over the spread of new technologies.”¹²⁶ Such “technological fatalism,” is certainly not consistent with democratic ideals. If consumers feel fatalistic about the entrance of biotechnology into the food supply, it logically follows that they also feel that they have no power to hold government agencies responsible for regulation of these foods.

3.

Market based arguments for labeling

In addition to these liberty and democracy based arguments, mandatory labeling of genetically engineered foods may also be necessary in order to correct for market failure. A standard law and economics argument

¹²² *Id.*

¹²³ *Id.*

¹²⁴ *Id.*

¹²⁵ *Id.* at 3.

¹²⁶ *Consumer Focus Groups*, *supra* note 5 at 3.

against labeling bioengineered foods might be that consumers can always get information about the products they purchase if they demand it. Under this line of reasoning, consumers are not being provided with information about whether their food is genetically modified because they are unwilling to pay the cost of receiving that information. Furthermore, this argument would posit that a labeling requirement would only force inefficiencies into the marketplace by forcing consumers to pay for the provision of information they would not otherwise demand.¹²⁷

However, there are good reasons to believe that there are heightened risks of market failure in the market for information.¹²⁸ Information is often a “public good” in which all individuals would benefit from the provision of information, but once this information has been gathered the first time, the transaction costs of discovering the results of the first gathering are extremely low.¹²⁹ Because the information will be widely available once one person takes the time to gather it, later comers can effectively “capture the benefits of information without having to pay for its production.”¹³⁰ Accordingly, each individual has an incentive to try to free ride on the efforts of others to gather the information, and ultimately the optimal amount of information is not generated.¹³¹ Although all consumers may have some interest in getting information about whether or not the products they are purchasing contain genetically modified ingredients, each individual consumer also has an incentive to free ride on the efforts of others. Moreover, the information gathering costs for any individual consumer would be cost and time prohibitive in this case, especially since most genetically engineered foods are found as ingredients in processed foods.¹³² Moreover, consumers are not even aware of the necessity of gathering this information because they are not aware that these foods have already entered

¹²⁷Interestingly, this argument has not been advanced by agricultural biotechnology proponents.

¹²⁸Sunstein, *Informing America: Risk Disclosure and the First Amendment*, *supra* note 117, at 655.

¹²⁹*Id.* at 656.

¹³⁰*Id.*

¹³¹Sunstein, *Informing America: Risk, Disclosure, and the First Amendment*, *supra* note 117, at 656.

¹³²Just consider the transaction costs that would be expended in attempting to research every single food product purchases to determine if any of these products contained genetically engineered products. Such a search would almost certainly prove fruitless. Greenpeace has put a tentative listing of foods that contain genetically engineered foods on the web available at <<<http://www.truefoodnow.org/shoppinglist.html>>>. However, this list is far from exhaustive, its existence is not well known, and the reliability of the list cannot be determined in the absence of large scale testing.

the marketplace.

Also, manufacturers of both hazardous and unhazardous products may have special incentives to keep information about product safety off the market because the resulting public debate “over the extent of danger may decrease total purchases of the product, rather than help any particular manufacturer to obtain greater sales.”¹³³ In this case, the debate over the extent of the danger of GM foods may simply decrease total purchases of particular foods that commonly contain GM foods rather than increasing sales of a particular brand. Accordingly, manufacturers may determine that would have nothing to gain from providing consumers with information about potential hazards, or factors that the public may perceive as public hazards.

The food market presents a classic example of “information asymmetry” in which consumers have virtually no information about products they purchase unless such information is provided by the food producers.

Sunstein notes that such situations commonly create the possibility of a

lemons’ problem in which dangerous products drive safe ones out of the market. Imagine, for example, that producers know which products are safe but that consumers cannot tell. Safe products may not be able to compete if they sell for a higher price than dangerous ones if safe products are more expensive to produce and if consumers are unable to tell the difference. In that case, the fact that sellers have information, while buyers do not, will ensure that ‘lemons’—here dangerous products—will dominate the market.¹³⁴

In fact, genetically engineered foods do not actually have to be dangerous in order for this “lemons effect” to apply. In the case of genetically engineered foods, producers often are eminently aware that some of their products or ingredients have been produced through genetic engineering techniques, and consumers are largely unaware of this information. Moreover, manufacturers (probably correctly) assume that consumers are likely to view genetically modified foods with an increased dose of suspicion, and that genetically modified products may be cheaper or more convenient for producers to produce. Under these constraints, it is hardly surprising that manufacturers have insufficient independent incentives to provide this information absent

¹³³Sunstein, *Informing America*, *supra* note 117, at 656.

government intervention. After all, why should manufacturers provide information to consumers when that information is only likely to damage the total market for the product, and when consumers otherwise cannot tell the difference between genetically engineered and non-engineered products? In fact, the provision of such information would almost surely require manufacturers to spend a great deal of money in efforts to convince consumers of the merits of the new technology, whereas withholding this information costs the producers nothing at all.

Moreover, manufacturers and food producers have a particular disincentive to acquiesce to labeling because such a disclosure system might compel a complete overhaul of the current food processing system. Under the current food production system, many genetically engineered products and non-engineered products are routinely mixed together.¹³⁵ A labeling regime would require food manufacturers to either (1) create a system for segregating bioengineered foods from non-bioengineered foods—which would inevitably involve some considerable infrastructure investment costs¹³⁶; or (2) risk consumer disinterest or suspicion of foods labeled “may contain genetically modified/bioengineered foods.”¹³⁷

Given these factors, it is easy to see why manufacturers would have insufficient incentives to provide this information on the market—the end result being that consumers are buying genetically modified foods without realizing it.¹³⁸ FDA’s current stand against mandatory labeling works to the advantage farmers and other food producers. Because producers do not need to segregate genetically engineered products from other products, “farmers are free to produce either variety or some combination thereof” without the pressure of predicting or influencing consumer preferences for either variety.¹³⁹

Nevertheless, while the current system of non-labeling may benefit farmers and other producers concerned

¹³⁵Matthew Franken, Comment, *Fear of Frankenfoods: A Better Labeling Standard for Genetically Modified Foods*, 1 MINN. INTELL. PROP. REV. 153, 170 (2000). See *infra*, section IIID.

¹³⁶See *infra* section IIID.

¹³⁷“May contain” labels are disfavored by some food producers because they “suggest the food industry doesn’t know what’s going into their products, and we don’t think that’s helpful.” FOOD CHEMICAL NEWS, July 13, 1998, *available at* 1998 WL 10981464.

¹³⁸See *supra* section IIC.

¹³⁹Franken, *supra* note 2, at 169.

about their ability to garner consumer acceptance of bioengineered foods, it is doubtful whether those dynamics contribute to the functioning of an efficient marketplace. Certainly accurate consumer information about products is a key assumption of the theory of efficient markets. A market in which consumers are not permitted to express their preferences (even if producers find such preferences irrational or inconvenient) does not conform with the traditional model of an efficient market.

Modern consumers have demonstrated savviness to the importance of their purchasing decisions on the biotech industry. The FDA consumer focus group study found that “[m]any participants recognized symbolic value in choosing not to buy products of biotechnology. They felt mere disclosure labeling gave them an opportunity to register their view about the wisdom of food biotechnology. . . They said they wanted to ‘send a message’ to the company.”¹⁴⁰ Although this “message” is probably not one that many biotech companies would be happy to receive, it is a message that at least some consumers wish to send through purchasing decisions. Of course, this may not be a “rational” way to make food purchasing decisions, but of course, the marketplace allows consumers to express all sorts of irrational preferences. Moreover, the government generally does not protect companies from consumer preferences.

The current lack of consumer awareness about the prevalence of genetically engineered foods creates a dangerous vacuum of public ignorance, raising risks of unbridled “interest group maneuvering.”¹⁴¹ Because consumers are largely ignorant of the introduction of biotech foods into their diets, they are in no position to lobby either the Congress or the FDA for regulatory action. This vacuum leaves the biotech industry free to lobby all government actors for favorable treatment with relatively public oversight.¹⁴² This state of public ignorance and lack of public FDA accountability creates increased risks of inappropriate biotech industry influence over FDA policymakers.

¹⁴⁰*Consumer Focus Groups*, *supra* note 5 at 5.

¹⁴¹Sunstein, *Informing America*, *supra* note 117, at 660.

¹⁴²Sunstein, *Informing America*, *supra* note 117, at 660. Sunstein argues that such a scenario is “poorly suited to democratically controlled risk reduction. It is highly likely that Congress will end up pleasing the relevant groups with a mechanism that helps the most powerful and well-organized lobbyists.” *Id.*

III.

Government and Other Aligned Parties' Responses to Demands for Labeling

A.

Mandatory labeling is not statutorily compelled—genetic engineering is not a material fact.

As outlined in Section IE, the government's first line response to labeling arguments is that information about genetic engineering is not material. Although the FDA has not explicitly stated that it does not have the statutory authority to mandate labeling of all genetically engineered foods, its policy rests on the assumption that labeling is not statutorily required. FDA has argued that it is only authorized to require labeling regarding "information about the attributes of the food itself,"¹⁴³ implying that it has no authority to require labeling information about a particular food process.

B.

The Current Government Policy is Based on Science.

From its inception, the FDA and other government actors have insistently defended the current biotechnology regulations as "science-based."¹⁴⁴ For instance, in announcing the most recent modifications in FDA's

¹⁴³58 Fed. Reg. 25837, at 25838.

¹⁴⁴David A. Kessler, et al., *The Safety of Foods Developed by Biotechnology*, 256 Science 1747 at 1832. See also, *Maryanski Statement*, *supra* note 34 at 3. See also, Joseph A. Levitt's, FDA Director of the Center for Food Safety and Applied Nutrition, public forum's statement that "we believe that our policies and processes in this area are well-grounded in science, and that we have an excellent track record in applying our policy." *Biotechnology in the Year 2000 and Beyond*, *supra* note 22 at 18;

policy, the White House released a press statement affirming that “[t]he Administration’s actions today will ensure that science remains the cornerstone of the nation’s regulatory system”¹⁴⁵ and noting the “federal government’s confidence in its independent, science-based regulatory approach to agricultural biotechnology”¹⁴⁶ Supporters of the FDA policy argue that it reflects a “scientific consensus that the risks associated with recombinant organisms, and with products derived from them, are fundamentally the same as for non-recombinant products.”¹⁴⁷ With respect to labeling, the FDA has suggested that it would not require labeling unless presented with evidence that “any of the bioengineered foods already on the market have adverse health effects.”¹⁴⁸ Thus, the FDA essentially argues that the agency’s policy is “science based” because no adverse health effects have yet been proven. The government relies on the opinions of scientists such as Robert McKinney, director of the safety division at the National Institutes of Health, who has stated, “I don’t see any problems at all for genetically modified plants in terms of human health. Researchers are being asked to prove negatives.”¹⁴⁹

C.

Critics are motivated by political not scientific considerations.

As a corollary to the “science” defense of FDA’s current non-labeling policy, biotech supporters often accuse those expressing apprehension about the risks of agricultural biotechnology of possessing “hidden political

statement of Maryanski at the same forum stating “Our policies are always based on the best science that is available” *Id.* at 26.

¹⁴⁵Press Release, White House, Clinton Administration Agencies Announce Food and Agricultural Biotechnology Initiatives: Strengthening Science-Based Regulation and Consumer Access to Information (May 3, 2000), *available at* <http://www.cfsan.fda.gov/~lrd/whbio53.html>.

¹⁴⁶*Id.*

¹⁴⁷Henry I. Miller, *A Rational Approach to Labeling Biotech-Derived Foods*, 284 SCIENCE 1471 (May 28, 1999), *available at* <http://www.sciencemag.org>.

¹⁴⁸66 Fed. Reg. at 4839.

¹⁴⁹Declan Butler & Tony Reichhardt, *Long-term Effect of GM Crops Serves up Food for Thought*, 398 NATURE 651, 651 (April 22, 1999).

agendas”¹⁵⁰ or playing on unscientific fears. For instance, one commentator has warned that the more cautious regulatory approach in Europe and Asia amounted to a system in which “regulators have permitted politics, public misapprehensions, and blandishments of anti-technology activists, and nescience to dictate policy.”¹⁵¹ Similarly, Gary Kushner, counsel to the Grocery Manufacturers of America, characterized misgivings about biotechnology as “unsubstantiated and unscientific thinking” and further warned that “activists with a political agenda... [might] kill the promise of biotech foods.”¹⁵² Legal arguments against mandatory labeling often take the same tack, characterizing the consumer’s right to know arguments are “unscientific.”¹⁵³ David Schmidt of the International Food Information Council has argued against a mandatory labeling policy by arguing, “Precious food-label real estate should be reserved for vital health and safety information, not for social statements.”¹⁵⁴

At least one biotech supporter has argued that calls for labeling are actually part of a conspiracy to get rid of the technology altogether. Referring to the “intentions and actions of ideological opponents of the new biotechnology,” Henry I. Miller argues that

[L]abeling raises costs, which discourages producers and consumers and destroys markets for new products, so for those wishing to block the commercialization of biotech products, forcing an increasing costs is an effective strategy. Regulatory stringency is also an unmistakable signal to the public that there is something fundamentally different and worrisome about biotech foods. Anti-biotechnology activists argue that we need regulation because consumers are apprehensive, and then, when consumers become apprehensive because the products are stringently regulated, these activists say we need more regulation to assuage consumers’ concerns... Heavy involvement by government, no matter how well intended, inevitably sends the wrong signals.¹⁵⁵

¹⁵⁰Andrew Pollack, *Critics of Biotechnology Are Called Imperialists*, N.Y. TIMES, February 4, 2001, available at <<http://www.nytimes.com/2001/02/04/weekinreview/04POLL.html>>. (Ingo Potrykus, a scientist who helped to create the golden rice strain, accuses anti-biotech advocates of being motivated solely by a hatred of science, stating “It is not so much concern about the environment, or the health of the consumer, or help for the poor and disadvantaged. It is a radical fight against a technology and for political success.”)

¹⁵¹Miller, *supra* note 147

¹⁵²Sharon Schmickle, *Genetic Engineering of Foodstuffs Sows Debate over Labeling*, STAR-TRIBUNE NEWSPAPER OF THE TWIN CITIES, Oct. 18, 1999, available at 1999 WL 7511348. Of course, the irony of this statement is that an “activist with a political agenda” is arguing that “activists with political agendas” should not influence the biotechnology debate.

¹⁵³Frederick H. Degnan, *The Food Label and the Right to Know*, 52 FOOD & DRUG L.J. 49, 57 (1997).

¹⁵⁴*Biotechnology in the Year 2000 and Beyond*, *supra* note 22 at 273.

Thus, he characterizes calls for labeling as merely disguised attempts to spread public fear, and ultimately destroy the biotech industry.

D.

Segregation required by mandatory labeling would be both infeasible and too costly.

On a practical level, the FDA and other biotech supporters often argue that a mandatory labeling policy would require extremely expensive, inefficient, and infeasible segregation system to separate genetically engineered foods from traditionally derived foods. The FDA has raised questions about the “practical difficulties and economic impact” of a labeling requirement.¹⁵⁶ Segregation of genetically engineered foods will probably create the most difficulties in the case of corn and other products handled in bulk.¹⁵⁷ For instance, “there are ten points of the trip from farm to ship at which different types of soyabeans [sic] are deliberately mixed to improve their quality.”¹⁵⁸ Some have argued that a segregation system for soybeans and maize could increase price of the non engineered categories of such foods by as much as 100%.¹⁵⁹ Moreover, identity testing would be required to ensure that the foods had been effectively separated, and such testing could add as much as 30% to the final food product.¹⁶⁰ Many argue that consumers would be unwilling to bear the burden of such added costs.¹⁶¹

VI.

¹⁵⁶58 Fed. Reg. 25837, 25840 (1993), cited in Whittaker, *supra* note 13 at 1240.

¹⁵⁷*Food for Thought*, ECONOMIST, July 17, 1999, available at 1999 WL 7363490.

¹⁵⁸*Food for Thought*, ECONOMIST, July 17, 1999, available at 1999 WL 7363490.

¹⁵⁹*Id.*

¹⁶⁰*Sticky Labels*, ECONOMIST, April 29, 1999, available at 1999 WL 7362891.

¹⁶¹*Sticky Labels*, ECONOMIST, April 29, 1999, available at 1999 WL 7362891.

Responses to the government argument

The FDA arguments against labeling center are founded on the assumption that neither the statute nor the relevant science compel labeling. However, the regulatory framework set out in the 1992 policy is not the only possible interpretation of the FDA's authority, and the scientific basis for the FDA's conclusions was not unassailable. Given this statutory flexibility and scientific uncertainty, the FDA had a great deal of discretion in making its policy determinations, and political considerations influenced the shape of the eventual policy.

A.

Statutory analysis does not compel the FDA's conclusions regarding bioengineering.

1. *Pre-market Notice*

FDA labeling policy is based on a conclusion drawn very early in the regulatory process that genetically engineered foods are essentially the same as other, traditionally derived, foods. However, since the labeling policy was developed, the agency has recognized the increased risks that the application of biotechnology to foods may raise. Most notably, the recently proposed pre-marketing notice represents FDA recognition that these foods do merit additional regulatory requirements. The FDA explicitly recognized, "FDA expects that these techniques are likely to be utilized to an increasingly greater extent by plant breeders and that the products of this technology are likely in some cases to present more complex safety and regulatory issues than seen to date."¹⁶² In addition, the FDA acknowledged that "there is a greater potential for foods developed

¹⁶²66 Fed. Reg. at 4709.

using rDNA technology to contain substances that are food additives” under the act.¹⁶³ Thus, although the FDA reiterated its view that “transferred genetic material can be presumed to be GRAS,”¹⁶⁴ the agency ultimately conceded that this new technology was more likely to pose heightened of safety and regulatory concerns. FDA also stated that agricultural biotechnology processes may “lead to unintended changes in foods that raise adulteration or misbranding questions,”¹⁶⁵ and that the application of rDNA technology may also increase the risk of allergenicity.¹⁶⁶

This acknowledgement of the increased likelihood of particular risks with the application of agricultural biotechnology presents a striking contrast to the FDA’s 1992 insistence that bioengineered foods and traditionally derived foods could be regulated under the exact same regulatory structure. By requiring pre-marketing notice of genetically engineered foods, the FDA implicitly acknowledged that the regulatory structure needed to respond to the unique concerns posed by the genetic engineering of foods. This softening of the FDA’s position indicates that the FDA is, at least on some level, recognizing that the 1992 pronouncement about genetically engineered foods had been somewhat premature, or at least no longer completely applicable.

Despite this acknowledgment of the need for increased regulatory scrutiny of genetically engineered foods, the FDA continued to argue that these regulations did not indicate that genetically engineered foods necessarily had any different “legal status” than traditionally derived foods. Instead the FDA argued:

¹⁶³66 Fed. Reg. at 4709.

¹⁶⁴66 Fed. Reg. at 4709.

¹⁶⁵66 Fed. Reg. at 4710.

¹⁶⁶The agency noted an “increased potential for introducing an allergen into a food developed using rDNA technology” or using rDNA technology to inadvertently create plants that express proteins at higher concentrations such that a protein that is normally safe for consumption could create allergenic affects at higher doses. 66 Fed. Reg. at 4709

[W]hether there is a change in the legal status of a food resulting from a particular rDNA modification depends almost entirely on the nature of the modification, and that not every modification accomplished with rDNA techniques will alter the legal status of the food. In other words, many modifications will result in a food that does not contain an unapproved food additive, does not contain an unexpected allergen, and does not differ significantly in its composition compared with its traditional counterpart or otherwise require special labeling. For this reason, FDA is neither proposing to require premarket approval for all foods developed using rDNA technology nor is the agency proposing an across-the-board requirement that all such foods require special labeling.”¹⁶⁷

Thus, the FDA went to great pains to indicate that these new regulations did not indicate a special “legal status” for genetically engineered products. Nevertheless, the new regulations did amount to an acknowledgment that particular risks were more likely to be raised by genetically engineered foods, and did undeniably create new requirements for genetically engineered foods that do not exist for traditionally modified foods. The FDA explicitly stated that it believes that bioengineered foods “are appropriately made subject to greater FDA scrutiny by FDA in the form of enhanced agency awareness of all such foods intended for commercial distribution. This increased agency awareness will ensure that at every stage of this continuously evolving technology, all market entry decisions about new bioengineered foods... are made consistently and in full compliance with the law.”¹⁶⁸ In the end, it is not surprising that FDA was finally forced to back away from its 1992 conclusions that the end products of genetically engineered foods were to be regulated exactly the same as traditionally derived food products. After all, this determination was keyed on assumptions about the technology that had been made while the technology was hardly in its infancy.

There are two noteworthy aspects to this shift in FDA policy. First, the FDA has at least implicitly acknowledged that it is not appropriate to subject traditionally derived foods and genetically engineered foods to exactly the same regulatory requirements—that genetic engineering poses particular kinds of risks that merit increased regulatory scrutiny. Second, the FDA acknowledged that these increased or different risks posed by genetic engineering merit an information-based remedy in order to facilitate monitoring.

¹⁶⁸66 Fed. Reg. at 4712.

These acknowledgements notwithstanding, the FDA remains committed to its 1992 labeling policy. Interestingly, the FDA seems to argue that it is proper for the food industry to be required to provide the agency with detailed information about the particular genetic engineering process applied to the food, but that information about food processing need not be provided to consumers. Ultimately, this labeling controversy is not so much about whether there are increased risks with genetically engineered foods; the FDA has already acknowledged those increased risks. Rather, the struggle over labeling is fundamentally about whether consumers should be allowed to control their exposure to these risks, and make purchasing decisions informed by this information. In essence, the FDA seems to be arguing that that genetic engineering merits “enhanced agency awareness” but not enhanced consumer awareness. Moreover, the agency’s stance seems premised on the argument that it has an interest in regulating the entry of these foods into the marketplace, but that consumers themselves do not have a sufficient interest in making purchasing decisions equipped with information that that would allow them to influence the success of these foods in the marketplace.

2. *GRAS determination*

In fact, although the FDA was careful to state that the new regulations would not affect the “legal status” of such foods (presumably the legal assumption that genetically engineered products were GRAS) the change in regulatory posture does provide reason to question precisely that decision to presume genetically engineered foods to be GRAS. In the 1992 document, FDA’s decisions (1) not to require labeling, (2) not to require premarket notification, and (3) to presume genetic material transferred during genetic engineering to be GRAS were all based on a basic assumption that genetically modified foods could be regulated exactly the same as other “foods derived from new plant varieties.” Thus, the FDA argued against labeling genetically engineered foods because it does not require special labeling of traditionally-derived foods. Similarly, there was no need for premarket notification because no such notification is required for foods derived from

traditional breeding techniques.

Arguable, the FDA might have argued that the genetically engineered foods did not need to be examined under the additive/GRAS regulatory structure at all, since those provisions had never been applied to plants derived from traditional breeding techniques. In fact an internal FDA document reveals that at least some FDA actors realized that the decision to regulate genetically engineered foods under the food additive/GRAS provisions was “difficult to reconcile with not regulating conventionally-altered whole foods in food additive/GRAS category.”¹⁶⁹ Nevertheless, the FDA made a decision to regulate genetically engineered foods under the food additive/GRAS structure, partly to “assure safety and satisfy the public that it is being protected.”¹⁷⁰ However, as in the case of premarket notice, the regulations concerning additive/GRAS determinations deviated from standard practice for GRAS determinations. The decision that transferred genetic material could be presumed to be GRAS was a policy judgment call made very early in the development of the technology, and not based on any particular statutory basis, or even on a conventional understanding of what would be “generally recognized as safe.”

In fact, analysis of the regulations concerning the GRAS exception reveals that genetically engineered material would probably not be considered GRAS under the FDA’s own regulations. In order for a food to qualify as GRAS, the food must be generally recognized as safe “based on the views of experts qualified by scientific training and experience to evaluate the safety of substances directly or indirectly added to food...[based on] either (1) scientific procedures, or (2) in the case of a substance used in food prior to January 1, 1958, through experience based on common use in food.”¹⁷¹ The FDA has argued that these two bases for GRAS must be kept distinct arguing, “section 201(s) of the act makes a clear distinction between qualifying for the GRAS exemption through scientific procedures and qualifying for the GRAS exemption through common

¹⁶⁹*FDA Regulation of Food Products Derived from Genetically-Altered Plants*, 2, available at <http://www.biointegrity.org/list.html>.

¹⁷⁰*FDA Regulation of Food Products Derived from Genetically-Altered Plants*, 1, available at <http://www.biointegrity.org/list.html>.

¹⁷¹21 C.F.R. § 170.30(a).

use in food.”¹⁷²

Nevertheless, FDA has never indicated on which of these bases it was declaring transferred genetic material to be GRAS. In fact, these substances would not meet the requirements of either of these provisions. In order to meet the common use criteria, the GRAS determination “shall be based solely on food use of the substance prior to January 1, 1958.”¹⁷³ Transfer of moth genes or other genes from bacteria in soil (Bt) (both genes transferred to create genetically engineered products) were not commonly used in food prior to January 1, 1958. Moreover, the statute specifically states, “A food ingredient of natural biological origin that has been widely consumed for its nutrient properties in the United States prior to January 1, 1958, without known detrimental effects, which is *subject only to conventional processing as practiced prior to January 1, 1958*” [italics added]¹⁷⁴ will qualify as GRAS. Thus, the statute makes it clear that the processing of the food, as well as the actual existence of the substance in food, are key to the GRAS determination. Even for substances that did exist in foods commonly consumed before 1958, the common use exception would not apply when those foods are added through genetic engineering techniques since those techniques were not in use until well after 1958. In fact, the FDA has made itself very clear on this point, stating “*it is the use of a substance, rather than the substance itself, that is eligible for the GRAS exemption.*” [italics added]¹⁷⁵ Thus, in order for food substances to qualify under the GRAS exception, the technique used to add that particular substance must also qualify as GRAS.

Nor do substances added through genetic engineering techniques qualify under the scientific procedures requirements for GRAS status. The decision to allow food producers to self-affirm the GRAS status of the products under a “decision tree” analysis was clearly not consistent with “emerging FDA legal interpretations” of GRAS requirements, particularly the “‘publication’ requirement.”¹⁷⁶ In order to be deemed GRAS

¹⁷²62 Fed. Reg. at 18950.

¹⁷³21 C.F.R. § 170.30(c)(1)

¹⁷⁴21 C.F.R. § 170.30(d)

¹⁷⁵62 Fed. Reg. at 18950.

¹⁷⁶*FDA Regulation of Food Products Derived from Genetically-Altered Plants*, 2 available at

based upon the scientific procedures criterion, the manufacturer must show “the same quantity and quality of scientific evidence as is required to obtain approval of a food additive regulation of the ingredient. General recognition of safety through scientific procedures shall ordinarily be based upon published studies.”¹⁷⁷ Moreover, under traditional GRAS jurisprudence, the substance must be “‘generally recognized’ by qualified experts as having been scientifically shown to be safe. To fall within this exception, the substance must be ‘generally recognized as safe *under the conditions of its intended use*. The burden of proving general recognition of safe use is placed on the proponent of the food substance in question.” [italics in original]¹⁷⁸ Moreover, it is not enough for the plaintiff to show that there is no evidence proving the added substance to be unsafe, rather, the food manufacturer has a burden to proof that the substance is “generally recognized by experts as *safe* based on scientific evidence.” [italics in original]¹⁷⁹ The FDA has stated that, “an ongoing scientific discussion or controversy about safety concerns raised by available data would make it difficult to provide a basis for expert consensus about the safety of a substance for its intended use.”¹⁸⁰

Nevertheless, genetically modified foods have been allowed to circumvent these requirements. Although current regulations do allow manufacturers to self-affirm GRAS status, the FDA has argued that it may challenge such affirmations “if the information provided in the notice: 1) does not adequately establish technical evidence of safety; 2) is not generally available; 3) does not convince the agency that there is the requisite expert consensus about the safety of the substance for its intended use; or 4) is so poorly presented that the basis for the GRAS determination is not clear.”¹⁸¹

These regulations make it clear that GRAS was always intended to be a very limited exception to the food additive requirements and that the standard was to be extremely strict. Although the FDA insists that

<<http://www.biointegrity.org/list.html>>.

¹⁷⁷21 C.F.R. § 170.30(b).

¹⁷⁸*United States v. An Article of Food*, 752 F.2d 11 (1st Cir. 1985), *cited in* PETER BARON HUTT & RICHARD A. MERILL, FOOD AND DRUG LAW: CASES AND MATERIALS, 333 (1991).

¹⁷⁹*Id.*

¹⁸⁰62 Fed. Reg. 18938 at 18949.

¹⁸¹Substances Generally Recognized as Safe; Proposed Rule, 62 FR 18,938 at 18950 (Apr. 17, 1997), *cited in* Steinborn & Todd, *The End of Paternalism: A New Approach to Food Labeling*, 54 FOOD & DRUG L.J. 401, 408 (1999).

genetically engineered foods can be presumed GRAS, if actually analyzed under the relevant regulatory framework, these foods would not meet the GRAS requirements. In creating a “decision tree approach” the FDA explicitly lowered the bar for manufacturers adding foods through genetic engineering processes. Producers of genetically engineered foods are (1) not required to provide published articles establishing the safety of the genetic modifications used; (2) not required to affirmatively establish the safety of those foods; and (3) are not required to demonstrate an expert consensus of safety.

The FDA may argue that genetic engineering should not be subjected to this GRAS analysis because, like plant breeding, these methods are “applied in the earliest stages of development of new plant varieties and are not processes applied to finished food.”¹⁸² However, the GRAS common use provisions focus on whether the use of the food, including the food processing method, was in place before 1958, not on the point of application of the processing method. Plant breeding clearly was in use before 1958, and genetic engineering clearly was not. The plant breeding analogy simply makes no sense in the context of the GRAS analysis because the GRAS exception was clearly meant to be a very limited exception for added substances that truly were generally recognized as safe. A presumption that any added substance is GRAS is out of sync with this intention. Given this disconnect between the FDA’s GRAS analysis in the biotechnology context and in all other food additive contexts, Goldberg for Environmental Defense Fund has observed that the policy “appears to do more to protect the biotechnology industry than to protect consumers. . . FDA’s policy gives manufacturers who use genetic engineering to add substances to food considerably more discretion than manufacturers who use other technologies to add substances to food.”¹⁸³

Although the FDA employs the “food additive” and “GRAS” language in describing its regulations of geneti-

¹⁸²58 Fed. Reg. 25837 at 25839.

¹⁸³*Biotechnology in the Year 2000 and Beyond*, *supra* note 22 at 94.

cally modified foods, it is at least arguable that these terms have different meanings in the genetic engineering context. FDA's determination to *presume* genetically added material to be GRAS is inconsistent with the heavy burden FDA usually places on food producers to *prove* that particular additives fit under the GRAS exception. Moreover, the FDA's explicit acknowledgment that it will only regulate added genetic material "in cases where safety questions exist sufficient to warrant formal premarket review . . . to ensure public health protection"¹⁸⁴ is not really consistent with the other food additive regulations that require the producer to "demonstrate to a reasonable certainty that no harm will result from the intended use of the additive."¹⁸⁵ In short, although FDA's claims to be regulating genetically engineered foods and other food substances in exactly the same way, it is clear that the regulatory framework applied to genetically engineered foods and other foods are extremely different.

The current FDA policy regarding the regulation of genetically added material creates anomalous results and stretches the statutory scheme. In order to reach the determination that materials inserted into plants are "generally recognized as safe," the FDA defines these materials extremely broadly as simply "nucleic acids" which it argued "are present in the cells of every living organism, including every plant and animal used for food by humans or animals, and do not raise a safety concern as a component of food."¹⁸⁶ Of course, by defining genetically added material generally as nucleic acids, rather than more specifically by the types of the genetic material added in each instance, the FDA framed the issue in extremely general terms, and obscured the underlying, very real, safety issues raised by this technology. FDA Commissioner Henney stated "adding an extra bit of DNA does not raise any food safety issues."¹⁸⁷ Alternatively, the FDA could have based its regulation of these substances more generally in the type and function of the

¹⁸⁴57 Fed. Reg. at 22990.

¹⁸⁵57 Fed. Reg. at 22988.

¹⁸⁶57 Fed. Reg. at 22990.

¹⁸⁷Larry Thompson, *Are Bioengineered Foods Safe?* available at <<http://www.cfsan.fda.gov/~dms/fdbioeng.html>>.

particular genetic material being added—for instance, defining the additive in Bt corn as genetic material from a bacteria found in soil known to have pesticidal effects. After all, the addition of any food additive would involve the addition of “an extra bit of DNA” since all substances are composed of DNA. The FDA’s position simply obscures the actual public concern. This extremely selective interpretation of the statute and the underlying technology strongly suggests that FDA determined its regulatory stance towards these materials first, and then decided how fit it could most conveniently fit those conclusions into the existing statutory and regulatory structure.

The very fact that FDA has created special GRAS determination standards for genetically engineered foods directly undercuts the that agency assertion that “a substance that would be a food additive if it were added during traditional food manufacture is also treated as a food additive if it is introduced into food through genetic modification of a food crop.”¹⁸⁸ In fact, before the release of the 1992 policy, the Head of the FDA’s Biological and Organic Chemistry Section, Dr. Mitchell Smith argued the policy “turns the conventional connotation of *food additive* on its head”¹⁸⁹ [italics in original] and that “just because the agency failed to evaluate ‘new substances’ introduced by conventional breeding gives it no reason to continue to do so now with new biotechnology.”¹⁹⁰

3. Comparison with Irradiation Labeling Policy

FDA’s labeling policy for irradiated foods demonstrates the extent to which the exact the same regulatory framework can be interpreted to compel labeling in extremely similar circumstances. FDA’s stance against

¹⁸⁸ *Mayanski Statement*, *supra* note 34 at 3. See also Memorandum from Louis J. Pribyl, “Biotechnology Draft Document, 2/27/92.” (March 6, 1992), available at <<http://www.biointegrity.org/list.html>>. (“Why should companies conduct tests as described in the flow charts [in the 1992 policy] if there are no differences between traditional foods and those produced by modern technology.” Internal FDA documents charged that the 1992 policy was “inconsistent, in that it says (implies) that there are no differences between traditional breeding and recombinant [breeding], yet consultations, and remarket approvals are being bantered around, when they have not been used for foods before. In fact the FDA is making a distinction, so why pretend otherwise. [sic]”)

¹⁸⁹ Memorandum from Dr. Mitchell Smith, Head, Biological and Organic Chemistry Section, to Dr. James Maryanski, Biotechnology Coordinator, “Comments on Draft Federal Register Notice on Food Biotechnology, Dec, 12, 1991 draft.” (Jan. 8, 1992), available at <<http://www.biointegrity.org/list.html>>.

¹⁹⁰ *Id.*

mandatory labeling of genetically engineered foods is founded on the argument that information about genetically engineering is not “material” for purposes of section 201(n) of the act.¹⁹¹ Although the FDA acknowledged the many comments it received requesting mandatory labeling,¹⁹² the agency has at least implied that it will not consider such information material unless it becomes aware of data indicating that “bioengineered foods already on the market have adverse health effects.”¹⁹³ At least one FDA official disputed this conclusion. Dr. Smith, Head of the FDA’s Biological and Organic Chemistry Section argued, “[i]t is immaterial that the FDA doesn’t believe methods of genetic modifications are material information important to consumers if regulations do indeed indicate that the former will be a material fact when consumers view such information as important.”¹⁹⁴ Although Dr Smith was a scientist, and not a lawyer, his analysis was consistent with FDA’s previous interpretation of the materiality standard in the irradiation context.

The FDA’s current insistence on scientific evidence of an adverse health effect as the primary justification for labeling is not consistent with FDA’s previous analysis of labeling and materiality issues. In the irradiation context the FDA explicitly stated that safety considerations were not the only legitimate basis for a labeling requirement.¹⁹⁵ Rather, the agency based its irradiation labeling requirements on a misbranding rationale rather than a safety or health rationale.¹⁹⁶ The agency stated that the act granted it authority to require labeling even in the absence of safety concerns under section 403(a), 201(n), and 409 of the act,¹⁹⁷ specifically noting that “[s]ection 409(c)(3)(B) of the act prohibits the approval of a food additive if a fair evaluation of

¹⁹¹ *Guidance for Industry: Voluntary Labeling Indicating Whether Foods Have or Have Not Been Developed Using Bioengineering* 3, available at <<http://www.cfsan.fda.gov/~dms/biolabgu.html>>.

¹⁹² *Id.*

¹⁹³ *Id.*

¹⁹⁴ *Id.*

¹⁹⁵ 51 Fed. Reg. at 13388 (“The agency emphasizes, however, that the labeling requirement is not based on any concern about the safety of the uses of radiation. . .”)

¹⁹⁶ 51 Fed. Reg. at 13389 (“The retail label requirements of existing 21 C.F.R. part 179 were based on misbranding considerations and not on food safety or health considerations. . .”)

¹⁹⁷ 51 Fed. Reg. at 13388

the data before the Secretary ‘shows that the proposed use of the additive would promote deception of the consumer in violation of this Act or would otherwise result in adulteration or in misbranding of food within the meaning of the Act’¹⁹⁸ The potential for consumer deception—not just potential health harms—was the focus of misbranding analysis.

Because the FDA’s focus was on misbranding and consumer deception, the materiality analysis was explicitly consumer-centered. The analysis considered “whether the changes brought about by the safe use of irradiation are material facts in light of the representations made, *including the failure to reveal material facts*, about such foods. Irradiation may not change the food visually so that in the absence of a statement that a food has been irradiated, the implied representation to consumers is that the food has not been processed.” [emphasis added]¹⁹⁹ The FDA’s misbranding analysis focused on what assumptions consumers would make about their food based on the presence or absence of a label. Moreover, the FDA explicitly considered consumer interest in information a key factor in determining materiality. The agency stated that materiality “depends not on the abstract worth of the information but on *whether consumers view such information as important* and whether the omission of label information may mislead a consumer.” [emphasis added]²⁰⁰ The FDA interpreted the many comments it received requesting labeling as evidence of the “significance placed on such labeling by consumers.”²⁰¹ This deference to consumer interests and rejection of an “abstract worth of information” standard in determining materiality is in direct contrast to the FDA’s current stance toward labeling requirements of biotechnology wherein consumer interest is deemed essentially irrelevant absent evidence of “adverse health effects.”²⁰²

Moreover, the FDA noted that classification of irradiation as a food process was not relevant for the ma-

¹⁹⁸51 Fed. Reg. at 13388.

¹⁹⁹51 Fed. Reg. at 13388.

²⁰⁰51 Fed. Reg. 13376, 13388.

²⁰¹*Id.*

²⁰²66 Fed. Reg. at 4840.

teriality determination.²⁰³ Instead, the FDA noted that it has “historically required the disclosure of a food processing agent whenever it is material”²⁰⁴ and cited specific precedents for requiring labeling of food processes. For instance, the labels of flours must indicate “bleached” or “bromated” in if those processes had been applied,²⁰⁵ juices made from concentrate must be labeled as such,²⁰⁶ and that pasteurized orange juice must also bear special labeling.²⁰⁷ Moreover, other non-technological processing techniques must also be disclosed: “[f]oods made in semblance of a traditional food must disclose the processing difference. Potato chips made from dehydrated potatoes, onion rings made from minced onions, and fish sticks made from minced fish are all required to disclose these material differences in processing.”²⁰⁸ In sharp contrast to the 1992 policy’s insistence that the final food product rather than the processing method is the proper focus of materiality,²⁰⁹ these examples demonstrate that the materiality inquiry historically has encompassed both process and final food product.

FDA has a long history of requiring information about the processing of food products to appear on the food label.²¹⁰ If the use of minced rather than whole onions in the making of onion rings constitutes a material fact that must be revealed on a food label, then it certainly seems that the use of bioengineering in a tomato sold fresh or as a part of tomato paste is also a material fact that ought to be revealed on a label. It would be hard to articulate a principled distinction under which the mincing of onions would be material, while the addition of genetic material intended to have pesticidal effects would not be material. The examples of material processes in document demonstrate consumer expectations are the key factor in any materiality

²⁰³51 Fed. Reg. at 13389 (“Nor is there any statutory provision that exempts processes from being declared on a food label (49 Fed. Reg. 5718) and the agency must examine whether the failure to declare such processing is misleading to consumers. In this context it is not relevant whether irradiation is considered a process in determining whether retail labeling is appropriate.”)

²⁰⁴51 Fed. Reg. at 13388.

²⁰⁵51 Fed. Reg. at 13388 *citing* 21 C.F.R. § 137.205.

²⁰⁶51 Fed. Reg. at 13388 *citing* 21 C.F.R. § 146.145.

²⁰⁷*Id.*, *citing* 21 C.F.R. § 146.140.

²⁰⁸51 Fed. Reg. 13376, 13388.

²⁰⁹57 Fed. Reg. at 22984-5 (“the key factors in reviewing safety concerns should be the characteristics of the food product, rather than the fact that the new methods are used.”)

²¹⁰These examples directly refute Degnan’s contention that the FDA has historically used its authority to strictly limit the kinds and types of information required to be disclosed on a label. Fred H. Degnan, *Biotechnology and the Food Label: A Legal Perspective*, 55 Food & Drug L.J. 301, 306 (2000).

analysis.

Thus, the FDA's own analysis of the labeling issues in the irradiation context demonstrates that the FDA may have the statutory authority to require labeling of genetically modified foods. Not only have consumers indicated to the FDA that they have a strong preference for such labeling,²¹¹ but it is clear that in the absence of such information, they would be unable to distinguish genetically engineered foods from their non-genetically engineered counterparts.²¹² In explaining the need for a mandatory labeling requirement to avoid the possibility of mislabeling, the FDA stated "irradiation may not change the food in any way that is visible to a consumer, so a label statement provides the only means of letting consumers know that a food has been irradiated. Thus, the absence of a label statement on retail foods may incorrectly suggest that an irradiated food is essentially unprocessed."²¹³ Similarly, there is no way for consumers purchasing bioengineered foods to know that these processing techniques have been applied to the food they are purchasing. In fact, this indistinguishability is precisely why consumers and consumer activists are pushing for mandatory labeling of genetic engineered foods.²¹⁴ Consumer expectations and preferences are properly at the heart of materiality and other labeling decisions.

In the irradiation labeling policy, the FDA noted that irradiation of certain foods may affect the organoleptic properties of food as a justification for the materiality decision.²¹⁵ In fact, in defending the non-labeling policy for genetically engineered foods the FDA has suggested that the irradiation labeling decision was based solely and entirely on its findings about changes in organoleptic properties caused by irradiation.²¹⁶ However, the FDA's original finding on irradiation and organoleptic changes was extremely limited in scope. The FDA noted that "irradiation cause certain changes in foods and that even small changes that pose no safety

²¹¹66 Fed. Reg. at 4840

²¹²Consumer Focus Group, *supra* note 5.

²¹³51 Fed. Reg. at 13390.

²¹⁴*Consumer Focus Groups*, *supra* note 5.

²¹⁵51 Fed. Reg. at 13390.

²¹⁶58 Fed. Reg. at 25838.

hazard can affect the flavor or texture of a food in a way that may be unacceptable to some consumers.”²¹⁷ Similarly, the agency noted that “under certain conditions irradiation causes substantial changes in the organoleptic properties of some foods”²¹⁸ Notably FDA does not argue that irradiation processing affects the organoleptic properties (i.e. taste, color, smell, or texture) of all foods to which it is applied, or that such changes would be noticeable to any significant percentage of consumers.²¹⁹ Rather, the agency suggests only that application of this process *may* affect the organoleptic properties of *some* foods as a justification for a blanket labeling requirement for all irradiated foods. Of course, this argument can be extended to the genetic engineering process. Genetic engineering could undoubtedly be used to change the organoleptic properties of some foods—in fact, in some instances changing taste and texture of a particular food is the precise purpose of the engineering. Thus, under the FDA’s line of reasoning in the irradiation context, such potential changes in organoleptic properties of some of the items to which the process is applied supplies sufficient justification to require labeling of all foods to which the process is applied.

The agency did, however, create one notable limit on its irradiation labeling requirement; mandatory labeling was only required in the case of “first generation foods,” i.e. fresh fruits, vegetables, raw meat, etc.²²⁰ The FDA does not require labeling if irradiation has been applied to “one ingredient in a multiple-ingredient food.”²²¹ The FDA based this distinction on consumer expectations—basically arguing that consumers have do not expect first generation foods to be processed in any way, but that consumers are generally aware that multi- ingredient foods have been processed.²²² It should be noted that this distinction is not statutorily required, particularly since many of the mandatory labeling of food processes cited by the FDA (i.e. minced fish in fish sticks, minced onions in onion rings, dehydrated potatoes in potato chips) apply in cases where

²¹⁷51 Fed. Reg. at 113390

²¹⁸51 Fed. Reg. at 13390.

²¹⁹Taste tests suggest that this change can often not be detected at all. See Public Voice for Food and Health Policy, national Food Processors Association, & International Food Information Council, *Identifying, Addressing and Overcoming Consumer Concerns*, February 18-19, 1998, available at <<http://www.purefood.org/lrrad/roundtable.html>>.

²²⁰51 Fed. Reg. at 13389.

²²¹51 Fed. Reg. at 13389.

²²²51 Fed. Reg. at 13389.

it is clear that the food has also been processed in other ways. Nevertheless, FDA has consistently focused its analysis on consumers' expectations, not on an abstract notion of the worth of particular pieces of information. In this instance, FDA may simply have been offering a political compromise between no mandatory labeling requirement, and an across the board labeling requirement.

The essential point for purposes of comparison with the FDA's genetic engineering analysis is the extent to which the FDA has historically emphasized consumer expectations. In fact, the FDA's focus on consumer expectations is entirely appropriate since the labeling was required under the FDA's misbranding authority. Any misbranding inquiry, by definition, hinges on determinations about consumers expectations about the product based on the information that appears on the label, and information that does not appear on the label. Nevertheless, FDA's responses to consumer calls for labeling of genetically engineered foods notably do not analyze consumer's expectations, but focus solely on safety and health issues. This analysis of safety and health issues as dispositive of labeling requirements is logically tenuous. After all, if the FDA had found genetically engineered foods to be unsafe or to cause damaging long term health issues, then presumably such problems would be handled under the FDA's adulteration authority, not its labeling authority. Thus, the FDA's standard "no proven health or safety risks" answer to calls for mandatory labeling simply seem inopposite. Consumer pressure for mandatory labeling are premised primarily on arguments about consumer expectations of food products, not on health or safety concerns. The misbranding analysis in the irradiation case demonstrates that these are legitimate statutorily based concerns²²³ by making it clear that irradiation

²²³Interestingly, the FDA does not explicitly state that health concerns would be the only material fact that it would consider. 66 Fed. Reg. 4839, 4840 ("comments [requesting mandatory labeling] do not provide data or other information regarding consequences to consumers from eating the foods or any other basis for us to find under section 201(n) of the act that such disclosure was a material fact... We are still not aware of any data or other information that would form a basis for concluding that the fact that a food or its ingredients was produced using bioengineering is a material fact that must be disclosed..."). Nevertheless, by dismissing calls for mandatory labeling so summarily, the FDA ignores its own misbranding analysis. Moreover, the fact that FDA considers genetic engineering "material" or significant enough a food process to mandate pre-market notice to the agency undercuts its insistence that genetic engineering is not a "material fact" for purposes of labeling authority. All of the arguments used to justify pre-market notice— increased possibility of allergenic materials, increased possibility that the added material would not meet the GRAS standard, increased possibility of misbranding or adulteration—could all be used to also justify labeling of these foods.

labeling requirement was “not based on any concern about . . . safety.”²²⁴

Notably, the FDA did not consider the possibility of consumer confusion or overreaction to an irradiation label to be a sufficient justification for abandoning a labeling requirement. Instead, the FDA declared that “any confusion created by the presence of a retail label requirement can be corrected by consumer education programs.”²²⁵ FDA acknowledged the need for public education, but indicated that “*FDA has no proper role as a promoter of a specific food additive or food process*. The agency believes the primary responsibility for such educational activities remains with industry in this instance.” [emphasis added]²²⁶ The FDA unambiguously stated that responsibility for consumer acceptance and ultimate success of a new processing technique lies squarely with the food producers, not with the FDA.²²⁷

Almost every FDA argument advanced in favor of labeling irradiated foods could also be made in support of mandatory labeling of bioengineered foods. In this section, I will discuss a number of possible explanations for the conflicting interpretations of the labeling requirements in these two cases.

Perhaps FDA’s divergent policies can be traced to the “legal status” of these processes, since irradiation is regulated as a food additive, while the FDA considers genetically transferred substances GRAS. Irradiation is specifically listed as a food additive in the statute,²²⁸ and the Senate Report on the Food Additives Amendment of 1958 stated that “[s]ources of radiation (including radioactive isotopes, particle accelerators and X-ray machines) intended for use in processing food are included in the term ‘food additive’ as defined in this legislation.”²²⁹ Irradiation is thus statutorily defined as an additive while the FDA has considered genetically engineered foods to fall under the GRAS exception to the food additive definition. Conceivably, bioengineered food products would properly be subject to the analysis set forth in the irradiation context if

²²⁴51 Fed. Reg. at 13388.

²²⁵51 Fed. Reg. at 13389.

²²⁶51 Fed. Reg. at 13395.

²²⁷This position is clearly necessitated by the need to ensure the FDA’s objectivity and ability to ensure public health. If FDA promotes, or seems to be promoting, the interests of a particular food or drug producer, or a particular food or drug industry, entanglement issues will inevitably arise.

²²⁸51 FR 13376, 13376, *citing* 21 U.S.C. § 321(s).

²²⁹51 FR at 13376, *citing* S. REP. NO. 2422, at 5 (1958).

these products were regulated under the food additives provisions. Perhaps because these foods fall under the GRAS exemption, it may be appropriate to analyze bioengineered foods to different standards than irradiated foods for FDA labeling analysis purposes.

Nevertheless, the language in the Senate report indicating that the food additive definition includes “sources of radiation intended for use in processing food” could reasonably be interpreted to mean that the legislature broadly intended to include all high-tech, or novel processing techniques in its definition of “food additive.” After all, it would have been impossible for the legislature to have even conceived of the possibility of bioengineering in 1958 when the Food Additives Amendment was passed. By analogy, if the Congress considered radiation to be a food additive for purposes of the Act, it is not unreasonable to assume that the legislature may also have considered bioengineering to be a food additive for purposes of the Act. Such an interpretation is consistent with the intent of the Food Additives Amendment which was to “require the processor who wants to add a new and unproven additive to accept the responsibility...of first proving it to be safe for ingestion of human beings”²³⁰ and to prevent food processors from “using an untested additive for as long a time as it may take for the Government to suspect the deleteriousness of his additives.”²³¹

As noted above,²³² the FDA’s determination that products added to food plants through bioengineering are GRAS is not statutorily mandated. The agency exercised considerable discretion in creating a presumption that added genetic material was “generally recognized as safe.” The fact that process and analysis for determining GRAS status for GM foods is different from determining GRAS status for other foods²³³ mitigates against the FDA’s position that the current statutory framework is sufficient to deal with all of the issues raised by GM foods. The FDA could just have appropriately treated transferred genetic material as “food

²³⁰S. REP. NO. 2422, at 2 (1958).

²³¹*Id.*

²³²*Supra* section IV.A.2.

²³³Memorandum “FDA Regulation of Food Products Derived From Genetically-Altered Plants: Points to Consider” available at <http://www.biointegrity.org/list.html>>>. (noting that the Food Additive/GRAS option is “at odds with emerging FDA legal interpretations of what is required to achieve GRAS status, including ‘publication’ requirement.”)

additives” rather than as GRAS.

Alternatively, perhaps the difference in the FDA’s treatment of irradiation and bioengineering can be attributed to the effects of processes on the foods themselves. Although irradiation is a discrete process with relatively identifiable effects on foods and food ingredients, bioengineering actually encompasses a number of techniques, and the possible effects on bioengineered foods are as variable as the number of different gene combinations. Genes from any number of living organisms can be added to foods, causing an almost infinite variety of effects. This variability in the effect and purpose of agricultural biotechnology may explain FDA’s reluctance to label all bioengineered foods in the same way. After all, in reading that a particular food product is irradiated, a consumer can be relatively sure of the technological process applied to that food. If a consumer reads a food label indicating that the food product is bioengineered, this could mean that a flounder gene has been added to its genetic code, that a bacterial gene has been added to its genetic code, or that a shelf life preserving gene has been added.²³⁴ This approach would explain the FDA’s resistance to labeling because the agency does not know of genetic modifications changing foods in any “meaningful or uniform way.”²³⁵ However, the mandatory irradiation labeling policy also acknowledges that the irradiation does not have the same effects on all irradiated foods.²³⁶

Moreover, the FDA already treats agricultural biotechnology as a single process at least for purposes of requiring premarket notice. To the extent that the FDA itself sees “genetically engineered foods” to be a single salient category for its own regulatory purposes, it could easily extrapolate that consumers also would consider the same category salient. The fact that a label would provide too little information, or information that is not detailed enough, is not a strong argument for the denial of any information at all. At any rate,

²³⁴This argument was advanced at the recent public forum on biotechnology by Mario Teisl, a Professor in the Department of Resource Economics and Policy, at the University of Maine. He stated, “A simple GE label will not allow most consumers to differentiate products in the manner they most desire because the process of genetic engineering can produce a wide variety of consequences.” *Biotechnology in the Year 2000 and Beyond*, *supra* note 22 at 141.

²³⁵57 Fed. Reg. at 22991.

²³⁶51 Fed. Reg. at 13390.

this was not an argument advanced directly by the FDA, although this argument has been advanced by other groups opposed to mandatory labeling.²³⁷

Another possible explanation for the inconsistency in approaches can be attributed to changes in the regulatory climate at the times these technologies were being regulated, rather than the characteristics of the processes themselves. In the case of biotechnology, FDA seemed to have been under substantial pressure to base its policies solely on *science*—which in this context seems to have been meant ignoring any possible, but as yet unproven harms,²³⁸ whereas regulations regarding irradiation exhibited much more concern for consumer expectations of their foods. The FDA’s respective Federal Register policy statements for irradiation and bioengineering reflect this shift in regulatory posture. In the 1986 irradiation policy, the FDA emphasized the importance of avoiding consumer misinformation, but in the 1992 genetic engineering policy, the same agency emphasized the importance of a strict adherence to “known scientific risks” as the only justification for labeling in the bioengineering context.

This shift towards an insistence on scientific evidence of risk as a justification for labeling between 1986 and 1992 may have corresponded to a more general shift in FDA labeling attitudes. In 1991, the FDA stated that it was “unwilling to require a warning statement in the absence of clear evidence of a hazard,”²³⁹ and later in 1993 the FDA again stated that it “does not intend to require warning statements on food labels except in specific instances where there is scientifically based evidence of a potential health hazard.”²⁴⁰ These statements suggest that the FDA might consider any labeling requirement as a “warning label,” and strictly

²³⁷ *Biotechnology in the Year 2000 and Beyond*, *supra* note 22 at 141.

²³⁸Memorandum from Dr. Gerald B. Guest, Director of the Center for Veterinary Medicine, to Dr. James Maryanski, Biotechnology Coordinator, Re: “Regulation of Transgenic Plants—FDA Draft Federal Register Notice on Food Biotechnology,” (Feb. 5, 1992), available at <<<http://www.biointegrity.org/list.html>>>.

²³⁹Lars Noah, *The Imperative to Warn: Disentangling the ‘Right to Know’ From the ‘Need to Know’ about Consumer Product Hazards*, 11 YALE J. ON REG. 293, 317-8 (1994), *citing* Food Labeling; Declaration of Ingredients, 56 Fed. Reg. 28,592, 28,615 (1991).

²⁴⁰*Id.*, *citing* Food Labeling; Declaration of Ingredients, 58 Fed. Reg. 2850, 2872 (1993).

limit the kind of information required to be disclosed on the label. However, a label indicating the presence of bioengineered products could easily be characterized as an informational label rather than a warning label. Just as labels indicating that orange juice has been pasteurized are not warning labels, information about genetic engineering could be regarded as informational.

Interestingly, in FDA's recent discussion of materiality in the "Voluntary Guidance for Industry" the FDA argued that it has historically interpreted the materiality standard narrowly. The agency argued that it has only required the disclosure of such information when "the absence of such information may: 1) pose special health or environmental risks. . . ; 2) mislead the consumer in light of other statements made on the label. . . ; 3) in cases where a consumer may assume that a food, because of its similarity to another food, has nutritional, organoleptic, or functional characteristics of the food it resembles when in fact it does not (e.g. reduced fat margarine not suitable for frying)"²⁴¹ Other commentators supportive of the current FDA policy also argue that the FDA has historically limited the amount of information considered material.²⁴² However, this position sharply contrasts with the FDA's 1986 broad interpretation of its labeling authority which stated that "FDA has historically required the disclosure of a food processing agent whenever it is material to the processing of foods."²⁴³

In fact, the FDA's has recently signaled that it is considering revising its irradiated foods labeling policy in response to the Food and Drug Administration Modernization Act of 1997 ("FDAMA") which "directed FDA to publish for public comment proposed changes to current regulations relating to labeling of foods treated with ionizing radiation".²⁴⁴ The legislative history directs that "any required irradiation disclosure

²⁴¹*Guidance for Industry: Voluntary Labeling Indicating Whether Foods Have or Have Not Been Developed Using Bioengineering*, available at <<http://www.cfsan.fda.gov/dms/BIOLABGU.html>>.

²⁴²Fred H. Degnan, *Biotechnology and the Food Label: A Legal Perspective*, 55 Food & Drug L.J. 301, 306 (2000) ("The agency has exercised that authority sparingly, largely reserving its use for the disclosure of truly important, noncollateral and nonlabel-cluttering 'material' information")

²⁴³51 Fed. Reg. at 13388.

²⁴⁴21 C.F.R. Part 179 available at <<http://vm.cfsan.fda.gov/~lrd/fr990217.html>>.

to be of a type and character such that it would not be perceived to be a warning or give rise to inappropriate consumer anxiety.”²⁴⁵ This shift in irradiation labeling policy may evidence of a growing general legislative and regulatory desire to keep food labeling to a minimum, at least in cases where the labels might “be perceived as a warning or give rise to inappropriate consumer anxiety.” This fear of an “inappropriate” consumer reaction may also drive the FDA’s determination to avoid labeling of GE foods.²⁴⁶

Another possible background explanation for the discrepancy in treatment of the two technologies might simply be the nature of the constituencies with a financial interest in the technologies at hand. The biotechnology firms may enjoy more concentrated political influence in lobbying government agencies than industries with an interest in promoting irradiation of foods. The biotechnology firms represent a cohesive interest group organized through the Biotechnology Industry Organization, or BIO,²⁴⁷ whereas those advocating irradiation were likely to be less well organized and spread across a number of food industries.²⁴⁸ Moreover, biotechnology firms may have noted how sparsely irradiation was actually used in the market after the decision to require mandatory labeling,²⁴⁹ and decided that mandatory labeling would signal the death knell for agricultural biotechnology as well.²⁵⁰

B.

²⁴⁵Irradiation in the Production, Processing, and Handling of Food, 64 Fed. Reg. 7834, 7835 (February 17, 1999), *quoting* CONF. REP. on S. 830, Food and Drug Administration Modernization Act of 1997, 143 CONG. REC. H10452, 10477 (November 9, 1997).

²⁴⁶*Infra* section V.

²⁴⁷Tanya E. Karwaki, Note and Comment, *The FDA and the Biotechnology Industry: A Symbiotic Relationship?*, 71 WASH. L. REV. 821, 835 (1996)

²⁴⁸Irradiation can be applied to everything from meats, to fruits and vegetables, to spices. See Marian Burros, *Irradiated Beef: In Markets, Quietly*, N.Y. TIMES, Feb. 28, 2001 available at <<http://www.nytimes.com/2001/02/28/living/28WELL.html?printpage=yes>> (“The federal government has also approved irradiation of poultry, pork, grains, fruits, vegetables and spices, but very little beyond spices is being irradiated.”)

²⁴⁹*Id.*

²⁵⁰*Id.* At least one of the causes of the relative lack of irradiated foods available in the supermarkets is due to fear of a negative consumer reaction.

The Science defense is not really absolute.

1. Science cannot dictate labeling policy.

Although the FDA generally defends its regulatory stance towards genetically engineered foods as science based, this defense is inopposite in the context of the labeling debate. Scientific data, no matter how complete or accurate, does not provide any clear policy answers to the fundamental question of what kinds of information producers should be required to provide to consumers. Although scientific data and analysis is the primary and proper focus of safety determinations for purposes of the adulteration sections of the act, labeling policy is first and foremost about what kinds of information would be useful to consumers. Scientific evidence may provide very relevant evidence about particular kinds of risks. However, the final choice over what information should be required to appear on a label has as much to do with one's understanding of the FDA's role in mediating consumer and industry preferences as it does with one's view of the scientific evidence. Labeling issues are not fundamentally questions of science, but questions of policy judgment. The irradiation rules indicate that an analysis of consumer expectations and preferences are clearly relevant in this debate.

All labeling arguments are political. The "consumer right to know" may be an unscientific standard, but the argument that consumers do not need to know about small or unproven risks is likewise an unscientific argument. Like all other labeling arguments, this controversy hinges on when the FDA should compel manufacturers and other food producers to provide consumers with information. Under a standard in which labeling would only be compelled in cases of a clear health risk, such labeling would virtually never be required since such foods would not be permitted in the market in the first place. Thus, in order for the interpret the statutory structure in such a way that ascribes the labeling provisions with independent meaning, labeling must be required in cases other than where a clear health risk has been demonstrated.

This issue fundamentally concerns whether manufacturers and the government trust consumers to make responsible use of this information, not whether the underlying products are safe for human consumption. These arguments involve the proper distribution of information in the market, and by extension, the proper distribution of *power* in the market. In such a debate, science does not and cannot provide any definitive answers.

Of course, it is easy to see why the FDA has an interest in arguing that the labeling policy is based solely on science. Scientific evidence seems “objective,” and is generally considered authoritative, and the FDA has a clear interest in being perceived as objective and not influenced by political factors.²⁵¹ Claiming that a political decision is based on “science” may give the agency political cover for controversial decisions. Nevertheless, in the case of labeling policy, all judgment calls implicate political, not just scientific, judgments.

2. Agricultural Biotechnology does Pose Risks.

Very few advocates would argue that the application of biotechnology to agriculture poses no risks whatsoever. The real question is over who should be equipped with information about possible risks when the extent of the risk is under real dispute or is unknown. Biotechnology is still a new technology, and many of the underlying biological and chemical implications and effects are not completely understood. According to Richard Lewontin, a Harvard geneticist, the effects of genetic engineering are not entirely predictable. He stated, “You can always intervene and change something in it [a gene], but there’s no way of knowing what all the downstream effects will be or how it might affect the environment. We have such a miserably poor understanding of how the organism develops from its DNA that I would be surprised if we don’t get one

²⁵¹Dan Glickman, *New Crops, New Century, New Challenges: How Will Scientists, Farmers, And Consumers Learn to Love Biotechnology and What Happens If They Don’t?*, Address Before the National Press Club (July 13, 1999), available at <<http://www.usda.gov/news/releases/1999/02/0285>>. [hereinafter *Glickman Address*]

rude shock after another.”²⁵²

FDA’s 1992 policy document argued that the labeling should not be required because “the agency is not aware of any information showing that foods derived by these new methods differ from other foods in any meaningful or uniform way, or that, as a class, foods developed by these new techniques present any different or greater safety concern than foods developed by traditional plant breeding.”²⁵³ The agency did not affirm that such foods were not different from other foods, or that that these foods were actually safe, but simply that it “was not aware of any information” indicating such foods were materially different or unsafe. Thus, FDA seems to have been operating under the working assumption that these foods would safe, and then required scientific evidence that the food was unsafe in order to justify additional regulatory scrutiny. This working assumption was probably based on its understanding that bioengineering was just an extension of traditional plant breeding techniques.

However, even at the time that the FDA made these determinations, these conclusions had been challenged by agency employees. For instance, Dr. Linda Kahl, an FDA compliance officer stated that “[t]he processes of genetic engineering and traditional breeding **are** different, and according to the technical experts in the agency, they lead to different risks.” [emphasis in original]²⁵⁴ Dr. Louis J. Pribyl also characterized the policy as “inconsistent, in that it says (implies) that there are no difference between traditional breeding and recombinant, yet consultations, and premarket approvals are being bantered around, when they have not been used before. In fact, the FDA is making a distinction, so why pretend otherwise.”²⁵⁵ Like Kahl, Pribyl noted the “profound difference between the types of unexpected effects from traditional breeding and genetic

²⁵²Michael Pollan, *Playing God in the Garden*, N.Y. TIMES MAG., Oct. 25, 1998, available at 1998 WL 22330020.

²⁵³57 Fed. Reg. 22991.

²⁵⁴Comments from Dr. Linda Kahl, FDA compliance officer, to Dr. James Maryanski, FDA Biotechnology Coordinator, Re: “Statement of Policy: Foods from Genetically Modified Plants,” 2 (January 8, 1992), available at <<http://www.biointegrity.org/list.html>>.

²⁵⁵Comments from Dr. Louis J. Pribyl, Re: “Biotechnology Draft Document, 2/27/92” 1 (Mar. 6, 1992), available at <<http://www.biointegrity.org/list.html>>.

engineering which is just glanced over in this document.”²⁵⁶ Similarly, Gerald B. Guest, Director for the Center of Veterinary Medicine argued that genetically engineered animal feeds “present unique animal and food safety concerns.”²⁵⁷ Interestingly, Dr Guest’s memo also suggests that the FDA 1992 policy backs away from previous safety standards, “I and other scientists [sic] at CVM have concluded there is ample scientific justification to support a premarket review of these products. . . The FDA will be confronted with new plant constituents that could be of toxicological or environmental concern. . . *It has always been our position that the sponsor needs to generate the appropriate scientific information to demonstrate product safety to humans, animals and the environment.*” [emphasis added]²⁵⁸ Thus, one of the FDA’s own senior scientists suggested that the 1992 policy lowered the safety standards for genetically engineered foods.

FDA employees also expressed discomfort with the FDA’s insistence that it’s policy was based on scientific evidence. Dr. Kahl further questioned whether the FDA’s position amounted to “asking the scientific experts to generate for this policy statement in the absence of any data.”²⁵⁹ In fact, Dr. Guest “urge[d] Mr Maryansky to eliminate statements that suggest that the lack of information can be used as evidence for no regulatory concern.”²⁶⁰ Dr. Pribyl noted that the FDA had adopted “the industry’s pet idea, namely that there are no unintended effects that will raise the FDA’s level of concern. But time and time again, there is no data to backup their contention.”²⁶¹

In fact, it seems that at least some divisions at the FDA had advised a more cautious regulatory stance and were not, at least initially, completely unanimous in their support of the 1992 document’s regulatory stance.

²⁵⁶Id.

²⁵⁷Memorandum from Dr. Gerald B. Guest, Director of the Center for Veterinary Medicine, to Dr. James Maryanski, Biotechnology Coordinator, “Regulation of Transgenic Plants –FDA Draft Federal Register Notice on Food Biotechnology,” 1 (Feb. 5, 1992), available at <<http://www.biointegrity.org/list.html>>.

²⁵⁸Id.

²⁵⁹Comments from Dr. Linda Kahl, FDA Compliance Officer, to Dr. James Maryanski, FDA Biotechnology Coordinator, Re “Statement of Policy: Foods from Genetically Modified Plants” 2 (Jan. 8, 1992), available at <<http://www.biointegrity.org/list.html>>. She continued, “It’s no wonder that there are so many different opinions—it is an exercise in hypotheses forced on individuals whose jobs and training ordinarily deal with facts.” Id.

²⁶⁰Memorandum from Dr. Gerald B. Guest to Dr. James Maryanski, “Regulation of Transgenic Plants—FDA Draft Federal Register Notice on Food Biotechnology,” 1 (Feb. 5, 1992), available at <<http://www.biointegrity.org/list.html>>.

²⁶¹Comments from Dr. Louis J. Pribyl, Re: “Biotechnology Draft Document, 2/27/92.” 3 (March 6, 1992), available at <<http://www.biointegrity.org/list.html>>.

An internal memo from Samuel I. Shibko, the FDA's Director of the Division of Toxicological Review and Evaluation recommended traditional toxicology studies for genetically engineered foods to ensure safety.²⁶² Nevertheless, the FDA chose not to adopt those recommendations.²⁶³ Ultimately the FDA's 1992 policy was premised on basic assumptions about the similarity of genetically engineered foods to their conventional counterparts. Because the FDA's conceptualized these foods as fundamentally similar to other traditional varieties of food, FDA argued that additional regulation would only be justified by scientific evidence proving genetically engineered foods unsafe.

While these internal FDA documents certainly do not prove that FDA was motivated by any improper motives in crafting its 1992 policy, they do demonstrate the extent to which FDA was making policy judgments in the face of a great deal of scientific uncertainty. The FDA made a decision to treat the lack of a demonstrated scientific risk as positive evidence of safety—a decision that was neither statutorily nor logically compelled. These documents demonstrate the extent to which reasonable, scientifically informed people, could hold different opinions on the extent to which GE foods should be regulated under the statutory framework. Matthew Franken has pointed out that “FDA’s reliance on *established* scientific knowledge could also be considered a weakness. Because this approach is based on known risks, it is reactionary rather than precautionary. Although scientific research has not yet discovered potential harms associated

²⁶²The memo suggested that the toxicology section be revised to say “At this time it is unlikely that molecular and compositional analysis can reasonably detect or predict all possible changes in toxicant levels or the development of new toxic metabolites as a result of genetic modifications introduced by new methods of biotechnology. FDA believes that, until scientific data and experience with the new techniques of gene transfer have accumulated, the possibility of unexpected, accidental changes in genetically engineered plants justifies a limited traditional toxicology study with the edible part of the plant. This study would provide a basis for assuring the absence of any new highly toxic materials that are not present in the parental plant variety, and would establish the wholesomeness of the food for subsequent limited studies in humans. Additional assurance of safety would be provided by *in vitro* genotoxicity and digestion studies with the food or appropriate extract.” Memorandum from Dr. Samuel I. Shibko to Dr. James Maryanski, Re: “Revision of Toxicology Section of the Statement of Policy: Foods Derived from Genetically Modified Plants,” 1 (January 31, 1992), *available at* <<http://www.biointegrity.org/list.html>>.

²⁶³The FDA's own Toxicology Department's recommendations notwithstanding, the toxicology section as actually published stated, “Feeding studies or other toxicological tests may be warranted when the characteristics of the plant or the nature of the modification raise safety concerns that cannot be resolved by analytical methods. FDA recognizes that feeding studies on whole foods have limited sensitivity because of the inability to administer exaggerated doses. Because of the difficulty of designing meaningful studies, FDA encourages companies to consult informally with the agency about test protocols.” 57 Fed. Reg. at 23004.

with these foods, this does not mean they do not exist.”²⁶⁴ FDA’s approach was based on an interpretation of scientific evidence, but it was not the only plausible interpretation of that evidence (or lack thereof). Similarly, FDA’s approach was based on an interpretation of the existing food regulations, but hardly the only plausible interpretation of those regulations.

In fact, an article in Nature Magazine has suggested that the current approach to regulating genetically engineered foods is not based on science at all. Instead, the authors contend that the FDA approach is not scientifically substantiated, arguing that “showing that a genetically modified food is chemically similar to its natural counterpart is not adequate evidence that it is safe for human consumption.”²⁶⁵ In fact this article points out that, given the current state of scientific wisdom, mere knowledge of the chemical composition of a genetically engineered food does not provide an adequate basis for scientists to accurately assess that biochemical and toxicological risks posed by that food; the article points out that “the relationship between genetics, chemical composition and toxicological risk remains unknown.”²⁶⁶ Thus, these authors condemn the current approach as “pseudo-scientific” and calls it “a commercial and political judgment masquerading as if it were scientific.”²⁶⁷ Further, they argue that such an approach is actually “inherently anti-scientific because it was created primarily to provide an excuse for not requiring biochemical or toxicological tests.”²⁶⁸ An examination of the FDA’s own analysis often reveals the FDA’s attempts to shield policy decisions by invoking “science.” For instance, in defending its labeling policy, the FDA argued that “[t]here is scientific basis to conclude that . . . genetic alternations do not change the essential nature of the plant.”²⁶⁹ However, the FDA cites no scientific evidence to support this proposition. In fact, scientific evidence could never prove such a proposition since the “essential nature” of any organism is a hopelessly philosophical, not a scientific,

²⁶⁴Matthew Franken, Comment, *Fear of Frankenfoods: A Better Labling Standard for Genetically Modified Foods*, 1 Minn. Intell. Prop. Rev. 153, 172 (2000).

²⁶⁵Erik Millstone, Eric Brunner & Sue Mayer, *Beyond “Substantial Equivalence”*, 401 NATURE 525, 525 (Oct. 7, 1999).

²⁶⁶Id. at 526.

²⁶⁷Id.

²⁶⁸Id.

²⁶⁹58 Fed. Reg. at 25829

question. In fact, from a scientific point of view, the only thing that could change the nature of an organism is a change in its genetic structure, since science would tell us that the only thing that distinguishes one organism from another is their genetic structure—the building blocks of physical existence. Science tells us that an organism’s genes dictate that organism’s properties, i.e. its nature.

3. The Risks of Genetically Engineered Foods are Still Not Fully Understood.

Despite FDA assurances that genetically engineered products had scientifically been proven safe, almost ten years after the release of the 1992 policy, the risk data regarding genetically engineered plants is still incomplete. Science has still not determined what the real risks of this technology are. Biotech proponents say that the benefits outweigh the risks, but the purported benefits (feeding the world, etc.) have yet to be proven, and the extent of the risks (bio-disaster) have also not yet been sufficiently determined.²⁷⁰ Even many scientists favoring the development of biotechnology concede that more research about the risks of this technology is in order.²⁷¹

Results of the few studies that have been conducted about the risks and benefits of biotech food products do not support all industry claims about the advantages of their products. Charles Benbrook, former executive director of the National Research Council’s Board on Agriculture, recently conducted a study testing the risks and benefits of Roundup Ready Soybeans. He found that the use of the Roundup Ready soybeans did allow farmers to substitute Roundup herbicides in place of other more hazardous herbicides, and allowed the farmers to till the soil less frequently, reducing soil erosion.²⁷² However, he did not find evidence to substantiate the manufacturer’s claims that the product required less herbicides than traditional soybeans;

²⁷⁰See L.L. Wolfenbarger & P.R. Phifer, *The Ecological Risks and Benefits of Genetically Engineered Plants*, 290 SCIENCE 2088 (Dec. 15, 2000), available at <<http://www.sciencemag.org>>; Dan Ferber, *Risks and Benefits: GM Crops in the Cross Hairs*, 286 SCIENCE 1662 (Nov. 26, 1999), available at <<http://www.sciencemag.org>>.

²⁷¹Dan Ferber, *Risks and Benefits: GM Crops in the Cross Hairs*, 286 SCIENCE 1662 (Nov. 26, 1999) available at <<http://www.sciencemag.org>>.

²⁷²Dan Ferber, *Risks and Benefits: GM Crops in the Cross Hairs*, 286 SCIENCE 1662 (Nov. 26, 1999), available at <<http://www.sciencemag.org>>.

to the contrary, he concluded that “farmers applied two to five times more herbicides of all kinds to their GM soybean fields than to fields growing conventional soybeans.”²⁷³ These results draw into question industry assertions about the environmental benefits of this product, since a greater total application of a less hazardous herbicide does not necessarily create a net benefit for the environment. Moreover, a study conducted by Michael Duffy at Iowa State University investigating the claims about the financial benefits of Roundup Ready found that farmers growing the Roundup Ready beans made no more money than farmers growing the non- genetically modified variety.²⁷⁴

These studies demonstrate that questions about the real risks and benefits of genetically modified foods are not raised solely by political activists and isolated scientists. Scientists and other risk analysis professionals acknowledge that much of the safety and environmental effects of genetically engineered foods have not been adequately studied. In fact, although drugs and pesticides have generally undergone risk analysis, according to James Cook, a plant pathologist at Washington State University in Pullman, risk analysis methods have never been applied to any plants, let alone genetically engineered plants.²⁷⁵ Nor did the FDA involve any experts in risk analysis in developing its 1992 policy.²⁷⁶ Accordingly, industry and government claims that the benefits of genetically engineered outweigh the risks have not been verified by risk analysis experts.

Respected scientific journals have also acknowledged the substantial degree of scientific uncertainty about the effects of genetically engineered foods.²⁷⁷ A recent article published in Science magazine by L.L. Wolfenbarger and P.R. Phifer noted that “key experiments on both the environmental risks and benefits [of genetically

²⁷³Dan Ferber, *Risks and Benefits: GM Crops in the Cross Hairs*, 286 SCIENCE 1662 (Nov. 26, 1999), available at <http://www.sciencemag.org>.

²⁷⁴Dan Ferber, *Risks and Benefits: GM Crops in the Cross Hairs*, 286 SCIENCE 1662 (Nov. 26, 1999), available at <http://www.sciencemag.org>.

²⁷⁵Dan Ferber, *Risks and Benefits: GM Crops in the Cross Hairs*, 286 SCIENCE 1662 (Nov. 26, 1999), available at <http://www.sciencemag.org>.

²⁷⁶Comments from Dr. Linda Kahl, FDA Compliance Officer, to Dr. James Maryanski, FDA Biotechnology Coordinator, Re: “Statement of Policy: Foods from Genetically Modified Plants” 3 (Jan. 8, 1992), available at <http://www.biointegrity.org/list.html>.

²⁷⁷Opinion, *GM Foods Debate Needs a Recipe for Restoring Trust*, 398 NATURE 639 (April 22, 1999), available at <http://www.nature.com>.

engineered foods] are lacking.”²⁷⁸ Additionally, some scientists worry that regulatory agencies such as the FDA may be “overestim[ing] their ability to predict allergenicity.”²⁷⁹ An article in *Nature* pointed out that there are still areas of scientific uncertainty regarding the potential for genetic engineering to trigger allergenic reactions and that “there is a broader consensus that the potential ecological disturbance caused by a growing dependence on GM crops by modern farmers could be significant.”²⁸⁰ In fact, the same article opined that “[t]he public is right to be concerned about the potential—and novel—hazards of modern food production techniques.”²⁸¹ Similarly, a recent article in the *Annual Review of Genetics and Human Genomics* noted that the public reaction to genetic engineering reflects its discomfort with the fact that “the reshaping of American farmland with millions of acres of transgenic crops has proceeded too quickly and in a manner that precludes adequate assessment of environmental and health issues; and that government has failed to discharge its regulatory obligations.”²⁸² Moreover, the article concludes describes this public unease as “a rational response to the discovery that a major change has taken place in the world that was conducted largely without public knowledge.”²⁸³ These claims of scientific uncertainty do not come from the political ideologues motivated by a deep seeded vendetta against the biotech industry, but from thoughtful scientists acknowledging the lack of scientific evidence.

4. Lack of Research.

The simple truth is that there is not enough research being conducted about the ecological affects of genetically engineered foods.²⁸⁴ This paucity in research is partly due to a lack of funds for research about

²⁷⁸L.L. Wolfenbarger & P.R. Phifer, *The Ecological Risks and Benefits of Genetically Engineered Plants*, 290 SCIENCE 2088, 2088 (Dec 15, 2000).

²⁷⁹Declan Butler & Tony Reichhardt, *Long-Term Effect of GM Crops Serves up Food for Thought*, 398 NATURE 651, 653 (April 22, 1999).

²⁸⁰Opinion, *GM Foods Debate Needs a Recipe for Restoring Trust*, 398 NATURE 639 (April 22, 1999), available at <<<http://www.nature.com>>>.

²⁸¹Id. [*GM Foods Debate Needs a Recipe for Restoring Trust*]

²⁸²Philip R. Reilly, *Public Concern About Genetics*, 1 ANN. REV. GENOMICS & HUM. GENETICS 485, 502 (2000).

²⁸³Philip R. Reilly, *Public Concern about Genetics*, 1 ANN. REV. GENOMICS. & HUM. GENETICS 485, 502 (2000).

²⁸⁴L.L. Wolfenbarger & P.R. Phifer, *The Ecological Risks and Benefits of Genetically Engineered Plants*, 290 SCIENCE 2088, 2088 (Dec. 15, 2000).

biosafety.²⁸⁵ The U.S. Department of Agriculture spends around \$1.5 million a year on biosafety research, amounting to only 1% of its total biotech research budget.²⁸⁶ Moreover, researchers have few natural incentives to become involved in biotech toxicity studies because such research “tend[s] to yield negative results that are difficult to publish and account for to funding agencies.”²⁸⁷ Although the Biotechnology Industry Organization has supported the call for more studies of ecological risks, biotech firms are unwilling to pay for such studies.²⁸⁸

Given the fact that much of the science on the potential risks of biotechnology in agriculture has been inconclusive or incomplete, it is hard to know what to make of the government’s steadfast insistence that its policy is based on science. Perhaps the government should consider the journal *Nature*’s admonition: “[b]oth sides should acknowledge the current limits to scientific certainty. The failure to ‘prove’ scientifically that a new food is dangerous is not the same as to have ‘proved’ that it is safe.”²⁸⁹ In calling for the regulation of GM foods based on “the soundest possible science”²⁹⁰ an opinion piece written in *Nature* noted that nothing is to be gained in “[b]asing regulations on scientific conclusions that later turn out to be false.”²⁹¹ Basing a policy on an assumption that biotech foods are safe for the environment and human health without requiring affirmative evidence for these propositions may lead to a situation in which evidence of such environmental or

²⁸⁵Dan Ferber, *Risks and Benefits: GM Crops in the Cross Hairs*, 286 *SCIENCE* 1662 (Nov. 26, 1999), available at <http://www.sciencemag.org>.

²⁸⁶*Basic Research Holds Key to Weighing Risks*, 398 *Nature* 652, 652 (Apr. 22, 1999).

²⁸⁷Declan Butler & Tony Reichhardt, *Long-Term Effect of GM Crops Serves up Food for Thought*, 398 *NATURE* 651, 653 (April 22, 1999).

²⁸⁸Carol Kaesuk Yoon, *What’s Next For Biotech Crops? Questions*, *N.Y. TIMES*, Dec 19, 2000, available at <http://www.nytimes.com/2000/12/19/science/19PLAN.html>.

²⁸⁹*Id.* [GM Foods Debate Needs a Recipe for Restoring Trust] One GM critic has said “It took us 60 years to realize that DDT might have oestrogenic activities and affect humans, but we are now being asked to believe that everything is OK with GM foods because we haven’t seen any dead bodies yet.” Declan Butler & Tony Reichhardt, *Long-Term Effect of GM Crops Serves up Food for Thought*, 398 *NATURE* 651, 653 (April 22, 1999).

²⁹⁰*GM Foods Debate Needs a Recipe for Restoring Trust*, 398 *NATURE* 639 (April 22, 1999), available at <http://www.nature.com>.

²⁹¹*GM Foods Debate Needs a Recipe for Restoring Trust*, 398 *NATURE* 639 (April 22, 1999), available at <http://www.nature.com>.

health risks may come too late to avoid real damage.²⁹² It is true that the scientific establishment generally believes that the current regulatory safeguards are adequate to protect the public,²⁹³ but “[e]ven among ardent supporters of GM foods. . . calls are being increasingly heard for more research on health risks, and for the introduction of monitoring systems that would allow the early detection of any long-term problems”²⁹⁴ The degree of scientific uncertainty about these foods only underscores the extent to which the current agricultural biotechnology is based on policy judgments. The FDA’s minimal regulatory approach towards genetically engineered foods “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.”²⁹⁵ At the very least, the FDA should acknowledge that the assumption that genetically engineered foods are safe “until it is conclusively proven otherwise”²⁹⁶ represents a policy, not a scientific, judgment.

C.

The FDA’s Policy Reflects Political Pressures.

FDA’s insistent characterization of its biotech policies as “science based” may reflect a defense against the suggestion that its regulations have been shaped by subject to inappropriate influence by the biotechnology industry. The FDA may be particularly worried about charges of “agency capture” through which a regulated industry “is able to use its political influence to force the agency to promulgate regulations that are preferential to the industry and perhaps contrary to the agency’s intended purpose.”²⁹⁷ Government

²⁹²Kirsten S. Beaudoin, Comment, *On Tonight’s Menu: Toasted Cornbread with Firefly Genes? Adapting Food Labeling Law to Consumer Protection Needs in the Biotech Century*, 83 MARQ. L. REV. 237, 266-7 (1999).

²⁹³*Who’s Afraid?*, ECONOMIST, June 17, 1999, available at 1999 WL 7363493.

²⁹⁴Declan Butler & Tony Reichhardt, *Long-Term Effect of GM Crops Serves up Food for Thought*, 398 NATURE 651, 651 (April 22, 1999).

²⁹⁵Kirsten S. Beaudoin, Comment, *On Tonight’s Menu: Toasted Cornbread with Firefly Genes? Adapting Food Labeling Law to Consumer Protection Needs in the Biotech Century*, 83 MARQ. L. REV. 237, 267 (1999).

²⁹⁶*Id.* at 266-7.

²⁹⁷Tanya E. Karwaki, Note & Comment, *The FDA and the Biotechnology Industry: A Symbiotic Relationship?*, 71 WASH. L. REV. 821, 836 (1996).

agencies may be vulnerable to such influence because of the agency's interest in preserving its prestige and power, or because individual employees may have an interest in eventually obtaining employment with the companies that they are policing.²⁹⁸ Both of these factors may lead FDA to attempt to cultivate "industry goodwill" by tailoring regulations to the concerns and needs of the biotech industry.²⁹⁹ Karwaki argues that the relationship between the FDA and the biotech industry, at least in the domain of pharmaceuticals, is adversarial rather than cooperative.³⁰⁰

Nevertheless, the activists have expressed concern about the possibility of inappropriate industry influence in the agricultural biotech arena. At a recent public forum on genetic engineering held by the FDA, critics of the current policy consistently noted the possibility of such inappropriate incentives for FDA to develop industry-friendly policies, particularly in order to expand career options. In particular, these participants charged that Michael Taylor, the deputy commissioner of policy for the FDA at the time that the genetically engineered bovine growth hormone was approved for marketing, and involved in the crafting of FDA's policy towards genetically engineered foods, was later hired as Monsanto's vice president for public policy.³⁰¹ Although the FDA clearly cannot exercise control over whether its employees are later hired by the regulated industries, such employment moves do elicit public suspicion.³⁰² The possibility of inappropriate agency influence over individual FDA employees with interests in career moves into the regulated industry threatens the public's willingness to trust regulatory agencies.³⁰³

²⁹⁸Karwaki, Note and Comment, *The FDA and the Biotechnology Industry: A Symbiotic Relationship?*, 71 WASH. L.REV. 821, 836 (1996).

²⁹⁹Id. at 837.

³⁰⁰Id. at 837, citing PETER B. HUTT AND RICHARD A. MERILL, FOOD AND DRUG LAW 1240 (1991).

³⁰¹*Biotechnology in the Year 2000 and Beyond*, supra note 22 at 113.

³⁰²*Biotechnology in the Year 2000 and Beyond*, supra note 22 at 170. ("We have an interesting situation with revolving door policy at FDA. I mean, where is the ex-FDA commissioner? Guess who he is working for. He is working for Monsanto" statement by Robert Cohen of America's Dairy Education Board).

³⁰³Secretary Glickman argued, "we created a food safety agency separate and distinct from any and all marketing functions to ensure that no commercial interests have even the appearance of influence on our decisions regarding food safety. It needs to be the same with biotechnology. The scientists who evaluate and approve biotech products for the market must be free of any hint of influence from trade support and other non-regulatory areas within USDA." *Glickman Address*, supra note 251.

An additional factor that may lead to concerns about agency capture in the agricultural biotech context is the industry and FDA's expressed shared interest in quelling consumer concerns about the biotechnology. There is much evidence to suggest that the FDA's policy was designed, at least in part, to meet a shared objective with the biotech industry of gaining public acceptance of genetically engineered foods. In fact, in FDA's 1992 policy announcement acknowledged that it was in part a response to appeals from the food biotechnology industry which "expressed to FDA the need for strong but appropriate oversight by Federal agencies to ensure public confidence in foods produced by new techniques."³⁰⁴ Agricultural biotech companies actually have an incentive to gain the public perception that their foods are just as safe as traditionally derived foods, and the FDA "stamp of approval" is extremely valuable in that regard.³⁰⁵ In fact, FDA regulatory approval is seen as valuable in helping new biotech companies to "establish an image of safety and credibility."³⁰⁶

The biotech industry often points to FDA review as evidence that the foods are being regulated.³⁰⁷ Kessler indicated that the decision tree approach in the 1992 policy "was a critical part of the document, because the industry wants to have an agreed upon scientific basis for evaluating (and assuring the public about) the safety of these products."³⁰⁸ Similarly, the new mandatory premarket review process recently proposed by the FDA was actually applauded by the industry because it was hoped that such review would reassure customers that these products were being examined by regulatory agencies. Ironically, the requirement did not actually create any additional burdens of producers of genetically engineered products since those products were already routinely being submitted in the voluntary review process.³⁰⁹

³⁰⁴57 Fed. Reg. at 22984.

³⁰⁵Tanya E. Karwaki, Note and Comment, *The FDA and the Biotechnology Industry: A Symbiotic Relationship?*, 71 WASH. L.REV. 821, 836 (1996).

³⁰⁶Tanya E. Karwaki, Note and Comment, *The FDA and the Biotechnology Industry: A Symbiotic Relationship?*, 71 WASH. L.REV. 821, 836 (1996).

³⁰⁷Andrew Pollack, *F.D.A. Plans New Scrutiny in Areas of Biotechnology*, N.Y. TIMES, January 18, 2001, available at <<http://www.nytimes.com/2001/01/18/health/18REGS.html>>.

³⁰⁸*Id.*

³⁰⁹*Id.* *FDA plans New Scrutiny in Areas of Biotechnology*, (Jan. 18, 2001) available at <<http://www.nytimes.com/2001/01/18/health/18REGS.html>>.

Documents from the FDA suggest that its policies have been designed to help the industry garner public support for these foods, and provide the industry with assurances about the regulatory structure to be applied to those foods. An internal FDA memo noted that the 1992 biotech policy was motivated partly by an objective to “provide assurance to the public that foods derived from modern biotechnology processes... are being adequately regulated.”³¹⁰ Commissioner Kessler himself argued that it was “critical not only to provide [agricultural biotech companies] with a predictable guide to government oversight, but also to help them win public acceptance of these new products.”³¹¹ Kessler specifically noted the FDA’s “extensive contact with the food biotechnology industry, outside scientists, and other interested parties”³¹² in establishing the 1992 policy. He also noted that the policy “responds to White House interest in assuring the safe, speedy development of the U.S. biotechnology industry,”³¹³ acknowledging that political actors had influence over the development over FDA’s policy. Moreover, the memo indicates that the FDA was aware, even before publication of the policy that it was likely to cause protest from a collation of groups which had advocated “formal food additive premarket approval” for genetically engineered foods.³¹⁴

These documents demonstrate that the FDA was not motivated purely by a desire to seek scientific truth, but also by desires to accommodate the interest of both the biotech industry and the White House. In fact, the impetus for releasing the 1992 policy was explicitly political, not scientific. The policy was “designed to promote a profusion of new products and... spur investment in agricultural biotech stocks.”³¹⁵ In fact, the atmosphere surrounding the release of this new policy was plainly political, it “reflect[ed] ...election-year

³¹⁰“FDA Regulation of Food Products Derived From Genetically Altered Plants: Points to Consider” 1, *available at* <http://www.biointegrity.org/list.html>.

³¹¹Memorandum from David Kessler, Commissioner of Food & Drugs, Re: “FDA Proposed Statement of Policy Clarifying the Regulation of Food Derived from Genetically Modified Plants—DECISION” 1 (Mar.30, 1992), *available at* <http://www.biointegrity.org/list.html>.

³¹²*Id.* at 1.

³¹³*Id.* at 2.

³¹⁴*Id.* at 3.

³¹⁵Bruce Ingersoll, *Biotechnology: New Policy Eases Market Path for Bioengineered Foods*, WALL ST. J., May 26, 1992, *available at* 1992 WL-WSJ 651219.

efforts by the White House to provide all industry with as much regulatory relief as possible.”³¹⁶

In fact, FDA policy has generally followed industry preferences for regulation. The biotechnology industry is generally supportive of both mandatory FDA review,³¹⁷ and voluntary labeling,³¹⁸ and the industry also supports the FDA policy against mandatory labeling. Of course, this correlation between government policy and industry preferences does not prove that government policy has been crafted by agency lobbying, but it certainly does not help to dispel the specter of agency capture. This correlation between the industry’s regulatory preferences and the FDA’s actual regulatory system suggests that the relationship between agricultural biotechnology companies and the FDA is less adversarial than might otherwise be expected.

In fact, almost from the inception of the application of biotechnology to agriculture, the federal government’s statements about the industry have been overwhelmingly positive and pro-industry. White House press releases touting the “enormous promise of this technology”³¹⁹ sound almost as if they could have been written by Monsanto itself, making the claim that the government regulations are based solely on known and proven scientific risks and benefits questionable. After all, although scientists speculate that biotechnology has the potential to “feed the world,” this is hardly a known and proven benefit of biotechnology. Just as concerns about the risks of biotechnology have been characterized by the FDA as “expressions of concern about the unknown,”³²⁰ similarly, the touted benefits of biotechnology could fairly be characterized as “expressions of hope about the unknown.” Nevertheless, government agencies and actors consistently tout the enormous promise of bioengineered food. For instance, Secretary of Agriculture Dan Glickman, has promoted the potential for agricultural biotechnology to do everything from “combat[ing] hunger” to “solv[ing] the most vexing environmental problems”³²¹

³¹⁶*Id.*

³¹⁷*Biotechnology in the Year 2000 and Beyond*, *supra* note 22.

³¹⁸*Biotechnology in the Year 2000 and Beyond*, *supra* note 22.

³¹⁹Press Release, White House, Clinton Administration Agencies Announce Food and Agricultural Biotechnology Initiatives: Strengthening Science-Based Regulation and Consumer Access to Information (May 3, 2000), available at <<http://www.cfsan.fda.gov/~lrd/whbio53.html>>.

³²⁰66 Fed. Reg. at 4840

³²¹*Glickman Address*, *supra* note 251.

As early as 1984, when the industry was still in its infancy, the government had seemed to have made a decidedly political decision to promote biotechnology. In the 1984 Proposal for Coordinated Framework for Regulation of Biotechnology,³²² the government explicitly framed its regulatory stance towards biotechnology in terms of its desire to promote the growth and success of the industry. The proposal states, “[t]he tremendous potential of biotechnology to contribute to the nation’s economy in the near term, and to fulfill society’s needs and alleviate its problems in the longer term, makes it imperative that progress in biotechnology be encouraged.”³²³ The language of the eventual recommendations were similarly effusive, describing the technology’s potential “to bring considerable benefits to mankind.”³²⁴ Biotechnology was cleared framed as a technology which the government had an interest in developing. Moreover, the benefits of the technology were framed in terms of the competitiveness of the American industry: “[t]he United States is now the world leader in biotechnology. This leadership is derived from a strong scientific base, a vigorous entrepreneurial spirit and availability of venture capital.”³²⁵

The 1984 framework explicitly stated its desire to encourage minimal regulation in order to encourage development of the industry, stating that it was aiming towards developing a regulatory process that would “minimize the uncertainties and inefficiencies that can stifle innovation and impair the competitiveness of the U.S. industry.”³²⁶ Notably absent from this policy was any direct discussion of the interests and concerns of consumers. Nor do these early pronouncements on the regulation of biotechnology mention risks that might be posed by this extremely new technology. Although Commissioner Kessler indicated that the agency had consulted extensively with “the food biotechnology industry, outside scientists, and other interested parties,”³²⁷ it is not clear whether he had considered consumers to be an “interested party” for purposes of

³²²49 Fed. Reg. 50856-01, Dec 31, 1984.

³²³49 Fed. Reg. 50856, 50856.

³²⁴51 Fed. Reg. 23302, 23308.

³²⁵49 Fed. Reg. at 50856

³²⁶49 Fed. Reg. at 50857. The document also stated, “The Working Group recognizes that the manner in which regulations for biotechnology are implemented in the United States will have a direct impact on the competitiveness of US producers in both domestic and world markets and the future development of basic science.” 49 FR at 50857

³²⁷Memorandum from David Kessler, Commissioner of Food & Drugs, Re: “FDA Proposed Statement of Policy Clar-

crafting the 1992 policy. In fact, Pribyl noted that the draft document “read very pro-industry”³²⁸ and that it “contain[ed] very little input from consumers and only a few answers for their concerns.”³²⁹

Interestingly, it was in the context of this extremely optimistic view of the promise of biotechnology and the stated goal of fostering the development of the industry that the working group indicated that “regulatory decisions should be based upon the best available science.”³³⁰ Indeed, the working group statement specifically framed its goal of minimizing regulation as motivated in part by its desire to maintain the “competitiveness of U.S. producers in both domestic and world markets.”³³¹ This policy statement represents a notably departure from FDA’s previous statement that “the FDA has no proper role as a promoter of a specific food additive or food process.”³³²

While the statements of the Working Group cannot be attributed solely to the FDA, it is worth noting that the FDA first started considering the issues surrounding the regulation of biotechnology in the context of this governmental directive explicitly advocating the promotion of the biotech industry and a minimalist regulatory framework. Although the FDA had not set forth an extensive policy statement until 1992, as early as 1986 the agency had already stated that it “would regulate genetically engineering products no differently tha[n] [sic] those achieved through traditional techniques.”³³³ The Working Group established through the Coordinated Framework stated that “[t]he new products that will be brought to market will generally fit within these agencies’ review and approval regimes.”³³⁴ This decision to regulate bioengineered products under the existing regulatory framework was explicitly regarded in terms of the advantage that such a regulatory stance would have for the industry: “existing health and safety laws ha[ve] the advantage

ifying the Regulation of Food Derived from Genetically Modified Plants—DECISION” 1 (Mar.30, 1992), *available at* <http://www.biointegrity.org/list.html>.

³²⁸Comments from Dr. Louis J. Pribyl, Re: “Biotechnology Draft Document, 2/27/92” 1 (Mar. 6, 1992), *available at* <http://www.biointegrity.org/list.html>.

³²⁹*Id.*

³³⁰49 Fed. Reg. at 50857.

³³¹49 Fed.Reg. at 50857.

³³²51 Fed. Reg. at 13394.

³³³51 Fed. Reg. 23302 at 23303.

³³⁴51 Fed. Reg. at 23304.

that they could provide more immediate regulatory *protection and certainty for the industry* than possible with the implementation of new legislation.” [italics added]³³⁵

Thus, even as early as the mid-1980s, the government had wholeheartedly embraced biotechnology and the biotech industry, and made a commitment to the industry’s growth and prosperity. Although these early government directives did indicate that safety regulation should be based on “science,” it did so clearly in a context of promotion of the industry rather than a thoughtful exploration of the possible risks and benefits of the technology. Those risks and benefits had simply not been scientifically established at that early date; in fact those risks and benefits are still far from certain. Moreover, although these documents indicated government and industry desires to promote or ensure success of genetically engineered foods in the marketplace, they did not acknowledge that the regulatory framework they set out would do little to inform consumers that they were even purchasing these foods.

Given this contextual framework for the FDA’s policy towards agricultural biotechnology, the FDA’s argument that its biotechnology policies are grounded solely on “science” while opponents of its policies are motivated purely by politics or ideology is not convincing. These early policy statements and internal documents provide strong evidence that FDA’s regulatory decisions were heavily influenced by political and economic pressures to foster the development of the biotechnology industry. Of course, only committed idealists would believe that government agencies are motivated solely by non-political considerations. Nevertheless, the FDA’s steadfast refusal to acknowledge that it’s biotech policy was motivated by anything other than sound science and its accusations that its opponents are guided by ideology ring especially disingenuous in light of this evidence. Moreover, this disconnect between the FDA’s public statements and its private internal memoranda ultimately only serve to undermine the agency’s credibility, and foster conspiracy-type theories of agency capture.

³³⁵51 Fed. Reg. at 23303.

D. *Segregation answers:*

Finally, although it is true that the system of segregation of GM crops from traditionally derived crops will probably be an inevitable outgrowth of a labeling system, such a system for segregation of various genetically engineered products probably should develop even in the absence of mandatory labeling. The recent controversy over StarLink demonstrates the extent to which genetic engineering techniques, even in the absence of labeling, necessitates a more sophisticated food handling system than the traditional model. The StarLink issue first came to light last year when Starlink, a genetically engineered corn strain not approved for human consumption due to concerns about allergenicity,³³⁶ was nevertheless found in foods in grocery stores. The controversy eventually led to a nationwide recall of more than 300 varieties of foods, including corn chips and taco shells.³³⁷ Despite that dramatic controversy, recent tests have confirmed that the genetically modified strain is still being found in seeds intended for sale.³³⁸ The continuing problems would seem to suggest that current food handling mechanisms are simply inadequate: “Agricultural officials said today that although it was unclear how the seed became tainted, many suspected cross pollination. Keeping StarLink segregated—field to factory to consumer—from corn that is meant for human consumption has proved difficult.”³³⁹ Moreover, these difficulties in ensuring that the separating genetically engineered foods may make it difficult for U.S. food producers to export internationally.³⁴⁰ Thus, even without a mandatory labeling system, the current system is not even protecting consumers from foods that have not been approved for use as human food. Regardless of changes FDA labeling policy, the food handling system needs to be adapted in order to avoid such contamination of the food supply.

³³⁶Elizabeth Becker, *New Worries of Planting Altered Corn*, N.Y. TIMES, March 2, 2001, available at <http://www.nytimes.com/2001/03/02/business/02CORN.html>

³³⁷*Id.*

³³⁸*Id.*

³³⁹Elizabeth Becker, *New Worries of Planting Altered Corn*, N.Y. TIMES, March 2, 2001, available at <http://www.nytimes.com/2001/03/02/business/02CORN.html>

³⁴⁰The Agriculture Dept has recently tightened testing requirements for corn exported to Japan in order to ensure that the corn does not include strains of StarLink corn in response to the discovery of StarLink in corn that had tested negative for the presence of StarLink before shipment from the United States. Associated Press, *U.S. Tightens Testing Rules for Japan-Bound Corn*, N.Y. TIMES, Feb. 23, 2001, available at <http://www.nytimes.com/2001/02/23/health/23ap-biotech.html>.

European mandatory labeling requirements may force segregation of genetically engineered crops grown in the United States. In fact, Deutch bank has predicted the emergence of a “a two tier market system ...with non-GM organisms the more desirable, and thus more valuable, commodity. Indeed, one of the largest traders in corn and soybeans, Archer Daniels Midland (ADM) in Decatur, Illinois, started offering farmers a premium of 18 cents per bushel for non-GM soybeans this spring.”³⁴¹ Thus, the market, perhaps prodded by European regulations, may force the farmers to segregate crops, regardless of whether or not the FDA imposes mandatory labeling requirement. Moreover, agricultural biotechnology firms may also voluntarily segregate their products from other products for marketing purposes, particularly producers of non-grain foods. For example, the Flavr Savr tomato was kept apart from traditional varieties for marketing purposes.³⁴² As the demand for segregation has increased, technology has been developed to test foods for contamination by genetically modified varieties. Scientists have developed extremely sensitive tests to screen both soy and corn for traces of genetically engineered products.³⁴³ Just as the testing technology has evolved to accommodate the demand for labeling overseas, the food commodity system may likewise naturally evolve in order to accommodate these concerns.

In addition, although the segregation and testing of foods will increase the costs of food production, those costs will probably be born by middlemen rather than by consumers.³⁴⁴ At least one genetically engineered food producer, Unilever, [has] expressed a willingness to absorb that short term loss in order to convince consumers of the desirability of their products.”³⁴⁵ Of course, producers unwilling to undergo segregation

³⁴¹Martin Enserink, *Industry Response: Ag Biotech Moves to Mollify Its Critics*, 286 SCIENCE 1666 (Nov. 26, 1999), available at <<http://www.sciencemag.org>>.

³⁴²Lara Beth Winn, *Special Labeling Requirements for Genetically Engineered Food: How Sound are the Analytical Frameworks Used by FDA and Food Producers*, 54 FOOD & DRUG L.J. 667, 685 (1999).

³⁴³Philip R. Reilly, *Public Concern About Genetics*, 1 ANN. REV. GENOMICS & HUMAN GENETICS 485, 500 (2000).

³⁴⁴*Food for Thought*, ECONOMIST, June 17, 1999, available at <<http://www.economist.com>>.

³⁴⁵*Food for Thought*, ECONOMIST, June 17, 1999, available at <<http://www.economist.com>>.

could simply label their products with the label “may contain genetically modified ingredients.” Of course, these are complicated business judgments that will be difficult to make, but the fact that regulation may require food producers to make difficult business decisions is not sufficient justification for abandoning regulation altogether. Ultimately, protecting producers from the whims of consumer preferences is simply not a legitimate basis for sidestepping regulation.

V. Anticipated Public Reaction to Biotechnology Risks.

Although the government has not explicitly made this argument, the opposition to mandatory labeling seems to be motivated by a desire to prevent consumer panic when regarding labels on genetically engineered foods. The FDA does not explicitly state this reasoning in explaining its labeling stance; nevertheless, there are several reasons to believe that the FDA may be motivated by this desire to avoid customer overreaction or confusion. First, the FDA’s own statements indicate the desire to ensure consumer acceptance of genetically modified foods, and the success of the agricultural biotechnology industry in the United States. To the extent that labeling might pose an obstacle to that success, mandatory labeling might be generally disfavored. Second, the FDA’s recent change of course in the irradiation labeling context indicates the extent to which the FDA has recently been sensitized to concerns about the potential for consumer overreaction to labeling. Third, there is solid evidence indicating that agricultural biotechnology raises the possibility of precisely the kinds of risks to which consumers are most sensitive. This sensitivity to consumer reaction may be the main concern driving the FDA reticence towards adopting a labeling policy. In the recent public forum on labeling of genetically engineered foods, L. Robert Lake, the agency’s Director of Regulations and Policy cautioned that “it is possible to put truthful information on a label in a way that causes consumers to draw a conclusion that is false...it is a constant challenge to the Food and Drug Administration in our enforcement activities

to try to assure that labeling statements, as they are commonly understood, will not mislead consumers.”³⁴⁶ This statement demonstrates a particular FDA concern about how customers will interpret labeling.³⁴⁷ This argument also implicitly acknowledges that “science” and scientific data is not the sole factor determining FDA’s labeling policy.

Most American agricultural biotechnology supporters oppose labeling precisely because of their fear of how consumers would react to such labeling. For the biotech industry, the greatest fear is that any labeling would be “interpreted by consumers as a skull and crossbones.”³⁴⁸ Even if consumers do not respond that dramatically, biotech producers are acutely aware that labeling may “increase public anxiety”³⁴⁹ about the technology being applied to their foods.

In fact, research on public risk perception confirms that consumers are especially likely to overestimate the particular types of risks that agricultural biotechnology raises. For instance, public risk perception is often subject to an alarmist bias whereby people are more likely to remember and react to distressing information than to reassuring information.³⁵⁰ Under the alarmist bias, “the worst possible scenarios loom large in people’s minds, distorting their risk perceptions and behaviors.”³⁵¹ This alarmist bias is likely to interact with the availability heuristic, whereby the “perceived likelihood of any given event is tied to the ease with which its occurrence can be brought to mind.”³⁵² In fact, “[c]ognitive psychologists consider the availability heuristic to be a key determinant of individual judgment and perception. They have demonstrated the

³⁴⁶ *Biotechnology in the Year 2000 and Beyond*, *supra* note 22 at 136.

³⁴⁷ Mr. Lake demonstrated a similar interest in customer interpretation of labeling statements in stating, “voluntary labeling raises the challenge of what is the message that the label is intended to convey to customers; also raises the question of what the consumer’s interpretation of the words on the label are going to be” *Biotechnology in the Year 2000 and Beyond*, *supra* note 22 at 136.

³⁴⁸ Andrew Pollack, *FDA Plans New Scrutiny in Area of Biotechnology*, N.Y. TIMES, Jan. 18, 2001, available at <http://www.nytimes.com/2001/01/18/health/18REGS.html>.

³⁴⁹ Henry I. Miller, *A Rational Approach to Labeling Biotech-Derived Foods*, 284 SCIENCE 1471 (May 28, 1999), available at <http://www.sciencemag.org>.

³⁵⁰ Cass R. Sunstein, *Informational Regulation and Informational Standing: Akins and Beyond*, 147 U. PENN. L. REV. 613, 627 (1999). (“frightening information is more salient and potent than comforting information, regardless of what is true”)

³⁵¹ Tim Kuran & Cass R. Sunstein, *Availability Cascades and Risk Regulation*, 51 Stan. L. Rev 683, at 706 (1999)

³⁵² Tim Kuran & Cass R. Sunstein, *Availability Cascades and Risk Regulation*, 51 Stan. L. Rev 683, at 685 (1999)

probability assessments we make as individuals are frequently based on the ease with which we can think of relevant examples.”³⁵³ Thus, not only are people likely to remember alarming information, but they are also more likely to believe such alarming scenarios to be more probable than they actually are. The more that these disastrous scenarios enter into the public discourse, people are even more likely to overestimate the likelihood of such scenarios.³⁵⁴

Given the fact that people are much more likely to believe and act on the alarming information about the risks of agricultural biotechnology rather than the potential benefits of such technology, the industry necessarily has an interest in keeping the public discourse about the technology to a minimum. Consumers are likely to find alarming information about the risks of biotechnology more salient and believable than reassuring information about the benefits. Moreover, the risks of biotechnology have generally been portrayed in the media in particularly salient ways—with headline grabbing phrases describing genetically engineered products “frankenfoods.”³⁵⁵ This type of information is especially difficult for the biotech industry to counteract with statistical information about the safety of biotech food because “vivid and personal information will often be more effective than statistical evidence. . . people will tend to respond to it by attaching a higher probability to the event in question.”³⁵⁶ Moreover, discourse that effectively links the risks of biotech foods to other well-recognized risks or disasters are likely to be especially effective in alarming consumers about risks.³⁵⁷ The more vivid the analogy, the more likely readers are to overestimate the risk of the underlying

³⁵³Tim Kuran & Cass R. Sunstein, *Availability Cascades and Risk Regulation*, 51 Stan. L. Rev 683, at 685 (1999), citing Amos Tversky and Daniel Kahneman, *Judgment under Uncertainty: Heuristics and Bias* in JUDGMENT UNDER UNCERTAINTY: HEURISTICS AND BIASES 3, 11 (Daniel Kahneman, Paul Slovic & Amos Tversky eds., 1982).

³⁵⁴Tim Kuran & Cass R. Sunstein, *Availability Cascades and Risk Regulation*, 51 Stan. L. Rev 683, at 285 (1999) (describing the availability cascade whereby “expressed perceptions trigger chains of individual responses that make these perceptions appear increasingly plausible through their rising availability in public discourse”). This hypothesis was confirmed by a recent study of public perception of agricultural biotechnology in Europe and the United States. The study found that negative public perceptions of genetically engineered foods correlated with the amount of press coverage, not the nature of the coverage. Gaskell et. al., *Worlds Apart: The Reception of Genetically Modified Foods in Europe and the U.S.* (5/7). Thus, although the study found the coverage in the European press to be generally more favorable than the coverage in the U.S., Europeans were still generally more wary of genetically engineered foods than their American counterparts.

³⁵⁵See, e.g., Matthew Franken, *Fear of Frankenfoods: A Better Labeling Standard for Genetically Modified Foods*, 1 MINN. INTELL. PROP. REV. 153 (2000)

³⁵⁶Christine Jolls et al., *A Behavioral Approach to Law and Economics*, 50 STAN. L. REV. 1471, 1537 (1998).

³⁵⁷Kuran and Sunstein describe the “anchoring effect” whereby “[p]eople who heard Love Canal characterized as a disaster

activity.³⁵⁸

Moreover, the public is likely to be especially sensitive to the particular types of risks raised by agricultural biotechnology. For instance, one commonly recognized factor affecting risk perception is the controllability effect whereby a risk is discounted to the extent that an individual believes that he or she has the ability to control that risk.³⁵⁹ The classic illustration of this effect is the fact that people are generally much more concerned about the risks associated with flying with the risks associated with driving because of their belief that they have more control the risks attendant with driving.³⁶⁰ At least part of the concern driving the push for mandatory labeling is this desire to have information as a way to control risk exposure. Consumers may be especially worried about the use of agricultural biotechnology in a world without labeling because they have no control over their exposure to this relatively new agricultural technique. This lack of control over exposure to a particular risk probably heightens any reservations they might otherwise have about the technology. Ironically, this heightened concern has probably not been exhibited thus far precisely because consumers are not aware of the extent to which biotech foods have entered the food stream.

Public tolerance of a particularly risk is often affected not only by the public's perception of the likelihood of a particular risk, but also by the particular characteristics of that risk. For instance, the public is particularly sensitive to risks that are "potentially catastrophic, likely to affect future generations, inequitably

akin to the Vietnam War, or as an official act of mass murder, tended to consider the risk more serious than dispassionate analysis of the scientific data would suggest. In other words, they underdiscounted the analogy, thus becoming overly alarmed by the revealed evidence." Tim Kuran & Cass R. Sunstein, *Availability Cascades and Risk Regulation*, 51 STAN. L. REV. 683, at 732 (1999)

³⁵⁸In fact, Kuran and Sunstein describe how "availability entrepreneurs" may emerge among "[s]ocial agents who understand the dynamics of availability cascades and seek to exploit their insights may be characterized as availability entrepreneurs. Located anywhere in the social system, including the government, the media, nonprofit organizations, the business sector, and even households, these entrepreneurs attempt to trigger availability cascades likely to advance their own agendas. They do so by fixing people's attention on specific problems, interpreting phenomena in particular ways, and attempting to raise the salience of certain information." Kuran and Sunstein at 687. "[E]ven when cognitive deception is involved availability cascades may serve a socially beneficial purpose. Indeed, the entrepreneurs who set them in motion may well be exploiting heuristic devices as a response to private ignorance and public apathy." Tim Kuran & Cass R. Sunstein, *Availability Cascades and Risk Regulation*, 51 STAN. L. REV. 683, at 735 (1999).

³⁵⁹*Id.* at 708.

³⁶⁰*Id.* at 708.

distributed, or involuntarily incurred,”³⁶¹ and less concerned about risks with “natural origins or unidentifiable victims.”³⁶² Kuran and Sunstein have identified risk characteristics that are likely to affect the public’s willingness to accept a particular risk. Interestingly, of the fifteen factors they identified as damaging the public’s willingness to accept a particular risk, eleven arguably apply in the agricultural biotechnology context. Among these applicable aggravating risk factors are “new/relatively unfamiliar risk, inability to control the risk personally, involuntariness in exposure, heavy media coverage, evenly distributed risk; children at special risk; future generations at risk; possibility of irreversible risks; risk derived from human generated source; low trust in institutions; and the underlying mechanisms of the source of the risk are poorly understood.”³⁶³

It is striking that so many of these aggravating factors characterize agricultural biotechnology. The technology clearly represents a new development in the food supply; consumers are not currently able to regulate when and how they are exposed to foods containing genetically engineered ingredients; there has been pretty heavy media coverage of biotechnology generally; the effects of this technology are pretty evenly distributed because food affects everyone; children may be put at special risk; the environmental effects may affect future generations; doomsayers predict irreversible damages; the technology clearly comes from a human derived source; the public has exhibited decreasing trust in government agencies generally; and people generally do not understand all of the technology driving genetically engineered foods.

The negative impact of these factors on the public’s willingness to accept a risk makes intuitive sense. For instance, consider the familiarity factor. It makes intuitive sense that accidents that occur with respect to unfamiliar technology, such as nuclear power, are likely to produce much more widespread social unease than accidents that occur with respect to a familiar technology, such as car or train accidents, because accidents in these new technologies are much more likely to be “perceived as a harbinger of future and possible catas-

³⁶¹Tim Kuran & Cass R. Sunstein, *Availability Cascades and Risk Regulation*, 51 STAN. L. REV. 683, 709 (1999)

³⁶²*Id.* at 709.

³⁶³*Id.* at 709.

trophic mishaps.”³⁶⁴

In addition, the public has exhibited a willingness to “tolerate higher risks from activities seen as highly beneficial” suggesting that the public undergoes an informal type of risk benefit analysis when deciding the acceptability of a particular risk.³⁶⁵ However, this factor that does no benefit the agricultural biotechnology industry since the major benefits from their products accrue to farmers rather than to consumers.

Finally, the public is generally risk (loss) averse.³⁶⁶ That is, people tend to weigh losses more heavily than gains. Accordingly, the public tends to “evaluate outcomes based on the change they represent from an initial reference point, rather than based on the nature of the outcome itself; also, losses from the initial reference point are weighted much more heavily than gains.”³⁶⁷ Moreover, “a perceived threat of a loss relative to the status quo weighs more heavily than a perceived threat of foregoing a gain.”³⁶⁸ In the context of genetically engineered foods, consumers are likely to weigh the benefits of the technology against the benefits of the agricultural products they are currently familiar with. This risk benefit analysis will weigh even more heavily against genetically engineered foods because consumers do not derive any direct benefit the genetically engineered products currently on the market. Moreover, all other things being equal, they are likely to favor the status quo, even at the potential cost of foregoing benefits of biotechnology rather than take a perceived risk. Accordingly, consumers are likely to be more concerned about the possible risks of biotechnology than they are to be concerned about the possibility of foregoing the benefits that might be brought about from the use of agricultural biotechnology. This consumer conservatism about food in particular is confirmed in the rhetoric that suggests that food is a special commodity that consumers have a particular relationship with food.³⁶⁹

³⁶⁴Paul Slovic, *Perception of Risk*, 236 SCIENCE 280, 284 (Apr. 17, 1987).

³⁶⁵*Id.* at 283.

³⁶⁶Christine Jolls et al., *A Behavioral Approach to Law and Economics*, 50 STAN. L. REV. 1471, 1484 (1998).

³⁶⁷*Id.* at 1535.

³⁶⁸*Id.* at 1536.

³⁶⁹Note *supra* p.2

Given these basic cognitive biases in the perception of risk, it is not surprising that the biotechnology industry is not eager to start a full flung debate on the merits of biotechnology. These studies strongly suggest that consumers are likely to be particularly wary of agricultural biotechnology and to be particularly concerned about the particular kinds of risk that the technology can pose. This basic conservatism is reflected in the available consumer data. Moreover, the data also indicates that it is extremely difficult to change people's initial risk perceptions once they are formed. People are likely to view evidence that contradicts their beliefs as untrustworthy.³⁷⁰ Thus, the biotechnology industry, and an FDA that strongly believes that the risks of biotechnology strongly outweigh its benefits, will inevitably have a hard time convincing the consuming public of the safety of these foods if the public is already predisposed to view such foods as potentially hazardous.

Given this data, the FDA may worry that mandatory labeling would be unwarranted, and even harmful in this case. It may worry about the fact that in most contexts mandatory labels are associated with products posing potential hazards or health risks (i.e. cigarette labeling), not safe products.³⁷¹ Thus, arguably, a non-mandatory labeling policy helps to avoid consumer confusion and unwarranted apprehension about foods containing genetically modified food ingredients.³⁷² The FDA's irradiation policy modification proposal indicates the extent to which the FDA seems to be concerned about the possibility that informational labeling might be interpreted by consumers as warning labels. For instance, the FDA's specifically requested comments on how the radiation label is publicly perceived ("as informational, as a warning, or as something else"?), and on whether the current label elicits "inappropriate anxiety."³⁷³

³⁷⁰Paul Slovic, *Perception of Risk*, 236 SCIENCE 280, 281 (Apr. 17, 1987). ("New evidence appears reliable and informative if it is consistent with one's initial beliefs; contrary evidence tends to be dismissed as unreliable, erroneous, or unrepresentative. When people lack strong prior opinions, the opposite situation exists—they are at the mercy of the problem formation. Presenting the same information about risk in different ways (for example, mortality rates as opposed to survival rates) alters people's perceptions and actions")

³⁷¹Matthew Franken, Comment, *Fear of Frankenfoods: A Better Labeling Standard for Genetically Modified Foods*, 1 MINN. INTELL. PROP. REV. 153, 170 (2000).

³⁷²*Id.* at 170.

³⁷³64 Fed. Reg. at 7837

B. It is hard to provide information without giving a judgment.

One of the fundamental problems animating this debate is that proponents of labeling portray a biotechnology label as simply informational, whereas biotech proponents generally indicate that such a label would inevitably be viewed as a warning label. Unfortunately, no label is purely informational. The FDA is probably concerned that any label will be interpreted as by consumers as a signal that agricultural biotechnology is a process that consumers should be aware of, in the same way that requiring food producers to print information about fat and nutrient content on labeling is a subtle signal that consumers should be aware of information about fat and nutrients.

Labels, even though primarily meant to be informational and to give consumers the opportunity to make independent choices, can never present information in a purely neutral way.³⁷⁴ In fact, the one legal commentator has stated that “in the real world, she who provides information ends up giving advice.”³⁷⁵ It is plausible that the FDA is concerned that a mandatory label would signal to consumers that the FDA is advising an increased level of precaution with respect to genetically engineered foods. Although labeling is seemingly a simple solution to the problem of consumer ignorance, communication about this or any other complex risk issue “necessitates walking a fine line separating facilitation and manipulation.”³⁷⁶ While there is a legitimate interest in facilitating consumer choice, the government should be wary of taking regulatory steps that may subtly influence or shape the choices that consumers make.³⁷⁷ Any law mandating disclosure necessarily confronts “a general tension in regulatory policy between consumer sovereignty and consumer protection.”³⁷⁸ Given this framework, it is not surprising that the FDA, viewing its mission as primarily one of consumer protection,³⁷⁹ would consider the “consumer sovereignty” issue as secondary in this context.

³⁷⁴Jolls et al, *supra* note 366 at 1534. (“there is often no ‘neutral’ way to present information”)

³⁷⁵Jolls, et al., *supra* note 366 at 1435.

³⁷⁶Sage, *supra* note 112 at 1730.

³⁷⁷Sage, *supra* note 112 at 1730.

³⁷⁸Sage, *supra* note 112 at 1821.

³⁷⁹Food and Drug Administration, *The Story of the Laws Behind the Labels*, FDA CONSUMER, June 1981, available at <<<http://www.vm.cfsan.fda.gov/~lrd/histor1b.html>>>.

Nevertheless, despite FDA's legitimate concerns about how a label might be perceived by the public, countervailing considerations should take precedence over these concerns. First, consumers may be much less likely to "overreact" to this labeling information in a food context than other products. After all, consumers are accustomed to all kinds of mandatory labeling on their food, and the information required on the label is generally not information that would be construed as warning statement. In such a context where consumers are accustomed to multiple labeling requirements,³⁸⁰ consumers may not inevitably perceive all new information on the label as an indicator of a hazard or danger. If genetic engineering labeling actually did cause consumer anxiety, it is arguably just as likely that consumer anxiety is triggered by knowledge of the presence of the genetically engineered ingredients, rather than by the fact that those ingredients are labeled.

C. Our current method of risk analysis is flawed:

The heart of the consumer overreaction argument is that the public is likely perceive the risk of this technology to be much higher than the scientists. However, the research literature indicates that even the scientists are not really sure of the extent of the risks of biotechnology. A recent article published in Science magazine by L.L. Wolfenbarger and P.R. Phifer noted that "key experiments on both the environmental risks and benefits are lacking."³⁸¹ Thus, consumer expression of concern about the presence of genetically engineered products in their food should not be automatically dismissed as "overreaction" since scientists themselves have not determined the extent of the risk posed by these products.

1.

³⁸⁰Including labeling about whether the potatoes in their potato chips were dehydrated before processing. See 208 Fed. Reg at 13388.

³⁸¹L.L. Wolfenbarger & P.R. Phifer, *The Ecological Risks and Benefits of Genetically Engineered Plants*, 290 SCIENCE 2088, 2088 (Dec. 15, 2000).

*Pro biotech arguments tend to engage in an inconsistent type of risk
benefit analysis.*

Although the evidence suggests that consumers are likely to be much more concerned about the risks posed by agricultural biotechnology than scientists, arguably the risk-benefit analysis as presented by biotechnology proponents is also systematically skewed. For instance, proponents often argue that risks of agricultural biotechnology are far outweighed by the potential for the technology to save the environment, feed the hungry, and help people to stave off dangerous diseases.³⁸² However, even those genetically engineered foods touted for their “humanitarian” benefits may have been over-promoted by the biotechnology industry. For instance, Golden Rice, a genetically modified rice altered to contain increased amounts of vitamin A has been promoted as a solution to blindness and other illnesses related to vitamin A deficiency.³⁸³ Nevertheless, scientists have recently pointed out that “the widely vaunted health benefits of the rice are likely to elude the poorest people who eat it,”³⁸⁴ because the enhanced levels of vitamin A will be of no nutritional benefit to people whose diets do not contain sufficient levels of fats necessary for their bodies to absorb the vitamin.³⁸⁵ Even more problematic are arguments that seem to be promoting the potential benefits of the most appealing types of genetic modifications (i.e. the Golden Rice variety) in order to advance the acceptance of other, unrelated genetically engineered foods. Thus, the potential of genetically engineered foods designed prevent blindness have been advanced in order to advocate the acceptance of genetically modified organisms with much less demonstrably humanitarian benefits—in fact, very few benefits for consumers at all.³⁸⁶ This type of argument is demonstrated by Clive James, Chairman of ISAAA, a not-for-profit agency [created to alleviate hunger in the Third World by facilitating the transfer of crop biotech applications] at Cornell who

³⁸² *Glickman Address, supra* note ??.

³⁸³ *Critics claim ‘Sight Saving’ Rice is Over-rated*, 410 NATURE 503 (2001)

³⁸⁴ *Critics claim ‘Sight Saving’ Rice is Over-rated*, 410 NATURE 503 (2001).

³⁸⁵ *Id.*

³⁸⁶ *Who’s Afraid?*, ECONOMIST, June 17, 1999, available at <<http://www.economist.com>>. (“companies still pitch their products as a cure for malnutrition, even though little that they are doing can justify such a noble claim.”)

has stated,

The most compelling [argument] for biotechnology is its potential contribution to global food security and the alleviation of hunger in the third world...It is important that the U.S. maintain [their] commitment to GM crops. In the absence of continued U.S. leadership, developing countries would be denied the opportunity to source U.S. technologies in their quest for food security and condemn up to a billion people in the Third World to unnecessary and unacceptable suffering from malnutrition, hunger and poverty.³⁸⁷

In response to such arguments, biotech critics charge that the biotech producers are “using the poor to justify selling their products to the rich”³⁸⁸ and point out that “the industry concentrates on crops like herbicide-resistant soybeans for farmers in the Midwest, not drought tolerant millet for subsistence farmers in Africa.”³⁸⁹

Of course, this form of argument is inconsistent with another of the biotech food industry’s fundamental claims. If genetically engineered foods really are not fundamentally different from their conventional counterparts, then the risks and benefits of each individual food product must be weighed individually. Thus, the consumer risks of Bt corn should be weighed solely against the consumer benefits of Bt corn. Of course, any unknown risk of an individual food product would be extremely hard to outweigh against the prospect of “feeding the world” as it has been speculated that bioengineering technology is capable of. But no one has argued that Bt corn holds the key to solving world hunger. Just as any other traditionally developed food product, bioengineered foods should stand or fall on their own merits. For instance, we would never argue that non-genetically modified apples that pose potential health environmental risks should be allowed on the market based on the health benefits of oranges or other non-genetically modified products. Each product should be evaluated separately for purposes of risk-benefit analysis.³⁹⁰ Wolfenbarger and Phifer noted that

³⁸⁸Andrew Pollack, *Critics of Biotechnology are Called Imperialists*, N.Y. TIMES, Feb. 4, 2001, available at <<http://www.nytimes.com/2001/02/04/weekinreview/04POLL.html>>.

³⁸⁹*Id.*

³⁹⁰The EU-U.S. Biotechnology Consultative Forum, Final Report, December 2000, 11, available at

“[n]either the risks nor the benefits of GEOs are certain or universal. Both may vary spatially and on a case-by-case basis.”³⁹¹ Accordingly, it is only appropriate to weigh the benefits of any particular genetically engineered crop against the risks of that same crop, at least to the extent that these factors are known.

In addition, the risk benefit analysis should also compare of the relative risks and benefits of foods produced through genetic engineering techniques with similar foods produced through conventional and organic farming techniques.³⁹² Thus, the risks and benefits of Bt corn should be compared with the risks and benefits of conventionally derived corn, and organically grown corn.

2.

Scientists and lay people have different conceptions of risk.

All differences in risk perception between lay consumers and scientists should not necessarily be interpreted as evidence that consumers are not rational enough to handle risk information. Much of the current debate over risk perception often portrays scientists’ risk perception as “objective, analytic, wise and rational—based on *real risks*,” [emphasis in original]³⁹³ whereas the risk perception of the lay public is depicted as “subjective, often hypothetical, emotional, foolish and irrational.”³⁹⁴ Thus, arguments against labeling often hinge on an assumption that the public cannot rationally assess the risks of genetically engineered foods, and argue that labeling would actually be “counterproductive” by raising unnecessary consumer fears.³⁹⁵

<http://europa.eu.int/comm/external_relations/us/biotech/report.pdf>. [hereinafter *Final Report*] (“We recommend that once the basic threshold of human safety has been met it is also appropriate to consider, on a case-by-case basis, the potential risks and benefits of each new product given the health and nutritional status of the people and the ecological and agricultural systems in a particular region of use.”) Of course, risk-benefit calculations are not appropriate in any case until “the basic threshold of reasonable certainty of no harm to human health has been reached.” *Id.*

³⁹¹ Wolfenbarger & Phifer, *supra* note 381 at 2092.

³⁹² Wolfenbarger & Phifer *supra* note 381 at p 2092.

³⁹³ Paul Slovic, *Trust, Emotion, Sex, Politics, and Science: Surveying the Risk Assessment Battlefield*, 1997 U. CHI. LEGAL. F. 59, 60 (1997) [hereinafter *Trust, Emotion, Sex, Politics*].

³⁹⁴ *Trust, Emotion, Sex, Politics*, *supra* note 393, at 60.

³⁹⁵ Miller, *supra* note 147.

However, given the fact that both scientists and the lay public are making risk predictions where there is very little actual data about those risks,³⁹⁶ it is not altogether clear that one assessment is more rational than another.

Rather, scientists and the public simply think about the risk in general, and the risks of agricultural biotechnology in particular, in radically different ways. For instance, Dr. Steven Kresovich, a plant breeder at Cornell, in attempting to counter public concern about the perceived potential hazards of agricultural biotechnology argued that “[g]enes should be characterized by function, not origin. It’s not a flounder gene but a cold tolerance gene that was introduced into strawberries [through agricultural biotechnology].”³⁹⁷ Nevertheless, although the scientists may think of this gene as simply a “cold tolerance gene,” the lay public is much more likely to think of the gene as a “flounder gene”—raising public concerns about breaching the order of nature.³⁹⁸ Although the scientist clearly thinks that the gene is more accurately characterized as a “cold tolerance gene” than as a flounder gene, both views are actually accurate. They simply illustrate two different ways of looking at the same problem, with neither view demonstrably more true or accurate than the other than the other. Although the gene genuinely does serve a particular function in an organism—allowing the plant to withstand cold—it is equally undeniable that the gene originally came from flounder. These different perspectives on the same facts can occur even within the scientific community. Monsanto and other agriculture biotech companies are likely to see themselves as the Microsoft of the new agriculture—with the process of biotechnology analogized to programming computers.³⁹⁹ However, other scientists are likely to see plants not as computers but as tiny complex, not fully understood, ecosystems, not as computer programs whose manipulations offer predictable, stable results.⁴⁰⁰ The important point is that both of these analogies

³⁹⁶Wolfenbarger & Phifer, *supra* note 381.

³⁹⁷Jane E. Brody, *Gene Altered Foods: A Case Against Panic*, N.Y. TIMES, December 5, 2000, available at <<http://www.nytimes.com/2001/12/05/science/05BR0D.html?printpage=yes>>

³⁹⁸Prince Charles in England has written a column arguing that biotechnology “takes mankind into realms that belong to God and to God alone.” *Playing God in the Garden*, *supra* note 3.

³⁹⁹*Playing God in the Garden*, *supra* note 3.

⁴⁰⁰*Playing God in the Garden*, *supra* note 3. In responding to Monsanto’s software metaphor, Richard Lewontin, a geneticist

offer descriptive power, but neither analogy has a lock on the truth.

The concept of risk itself is hardly neutral.⁴⁰¹ Any risk assessment is likely to reflect the values of the assessor, and scientists and the public often start with different belief systems and world-views.⁴⁰² Scientists and risk experts tend to judge risk according to a single dimension—technical, statistical data regarding human fatalities.⁴⁰³ The public, on the other hand, is more likely to judge risk according to the qualities of the risk posed, for instance, possible impacts of a risk, whether the risk might impact future generations, etc. Interestingly, the public can often somewhat accurately estimate the kinds of annual fatalities statistics that scientists generally rely on for their risk assessments; but nevertheless, the public systematically prefer certain kinds of risks over others, regardless of the annual fatalities statistics.⁴⁰⁴ These findings suggest that the public simply prefers certain kinds of risks over others, regardless of their probabilities. Moreover, any strict dichotomy between science and ideology is a false one. Any individual’s position on the issues raised by biotechnology are likely to be influenced by both scientific evidence, *and* their political beliefs. In fact, one’s view towards scientific evidence is likely to be influenced by one’s ideological framework.

The risk assessments of scientists are likewise influenced by a myriad of subjective factors.⁴⁰⁵ Although scientists undoubtedly strive to minimize the influence of subjective factors on their results, such factors occasionally creep into their ultimate risk assessments. Scientists’ risk assessments are most likely to be in-

at Harvard argued that the analogy was not particularly descriptive of the actual biotechnological process itself. He argued that the analogy is not accurate because “[i]t implies you feed a program into a machine and get predictable results. But the genome is very noisy. If my computer made as many mistakes as an organism does”—in interpreting its DNA, he meant—“I’d throw it out”’ *Id.* In offering the ecosystem metaphor, he explained that “You can always intervene and change something in it [a plant’s genetic makeup], but there’s no way of knowing what all the downstream effects will be or how it might affect the environment. We have such a miserably poor understanding of how the organism develops from its DNA that I would be surprised if we don’t get one rude shock after another.”’ *Id.*

⁴⁰¹Paul Slovic, *Perception of Risk*, 236 SCIENCE 280, 283 (Apr. 17, 1987).

⁴⁰²Derek Burke, *Time for Voices to be Raised*, 405 NATURE 509 (2000), available at <<http://www.nature.com>>.

⁴⁰³Slovic, *supra* note 401 at 283.

⁴⁰⁴Slovic, *supra* note 401 at 283.

⁴⁰⁵*See Trust Emotion, Sex, Politics*, *supra* note 393 at 83 (“Affect and worldviews seem to influence the risk-related judgments of scientists, as well as laypersons”). *See, e.g., id.* at 63. (“One way in which subjectivity permeates risk assessments is in the dependence of such assessments on judgments at every stage of the process, from the initial structuring of a risk problem to deciding which endpoints or consequences to include in the analysis, identifying and estimating exposures, choosing dose-response relationships, and so on. For example, even the apparently simple tasks of choosing a risk measure for a well-defined endpoint such as human fatalities is surprisingly complex and judgmental.”)

fluenced by their own worldviews and value systems when they are “working at the limits of their expertise.”

⁴⁰⁶ Thus, when scientists have the least hard data, as in the case of genetically engineered plants, their risk assessments are most likely to be influenced by subjective factors.⁴⁰⁷ Moreover, American scientists in particular may have personal, professional interests in the success of the technology; Dr. Goldberg has pointed out that “biotechnology is the baby of the U.S. scientific community and . . . scientists in this country have all sorts of interest in its development.”⁴⁰⁸ Additionally, just as the public’s risk assessment reflect a inclination in favor of protecting future generations, the scientific community’s risk assessments may reflect a inclination to view scientific advances as beneficial,⁴⁰⁹ particularly when they have invested their careers in this technology.

The public’s aversion to particular kinds of risks does not reflect irrationality but public values. In fact, a study of public attitudes towards agricultural biotechnology suggested that “respondents with concerns about gene technology tended to think principally in terms of moral acceptability rather than risk—a significant difference from the way in which experts normally judge the acceptability of new technologies.”⁴¹⁰ These non-risk factors should also be taken into account in setting policy. A bias in favor of protecting future generations against technologies with catastrophic potential such as nuclear power, or against technologies presenting risks to particularly vulnerable populations such as children or the elderly reflect public values that are properly involved in public policy decisions. Ultimately, all public policy decisions rely on evidence and judgment, not scientific evidence alone.⁴¹¹ This is especially true with respect to the genetic engineering debate, since the scientific data have not established the risks and benefits of this technology to any degree

⁴⁰⁶ *Trust, Emotion, Sex. Politics*, *supra* note 393 at 95.

⁴⁰⁷ Slovic, *Perception of Risk*, 236 *SCIENCE* 280, 281 (Apr. 17, 1987) (“[e]xperts’ judgments appear to be prone to many of the same biases as those of the general public, particularly when experts are forced to go beyond the limits of available data and rely on intuition.”)

⁴⁰⁸ *Biotechnology in the Year 2000 and Beyond*, *supra* note 22 at 63.

⁴⁰⁹ Derek Burke, *Time for Voices to be Raised*, 405 *NATURE* 509 (2000), available at <<http://www.nature.com>>.

⁴¹⁰ George Gaskell et al., *Worlds Apart? The Reception of Genetically Modified Foods in Europe and the U.S.*, 285 *SCIENCE* 384 (July 16, 1999), available at <<http://www.sciencemag.org>>.

⁴¹¹ Derek Burke, *Time for Voices to be Raised*, 405 *NATURE* 509 (2000), available at <<http://www.nature.com>>.

of certainty.⁴¹²

Although risk decisions should be informed by the most accurate scientific data possible, it is also legitimate to allow public judgments about risk acceptability to inform public regulation.⁴¹³ Democratic governments properly seek on accurate and science-based risk assessments, but it is also eminently proper for such a government to also regulate in such a way to reflect the public's risk preferences.⁴¹⁴ Although scientific data is a critical part of the decisionmaking process, science alone does not offer any clear solutions. Moreover, even a risk deemed to be low does not mean that the technology is necessarily desirable; policy makers must still balance "options, benefits, and other costs—not just risk"⁴¹⁵ in order to come to a proper result. Thus, even if a particular genetically engineered product is deemed to present a low risk of health or environmental harms, a full benefit analysis should also include a comparison with the non-genetically engineered variety of the same product. In other words, even if the product presents low risks, it is only socially desirable if it presents lower risks and or more benefits than the products already on the market. Interestingly, although science has found a relatively objective measure of risk (annual fatalities), it is less clear what standard the scientific community would use in order to measure benefits. Ultimately, only the public can decide the desirability of particular benefits.

The purchasing public is likely to take a "hazard model" approach towards agricultural biotechnology based on the public's experiences with other recent technological changes in food production.⁴¹⁶ Drawing on their experience with such modern food processing techniques the use of pesticides, growth hormones, the use of antibiotics in animal husbandry, the public is generally skeptical that the use of these innovations really

⁴¹²"Neither the risks nor the benefits of GEOs are certain or universal. Both may vary spacially and temporally on a case-by-case basis. Comparisons among transgenic, conventional, and other agricultural practices, such as organic farming, will elucidate the relative risks and benefits of adopting GEOs." L.L. Wolfenbarger & P.R. Phifer, *The Ecological Risks and Benefits of Genetically Engineered Plants*, 290 SCIENCE 2088, 2092 (Dec. 15, 2000).

⁴¹³Kuran & Sunstein, *supra* note 361 at 738.

⁴¹⁴Kuran & Sunstein, *supra* note 361 at 738.

⁴¹⁵*Trust Emotion Sex, Politics*, *supra* note 393 at 96.

⁴¹⁶*Consumer Focus Groups*, *supra* note 5 at 3.

advantage for consumers in any way.⁴¹⁷ Instead, “[i]n each case, participants saw a technological innovation that was introduced mainly for the sake of producers/distributors, with little apparent benefit to the consumer. Such innovations are seen as being approved by scientists and regulators, but later found to have unanticipated long-term health effects.”⁴¹⁸ In this case the public intuition that the biotechnology products on the market were not really put on the market to appeal to their needs is correct.⁴¹⁹

Biotech companies interested in gaining consumer acceptance of their products should take note that the public is fully aware that biotech products were not designed to suit their needs or interests. From the perspective of the public, any perceived benefits of the technology are also likely to affect both sides of the equation; perceived benefits affect both their assessment of the risks of the technology as well as their assessment of the benefits of the technology. Thus a “higher perceived benefit is associated with lower perceived risk; lower perceived benefit is associated with higher perceived risk.”⁴²⁰ The public’s assessment of a product’s risks and benefits are keyed primarily to their “affective evaluation,” or emotional response, to that product.⁴²¹ For instance, cars—generally seen as extremely socially desirable—are perceived as offering high benefits and posing relative low risk technology whereas pesticides—with a much lower “affective evaluation”—are generally perceived as presenting high risks, for relatively low benefit.⁴²²

A comparison of public attitudes towards pharmaceutical biotechnology and agricultural biotechnology confirms that customers are much more willing to accept a new technology if it offers them tangible benefits.

In the case of pharmaceutical biotechnology, people are much more accepting of any potential risks partly

⁴¹⁷ *Consumer Focus Groups*, *supra* note 5 at 3.

⁴¹⁸ *Consumer Focus Groups*, *supra* note 5 at 3.

⁴¹⁹ *Who’s Afraid*, *ECONOMIST*, June 17, 1999, available at <<http://www.economist.com>>. (“the clearest gains from the current crop of GM plants go not to consumers, but to producers. Indeed, that was what their developers intended; an appeal to farmers offered the purveyors of GM technology the best hope of a speedy return. For consumers, especially in the rich world, the benefits of super-yielding soybeans are less clear: the world, by and large, already has too much food in its stores; developing countries principally lack money, not food as such.”). According to Carol Tucker Foreman, “none of [the GM foods] that have been developed yet have any benefit to the consuming public. We keep hearing that there are those in the pipeline that will, but they are way back in the pipeline, way, way back” *Biotechnology in the Year 2000 and Beyond*, *supra* note 22 at 119.

⁴²⁰ *Trust, Emotion, Sex, Politics*, *supra* note 393 at 81.

⁴²¹ *Trust, Emotion, Sex, Politics*, *supra* note 393 at 81. (“It thus appears that the affective response is primary, and the risks and benefit judgments are derived (at least partly) from it”)

⁴²² *Trust, Emotion, Sex, Politics*, *supra* note 393 at 81.

because the benefits of improved drugs and better diagnostic techniques; however, agricultural biotechnology, which does not offer any such noticeable concrete benefits to the public, is viewed with considerably more suspicion.⁴²³ This tendency to overlook risks when a product is deemed socially beneficial suggests that agricultural biotechnology's best hope of public acceptance lies in its ability to create products that customers actually prefer to conventionally derived products. The best way to gain consumer acceptance of agricultural biotechnology is not to withhold information about the use of the technology, but to use the technology to produce product traits that are valued by consumers. Thus, the evidence about public perception of risks does not provide the biotechnology companies with all bad news. However, in order to use this information to gain public acceptance of their products, the biotechnology companies, like all other companies, must be willing to change their marketing strategies to suit customer preferences.

Of course, some of the cognitive biases and phenomenon discussed—such as availability cascades, and the alarmist bias—do not involve risk preferences, but actual cognitive distortions of the probability of a risk. Nevertheless, these cognitive distortions are not unique to the agricultural biotechnology context. Any democratically informed public policy debate over risks will be informed by these cognitive distortions. Ultimately, the fact that the public may misperceive the probability of a risk does not justify a policy designed to keep the public in the dark about the risk. Any democratically informed debate is, by definition, vulnerable to the weaknesses and shortcomings of human understanding. However, these distortions in human understanding do not justify taking people out of the decisionmaking process.

Moreover, this argument is particularly true in the labeling debate. Although the FDA might be justified in arguing that cognitive distortions should not shape or influence substantive safety regulations, the debate over labeling is over whether or not people should be informed about what is in their food. Any argument

⁴²³ *Who's Afraid*, *ECONOMIST*, June 17 1999, available at <<http://www.economist.com>>.

against labeling based on an attempt to avoid consumer knowledge and consumer overreaction about the risk of this technology should be viewed with particular suspicion. While it may be proper to limit the extent to which cognitive distortions influence the degree of regulation of a particular risk, cognitive distortions should not be used to justify withholding information from consumers.

C. A Possibility of Public Overreaction Does not Justify Withholding Information.

Even assuming that the public is likely to be especially worried about potential risks posed by genetically modified foods, a desire to avert public overreaction ultimately cannot sufficiently justify a decision to keep information from the public. In *44 Liquormart*, Stevens, in an opinion joined by Kennedy and Ginsburg, stated that “[t]he 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.”⁴²⁴ In fact, in *Virginia Board of Pharmacy*, the Court stated, “It is a matter of public interest that those [private economic] decisions be intelligent and well informed.”⁴²⁵ Moreover, the Stevens jointed by Kennedy Souter and Guinsburg explained that the *Virginia Board of Pharmacy* case rested on the belief that “a State’s paternalistic assumption that the public will use truthful, nonmisleading commercial information unwisely cannot justify a decision to suppress it.”⁴²⁶

Although both the *44 Liquormart* and *Virginia Board of Pharmacy* cases involved government suppression of commercial speech, rather than a government regulation mandating speech, the reasoning in those cases can be extended to the present context as well. We should be suspicious of the government’s refusal to require labeling to the extent that the government refusal to require such labeling is a desire to avoid consumer overreaction, and for “the public’s own good.” Of course, it is possible that the refusal to require labeling stems simply from a sincere belief that bioengineering is not a “material fact.” However, to the extent that

⁴²⁴44 *Liquormart v. Rhode Island*, 517 U.S. 484, 503 (1996).

⁴²⁵*Virginia Bd. of Pharmacy v. Virginia Citizens Consumer Council*, 425 U.S. 748, 765 (1976).

⁴²⁶517 U.S. at 497 (1996)

the government policy is aimed at avoiding consumer overreaction by keeping information from consumers, such policy should be viewed skeptically.

In the end, the argument for labeling is based on the fact that people simply do not and cannot realize that so many of the foods that they are currently eating have genetically engineered products, and that people have indicated a desire for this kind of information. Moreover, even consumers informed of the extent to which genetically modified foods have entered the marketplace, currently have no way of knowing whether or not a particular food product they are purchasing contains genetically engineered ingredients. In this context, any argument against labeling based on a fear of “consumer overreaction” seems paternalistic at best. After all, such an argument hinges on the assumption that consumers will find information about genetic engineering salient and material. In fact, such a position basically argues that people will find this information too salient, and will make irrational purchasing decisions. Nevertheless, the entire market economy rests on the assumption that consumers should be allowed to make purchasing decisions based on the information they consider important.

In the end, it is not FDA’s responsibility to encourage the growth of a particular industry or technology, no matter what the potential benefits.⁴²⁷ Agency attempts to promote a particular industry raises immediate questions about agency capture. The biotechnology industry has thus far argued against labeling based on the conclusion that such labels will raise consumer questions about biotechnology, and make it harder to sell these products. However, opposition to labeling based on the belief that the market will respond to this information is especially troubling. Winn has argued that such a desire to keep information off the market because of a fear of consumer rejection itself should trigger traditional FDA concerns about “intentional consumer deception.”⁴²⁸ After all, the manufacturers are marketing these products with the express hope

⁴²⁷Irradiation in the Production, Processing, and Handling of Food, 51 Fed. Reg. at 13395.

⁴²⁸Winn, *supra* note 342 at 678. (“Arguably, this is a form of intentional consumer deception, which should suggest to FDA that genetic engineering information would be rather powerful in the hands of consumers, especially in light of FDA’s concerns about preventing consumer deception. Although FDA does not subscribe to the extreme position that the government is responsible for regulating everything the public perceives to be a risk, the power of information in consumers should be given

that consumers will not realize that their products contain genetically modified ingredients.

Agricultural biotechnology food producers should bear the responsibility of gaining consumer acceptance of their products. This is how the market traditionally works, and the use of a materiality analysis to shield the manufacturers from their traditional responsibility to convince consumers to purchase their products is improper. Winn argues,

It is in the best interest of manufacturers to convince consumers of the value of their products. This is generally how the market works; manufacturers develop a product and convince consumers to buy that product. The correct response, therefore, to a negative reaction to special labeling, is not for FDA to withhold labeling requirements. Instead, the correct response is to make manufacturers responsible for educating consumers, allaying their fears, and instilling their confidence in biotech food.⁴²⁹

While it is true that biotech manufacturers will probably have to face difficult consumer concerns about the long-term health, allergenic, and environmental effects of these foods, this is not a special burden placed solely on agricultural biotechnologists. Rather, virtually any producer of a new technology must ultimately gain acceptance of the public—even when the public is prone to irrational decisionmaking. The airline industry faces especially strict safety regulations even though flying is generally much safer than driving. While professional risk analysts may question the efficiency of such regulations, ultimately those regulations exist because of public preferences. Moreover, many of the heightened risk preferences triggered by agricultural biotechnology actually reflect public values, not irrationality. Consumers have every right to prefer traditionally grown food over foods that they are less familiar with. Similarly, the consumer desire to control exposure to the particular kinds of risks posed by biotechnology, even if those risks are extremely small, is simply not irrational; this desire simply reflects the value that consumers place on their ability to control

as much consideration in the biotech food context as in other areas under FDA regulation”)

when they are facing particular kinds of risks. To the extent that consumer risk preferences reflect such personal values, biotech food companies can do little to change those underlying values.

It was proper for the FDA to consider whether a mandatory label requirement may be perceived as a warning statement and the potential for the public to be misled by the implications of such a label. However, the FDA's analysis stopped one step short. It should also have considered the public's perception of foods that do not contain labels indicating that ingredients have been genetically modified. Under 21 U.S.C. § 321(n), a label or lack thereof may be misleading if the labeling "fails to reveal facts . . . material with respect to consequences which may result from the use of the article . . . under such conditions of use as are customary or usual."⁴³⁰ Accordingly, the omission of labeling information may be misleading under the statute. Nevertheless, although the FDA has indicated that it considers how the public might perceive a genetic engineering label, it does not consider the extent to which the omission of information regarding the genetic engineering of products is widely perceived. The evidence strongly suggests that foods without the labeling of genetically engineered ingredients are presumed *not* to contain such ingredients, since the public is largely unaware of the presence of these foods in their supermarkets. To the extent that that presumption is incorrect, the FDA should also be concerned about currently occurring violations of the mislabeling prohibition.

VI. *Labeling Realities.*

A.

Monsanto's changed stance.

Perhaps sensing the strength of public support for labeling, Monsanto has recently decided to support the labeling of its bioengineered products in the European Union.⁴³¹ A Monsanto spokesman framed the re-

⁴³⁰21 U.S.C. §321(n).

⁴³¹*Monsanto Changes Stand on Labeling Genetically Modified Food in European Union*, PESTICIDE AND TOXIC CHEMICAL

versal of position as part of a process to gain consumer acceptance of bioengineered products, explaining that the label represented “a question of transparency, openness, and trust.”⁴³² Moreover, reiterating the company’s basic position that bioengineered foods are not essentially different from conventional agricultural products, he stated that “the company has decided [to] . . . accept[] the reality that European consumers want to know when they are purchasing genetically engineered foods.”⁴³³ Most dramatically, Monsanto’s CEO Robert Shapiro admitted that “[t]he company’s attitude had widely been seen, and understandably so, as condescension or indeed arrogance. . . . Because we thought it was our job to persuade, too often we forgot to listen.”⁴³⁴ In acquiescing to labeling, Monsanto followed the lead of some of its European competitors. For example, Novartis does not oppose mandatory labeling of GM foods, instead choosing to view labeling as “a way to show confidence. . . in the safety and quality of [their] products.”⁴³⁵

Monsanto’s change in position on mandatory labeling in the EU demonstrates that mandatory labeling does not necessarily have to signal the death knell of the biotechnology industry,⁴³⁶ and also represents an ultimate acknowledgement by industry that they have a responsibility to respond to consumers’ preferences, if only as a matter of business survival. Although Monsanto has not changed its position on mandatory labeling in the U.S., it would be difficult for the company to argue on principle against labeling in the U.S. when it has

NEWS, May 7, 1998, *available at* 1998 WL 11008899.

⁴³²*Id.* In deciding to change its stance to favor labeling, Monsanto has followed the lead of the European food industry, which also initially opposed labeling requirements, but acquiesced to consumer demand when “they realized it was a battle they could not win, [and] they began portraying the biotech label as a quality label, arguing that such products are safer than conventional raw materials because they’ve been more thoroughly tested, and safer for the environment because they dramatically reduce the use of plant protection chemicals in some cases. ‘We now see the biotech label as an opportunity rather than a potential threat.’ [stated a Nestle official]” *Next Generation Biotech Products Will Face Traditional Labeling Issues in U.S.*, Maryanski Notes, *available at* 1998 WL 10981464.

⁴³³*Monsanto Changes Stand*, *supra* note 431. “Indeed most agree that the next couple of years will be crucial for the future of GM crops” and that although the biotech industry has until recently focused its marketing efforts on farmers, it has finally realized that it must market its products with an eye to pleasing the end consumers making decisions in the grocery store. Mike Phillips, a representative of the BIO, has stated that “it’s finally dawning on Monsanto, as well as other companies, that it’s what the customer wants [that counts].” Martin Enserink, *Industry Response: Agricultural Biotech Moves to Mollify Its Critics*, 286 SCIENCE 1666 (Nov 26, 1999), *available at* <<http://www.sciencemag.org>>.

⁴³⁴Enserink, *supra* note 433. This admitted arrogance is not hard to find. On Monsanto Spokesman was on record as having stated “Monsanto should not have to vouchsafe the safety of biotech food. . . . Our interest in selling as much of it as possible. Assuring its safety is the FDA’s job.” *Playing God in the Garden*, *supra* note 3.

⁴³⁵Enserink, *supra* note 433.

⁴³⁶*Id.* (“In the Netherlands, GM foods have carried the neutral phrase ‘produced with modern biotechnology’ since 1997. ‘There were some jitters at first, but eventually sales have stabilized,’ De Greef says”)

already acquiesced to labeling the EU. In fact, biotech companies may well have made a strategic mistake in opposing labeling. Because the industry had no need to engage in the kind of consumer education that would have been necessitated by a mandatory labeling regime, it essentially “left the public education to the industry’s foes.”⁴³⁷ Moreover, because there was no need to educate and gain the confidence of the consumers buying the products in the grocery store, the biotech companies marketed the products towards farmers,⁴³⁸ and ultimately customized the benefits of the biotech products towards farmers, not consumers.⁴³⁹ Consumers are predisposed to be more wary of the risks posed by these products precisely because they gain no salient benefits from them. The industry’s biggest obstacle to success is public acceptance.⁴⁴⁰

Ultimately, consumer acceptance is necessary in order to ensure the development of this technology,⁴⁴¹ just as consumer acceptance is the key to the success of any other new product or technology. A recent article in Nature magazine notes, “[t]he industry complains that the public has lost trust in its scientific experts, but it will only make matters worse by declaring its own loss of trust in the judgment of the consumer. If labeling all foods produced by GM techniques, as many argue, turn out to be a necessary step in regaining trust on both sides, it could be a small price to pay.”⁴⁴² Even some government actors seem to have accepted that the industry ultimately must bear the responsibility for the success or failure of this technology. Referring to a labeling protocol to be applied to biotech food sold abroad, Quentin Kubicek, of the U.S. Department of Agriculture has said that the key to selling bioengineered foods “will come from industry, not the U.S. Government. A good product will sell abroad and make the protocol moot... It’s up to industry.”⁴⁴³ This

⁴³⁷Floyd Norris, *How to Make a Scientific Breakthrough Seem Horrifying*, N.Y. TIMES, Dec 17, 1999, available at 1999 WL 31760146.

⁴³⁸*Who’s Afraid*, ECONOMIST, June 17, 1999, available at 1999 WL 7363493.

⁴³⁹Norris, *supra* note 437.

⁴⁴⁰Declan Butler, *Biotech Industry Seeks “Honest Brokers,”* 398 NATURE 360 (Apr. 1 1999).

⁴⁴¹Dr. Cutberto Garza, co-chairman of the EU-U.S. Forums stated, “In order not to kill this technology we must gain consumer acceptance and we must aim for the common ground.” Marian Burros, *Labeling Foods with Designer Genes*, N.Y. TIMES, January 3, 2001, available at <<<http://www.nytimes.com2001/01/03/living/03WELL.html>>>.

⁴⁴²Opinion, *GM Foods Debate Needs A Recipe for Restoring Trust*, 398 NATURE, 639 (22 April 1999).

⁴⁴³*Biosafety Protocol Could Impeded Biotech Trade, Analyst Warns*, FOOD CHEMICAL NEWS, Nov. 15, 1998, available at 1998 WL 10981949.

statement seems to be an acknowledgment that the ultimate responsibility for the success of biotechnology (as with all other industries) lies with the industry and not the government, and offers a sharp contrast with tone of the Coordinated Framework statements.⁴⁴⁴

B.

EU-US Biotechnology Consultative Forum

Increasingly, advocates on both sides have been noted the need for “honest brokers” trusted by the public to evaluate the issues raised in the biotechnology debate.⁴⁴⁵ One potential candidate for the position of a neutral broker is the EU-U.S. Biotechnology Consultative Forum. Created through an agreement between the EU’s President Prodi and President Clinton, and comprised of both EU and US experts in a broad spectrum of fields related to the biotechnology issues (including scientists, lawyers, ethicists, consumer activists, farmers, environmentalists, and business people), the Forum was charged with the task of writing a “consensus report reflecting the views and assessments of the benefits and risks” of the use of biotechnology in food and agriculture.⁴⁴⁶

Despite the broad range of disciplines and cultural and professional differences involved, this group of European and American experts was able to come to a consensus. Notably, the report recommended mandatory labeling requirements for genetically engineered products in both the EU and the U.S.,⁴⁴⁷ noting that

⁴⁴⁴The government’s official stance towards regulation of biotechnology abroad in the Coordinated Framework was aggressively pro-biotechnology, arguing that there was “no scientific basis for specific legislation for specific implementation of rDNA technology and applications” and that members of the OECD should “examine their existing oversight and review mechanisms to ensure that adequate review and control may be applied while avoiding undue burdens that may hamper technological developments in this field.” 51 Fed. Reg. at 23308.

⁴⁴⁵Declan Butler, *Biotech Industry Seeks “Honest Brokers,”* 398 NATURE 360 (Apr. 1, 1999).

⁴⁴⁶The EU-U.S. Biotechnology Consultative Forum, Final Report, December 2000, 4, available at <http://europa.eu.int/comm/external_relations/us/biotech/report.pdf> [hereinafter *Final Report*]

⁴⁴⁷The EU-U.S. Biotechnology Consultative Forum, Final Report, December 2000, 16, available at <http://europa.eu.int/comm/external_relations/us/biotech/report.pdf>. The report recommended “content-based mandatory labeling requirements for finished products containing novel genetic material.” *Id.*

“[c]onsumers should have the right of informed choice regarding the selection of what they want to consume.”⁴⁴⁸

In general, the Forum generated a much more cautionary attitude toward agricultural biotechnology than the FDA’s approach. For instance, one committee member, Dr. LeRoy B. Walters, a leading ethicist specializing in human gene transfer research, characterized the report as a “a reasonable middle ground [that] provides an extra measure of safety for consumers. We need to treat biotech food more like new drugs or food additives in the early years until we have a better picture of how they react in the human body.”⁴⁴⁹

Moreover, the Forum advocated a much more inclusive regulatory process, arguing that the regulatory assessment of risk should include a broad range public stakeholders, including “social scientists, ethicists, representative of civil society,” not exclusively scientists.⁴⁵⁰ The Forum also argued that the regulatory process should take into account the public’s preferences and aversions for particular kinds of risk including “whether the risk is voluntary or involuntary, perceived benefits, or whether the risk could cause hidden or irreversible damage.”⁴⁵¹ The Forum further stated that “An inclusive regulatory system will also enable decisions to be made in a way that respects societies’ judgments of appropriate societal goals, ethical boundaries, and value concerns. Finally, an appropriate regulatory system will recognize and consider the special concerns attending applications that break new ground.”⁴⁵² In short, the Forum advocated a regulatory process and agenda that responds to public concerns.

Nevertheless, the Forum’s recommendations do not bind any governmental body, European or American, and it is not clear how the Bush Administration will choose to respond to the Forum’s recommendation.⁴⁵³

Moreover, at least one committee member has argued that the recommendation would require labeling only

⁴⁴⁸*Id.* at 16. [*Final Report*]

⁴⁴⁹Marian Burros, *Eating Well: Labeling Foods with Designer Genes*, January 3, 2001 available at <<http://www.nytimes.com/2001/01/02/living/03WELL.html>>.

⁴⁵⁰*Final Report*, *supra* note 390 at 15.

⁴⁵¹*Final Report*, *supra* note 390 at 15.

⁴⁵²*Id.* at 15.

⁴⁵³Andrew Pollack, *Panel Backs Stronger Rules for Some Food*, N.Y. TIMES, Dec. 18, 2000, available at <<http://www.nytimes.com/2000/12/18/business/18FOODh.html>>.

if the genetic engineering significantly changed the food⁴⁵⁴ a standard that is arguably consistent with the labeling position already taken by the FDA. Given the diversity of the Forum's membership, and the fact that such a group was able to come to a consensus in this document, however, should give the Forum's recommendation's at least moral legitimacy.

C.

***Both the FDA and the Biotechnology Industry Need to Gain Consumer Trust
in Order to Ensure the Success of the Technology.***

Fred H. Degnan, a legal commentator favoring the FDA's current labeling policy, has argued that "issues of public trust" should be "kept distinct from the legal issues of essentiality and materiality" that govern the FDA's labeling authority.⁴⁵⁵ However, this strict dichotomy between issues of public trust and issues of FDA policy is misleading. The FDA will ultimately not be able to fulfill its mission of protecting public health if the public loses faith in the agency.

Ultimately, FDA credibility is the key to the agency's ability to regulate biotechnology effectively. Former Secretary of Agriculture Dan Glickman has acknowledged that the success of biotechnology hinges to a large part on "trust in the regulatory process."⁴⁵⁶ Unfortunately, consumer confidence in the FDA may have been damaged in the course of other recent food additive controversies such as the alar and saccharine debates.⁴⁵⁷ One commentator has argued "[b]ecause the FDA's credibility has been undermined, consumers are more willing to listen to environmental and consumer groups on issues of food safety than they used to be."⁴⁵⁸ Ultimately, consumer "[c]onfidence in the truthfulness, effectiveness, and completeness of the food label is

⁴⁵⁴*Id.* [Panel Backs Stronger Rules for Some Food]

⁴⁵⁵Fred H. Degnan, *Biotechnology and the Food Label: A Legal Perspective*, 55 FOOD & DRUG L.J. 301, 309 (2000).

⁴⁵⁶*Glickman Address*, *supra* note 251.

⁴⁵⁷John Beiswenger, Note, *Moving Beyond Risk in Assessing Technological Artifacts: The Case of Recombinant Bovine Somatropin*, 61 VT. L. REV. 667, 681 (1992).

⁴⁵⁸*Id.* at 681.

in the interest of FDA, consumers, and industry alike.”⁴⁵⁹

Even in arguing against calls for mandatory labeling, former FDA Commissioner Jane E. Henney acknowledged for the necessity of consumer confidence in food safety and in government agencies charged with protecting that safety.⁴⁶⁰ Moreover, former Commissioner Henney has also indicated that the provision of information is important for consumer acceptance, stating “[w]hat any product doesn’t need is for there to be suspicion on behalf of consumers that something is being slipped by them.”⁴⁶¹ Although this statement was made in the context of the public disclosure of the clinical data on gene therapy and animal organ transplants, the same argument also applies in the genetically engineered food context.

FDA’s current labeling policy is likely to only further undermine consumer trust in the agency and the underlying technology. Although the agency may continue to be firmly convinced that those advocating mandatory labeling do not have a scientific leg to stand on, their adamant refusal to listen to consumers may ultimately backfire by further eroding public trust in the agency itself. As Monsanto has apparently acknowledged in its grudging acceptance of consumer calls for labeling in Europe, regardless of biotechnology’s potential benefits, the science depends on public acceptance in order to develop. Again in the words of former Secretary Glickman, “[w]ith all that biotechnology has to offer, it is nothing if it’s not accepted. This boils down to a matter of trust—trust in the science behind the process, but particularly trust in the regulatory process that ensures thorough review—including complete and open public involvement.”⁴⁶² The credibility of the FDA, like the credibility of all other government agencies, is contingent in large part to the public’s confidence that it is independent from the industries they regulate.⁴⁶³ Any hint of agency capture risks alienating the public’s confidence. Moreover, at least some believe that the FDA’s history of mini-

⁴⁵⁹Steven B. Steinborn & Kyra A. Todd, *The End of Paternalism: A New Approach to Food Labeling*, 54 FOOD & DRUG L.J. 401, 422 (1999).

⁴⁶⁰Larry Thompson, *Are Bioengineered Foods Safe*, interview with Jane E. Henney, FDA CONSUMER, Jan-Feb 2000, available at <<<http://www.cfsan.fda.gov/~dms/fdbioeng.html>>>.

⁴⁶¹Andrew Pollack, *F.D.A. Plans New Scrutiny in Areas of Biotechnology*, N.Y. TIMES, Jan. 18, 2001, available at <<http://www.nytimes.com/2001/01/18/health/18REGS.html>>.

⁴⁶²Glickman Address, *supra* note 251.

⁴⁶³Glickman Address, *supra* note 251.

mal regulation of agricultural biotechnology has only alienated public confidence. Tucker of the Consumer Federation of America has remarked, the regulation “process began under a cloud of political influence and managerial bean counting, and FDA has not dispelled that cloud.”⁴⁶⁴

Until recently, FDA seems to have been built under the assumption that the American consumer has already come to accept bioengineered food products. In 1993, Kessler noted that the public had initially feared agricultural biotechnology, causing them to instinctively “distrust the scientist who developed [genetically engineered plants], the companies who plan to market them, and the government that will regulate them”⁴⁶⁵ and that further the public’s perception of GM foods summoned “scenes from a B movie ‘Attack of the Killer Tomatoes’—where six feet high tomatoes roll down the street ‘burning, pillaging, and raping.’”⁴⁶⁶ Nevertheless, despite that early lack of trust of biotech foods, he argued that currently there is “widespread acceptance” in the United States of agricultural biotechnology “among producers, consumers and policy-makers”⁴⁶⁷

Although it is true that producers and policymakers have embraced this new technology, consumers’ attitudes toward this technology may not be most accurately characterized as “widespread acceptance.” In fact, in a recent international poll, 57% of Americans surveyed indicated that they were less likely to be foods that were genetically modified,⁴⁶⁸ and only 4% reported being more likely to buy a food if it were genetically engineered.⁴⁶⁹

Moreover, the FDA’s own consumer focus groups findings provide clear evidence that average Americans do not realize that they are current eating GM foods.⁴⁷⁰ Most notable about this research is the how consumers

⁴⁶⁴Biotechnology in the year 2000 and Beyond, *supra* note 22 at 57.

⁴⁶⁵Judith E. Beach, *No Killer Tomatoes’: Easing Federal Regulation of Genetically Engineered Plants*, 53 FOOD & DRUG L.J. 181, 181 (1998).

⁴⁶⁶*Id.* at 181-2.

⁴⁶⁷Judith E. Beach, *No Killer Tomatoes’: Easing Federal Regulation of Genetically Engineered Plants*, 53 FOOD & DRUG L.J. 181, 182 (1998), *citing* David A. Kessler, Remarks on Regulation of Food Biotechnology, Speech to the University of Washington, Seattle, Washington (April 23, 1993).

⁴⁶⁸*Blech*, *ECONOMIST*, Jan. 13, 2000, *available at* 2000 WL 8140425.

⁴⁶⁹*Id.*

⁴⁷⁰U.S. FOOD AND DRUG ADMINISTRATION, CENTER FOR FOOD SAFETY AND APPLIED NUTRITION, REPORT ON CONSUMER

react when informed of the prevalence of genetically engineered foods. Most consumers, even those who consider themselves well informed about biotechnology, “register amazement” when informed of the degree to which bioengineered foods have entered the food supply,⁴⁷¹ and typically express “outrage that such a change in the food supply could happen” without their being informed.⁴⁷² Most importantly, this information often undermined confidence in both FDA and “served to reinforce the most negative and cynical views some participants held about food biotechnology.”⁴⁷³ Consumers expressed concern that GM foods had been “snuck into’ the food supply”⁴⁷⁴ and interpreted this lack of disclosure in the marketplace as evidence of a “conspiracy to consumers in the dark.”⁴⁷⁵ Most importantly, some participants concluded that “the rationale for not informing the public must be that there is something to hide.”⁴⁷⁶ This is precisely the kind of suspicion that most damages the credibility of the agency. Although the FDA may defend its policy as purely science based, this study indicated that consumers may be convinced of the very opposite. One participant at the recent public hearings held by the FDA in Washington, D.C. stated, “It looks an awful lot like the process of easy approval for transgenic foods is driven more by political influence than by science based concern for human health or the environment.”⁴⁷⁷

By steadfastly refusing to mandate labeling, the FDA risks furthering the perception that it is in cahoots with the biotech industry, undermining its own credibility, and furthering distrust of the underlying technology. The Consumer Focus Group results only confirm Glickman’s observation that it “does America little good to be seen ‘force-feeding genetically modified organisms down people’s throats.’”⁴⁷⁸ Consumers in the focus groups expressed “skepticism that the interests of consumers are sufficiently taken into account by

FOCUS GROUPS ON BIOTECHNOLOGY 6 (Oct. 20, 2000), available at <<http://www.cfsan.fda.gov/~comm/biorpt.html>>. [hereinafter *Consumer Focus Groups*]

⁴⁷¹ *Id.*

⁴⁷² *Id.*

⁴⁷³ *Id.*

⁴⁷⁴ *Id.*

⁴⁷⁵ *Id.*

⁴⁷⁶ *Id.*

⁴⁷⁷ *Biotechnology in the Year 2000 and Beyond*, *supra* note 22 at 246.

⁴⁷⁸ *Food for Thought*, *ECONOMIST*, June 17, 1999, available at 1999 WL 7363490.

other actors [responsible for developing agricultural biotechnology policy]. Some participants complained that consumers are being used as ‘guinea pigs’ and many were doubtful that government regulators and scientists have the ability to counteract the powerful profit motives of industry and producers.”⁴⁷⁹ Ultimately, a policy that results in consumers not getting information about a dramatic change in the way the food they eat is produced and dismissing concerns about the technology as “irrational and unscientific” will do “do little to win hearts and minds.”⁴⁸⁰ Although the American public has much more confidence in the FDA’s ability to protect the public health than Europeans have in their regulatory agencies,⁴⁸¹ it is hardly surprising that even Americans do not react positively when they learn about a major change in the food supply which has occurred without their knowledge.

Moreover, public distrust of the biotech industry might be due to more than just sheer ignorance or panic. According to a recent study by the National Science Board, well-educated Americans have less favorable attitudes towards genetic engineering than five years ago.⁴⁸² Moreover, it is likely that this distrust may be directed less at the underlying science, than at the biotech industry.⁴⁸³ In fact, it is possible that the intense protests about the introduction of biotech foods to the marketplace in Britain “was driven as much by public suspicion about the motives of large companies as by unease about biotechnology.”⁴⁸⁴ According to Dorothy Nelkin, a professor of sociology at NYU specializing in science and law, “[c]ommercialization [of technology] enhances mistrust”⁴⁸⁵ The best way to counter consumer concerns about the commercialization of this technology may be to ensure that the FDA truly is independent and concerned solely with protecting the consumer interests.

Although the FDA has not officially commented on the fact that its own focus groups largely called for label-

⁴⁷⁹ *Consumer Focus Groups*, *supra* note 5 at 3.

⁴⁸⁰ Enserink, *supra* note 433.

⁴⁸¹ *Food for Thought*, *ECONOMIST*, June 17, 1999, available at 1999 WL 7363490.

⁴⁸² Paul Smaglik, *Educated US Public Get More Wary of Genetic Engineering*, 405 *NATURE* 988 (June 29, 2000).

⁴⁸³ *Id.*

⁴⁸⁴ *Is There a Spin Doctor in the House?* 404 *NATURE* 211 (Mar. 16, 2000).

⁴⁸⁵ *Id.*

ing, other government officials have acknowledged this consumer demand for labeling. For instance, Frank Loy, U.S. Undersecretary of State for Global Affairs has stated, “I have a sense that the consumers have spoken, and they say: ‘We want the damned stuff labeled. . . so one ought to discuss labels.’”⁴⁸⁶ Similarly, at a 1997 speech, Glickman voiced the opinion that “At the end of the day. . . some type of informational labeling is likely to happen.”⁴⁸⁷ This rather calm acceptance to labeling is in sharp contrast to his earlier stated position that segregation of foods on the basis of genetic modification was “scientifically unfounded and commercially impossible,” and his strong opposition to mandatory labeling just two years earlier.⁴⁸⁸ Even some scientists have even voiced the opinion that genetically engineered foods will eventually be labeled.⁴⁸⁹ Labeling can help build consumer trust. As the most effective way to inform consumers about the genetically engineered content of their food, labeling can represent a “necessary first step” in starting a honest public dialogue about the risks and benefits of these products.⁴⁹⁰ By bringing the consumers into the debate, FDA labeling policy can play a vital role in promoting consumer confidence in the technology, the industry, and the FDA.⁴⁹¹ As Whittaker has noted, “[o]nly open communication and prudent education will help to establish confidence in bio-engineered products. For the typical consumer, communication and education begins with labeling.”⁴⁹²

Moreover, the FDA should acknowledge that consumer demands for labeling of genetically modified foods are not irrational. As Philip R. Reilly has written in a very recent article in the *Annual Review of Genomics and Human Genetics*, “the public reaction to GMOs is. . . a rational response to the discovery that a major

⁴⁸⁶Enserink, *supra* note 433.

⁴⁸⁷Glickman Address, *supra* note 251.

⁴⁸⁸Beach, *supra* note 467 at 187, citing *European Stance on Labeling Genetically Modified Crops Prompts Farm Chemicals Association Response*, FOOD LABELING & NUTRITION NEWS, July 17, 1997, at 11.

⁴⁸⁹Reilly, *supra* note 9 at 502.

⁴⁹⁰Michael A. Whittaker, *Reevaluating the Food and Drug Administration’s Stand on Labeling Genetically Engineered Foods*, 35 SAN DIEGO L. REV. 1215, 1220 (1998).

⁴⁹¹*Id.*

⁴⁹²*Id.* at 113 citing Kurt Danner, *Acceptability of Bio-Engineered Vaccines*, 20 COMP. IMMUNOLOGY, MICROBIOLOGY, AND INFECTIOUS DISEASES 3, 11 (1997). See also *Who’s Afraid*, *supra* note 438. (“The best ways to win public support are to offer full information; to regulate openly and responsibly; and to ensure that the benefits of genetic engineering are seen to go not only to companies. Doing all of this would go a long way to allaying people’s fears about GM food—and might even persuade them of its potential benefits.”)

change has taken place in the world that was conducted largely without public knowledge.”⁴⁹³ The notion that the large scale introduction of genetically modified foods into grocery stores signals a major change in our food supply is by no means a novel or unfamiliar argument. Although biotech companies usually stress the similarity of genetically engineered foods to conventional foods when facing demands for labeling, in other contexts they are happy to tout their products as unique and revolutionary when touting the benefits of biotechnology to feed the world and save the planet.⁴⁹⁴ The industry portrays its products “as the linchpins of a biological revolution—part of a ‘new agricultural paradigm’ that will make farming more sustainable, feed the world, and improve health and nutrition—and, oddly enough, the same old stuff, at least so far as those at the eating end of the food chain should be concerned.”⁴⁹⁵ Similarly, at least some government actors involved in the regulation of these foods grasp the significance of the approval of these foods for human consumption. For instance, one member of a government advisory panel responsible for determining the safety of the FlavrSavr tomato remarked, “We are changing the relationship between humans and nature on a scale of the industrial revolution.”⁴⁹⁶ The grand pronouncements about the significance of the technology undermine FDA arguments that genetically engineered products are simply extensions of traditional plant breeding techniques.

Although science has an important role to play in determining the risks and benefits of genetically engineered food products, the issue of labeling cannot ultimately be determined by science. Negative public reactions to the realization that these foods have not been labeled have as much to do with people’s feeling of disenfranchisement in making fundamental decisions about what they put into their bodies as they do with concerns about the long-term safety of these products. FDA’s concerns that not all information can be required on the food label represents are legitimate. Nevertheless, given the major change in food production that genetic

⁴⁹³Reilly, *supra* note 9 at p 502.

⁴⁹⁴*Playing God in the Garden*, *supra* note 4.

⁴⁹⁵*Id.*

⁴⁹⁶Reilly, *supra* note 9 at 499, *citing* C.M. Elliot, *Genetically Engineered Tomato Approved for Market*. BIOWORLD, Sept. 17, 1994, at 4.

engineering represents, the case for including information about genetic engineering on food labels represents is particularly strong.

Moreover, any case against labeling based on a fear of a consumer overreaction to information about genetic engineering should be regarded with suspicion. In a market economy, consumers should be allowed to make decisions based on their preferences—not solely based on the government or scientists’ conclusion about what food products are safe. Like any other food product, foods containing genetically engineered ingredients need to compete on the basis of consumers’ preferences, no matter how irrational or unscientific. Although the government has a proper role in determining that products marketed for human consumption meet some basic threshold safety requirement, it has no proper role in withholding information about those products in order to influence consumers’ purchasing choices.⁴⁹⁷

Similarly, democratic principles weigh in favor of giving consumers information about the products they are purchasing. One of the most telling results of the FDA’s Consumer Focus Group results was the angry reaction of the consumers’ when told of the prevalence of GM foods in their grocery stores. As citizens in a democracy, these participants naturally assumed that they would be informed about major changes in the food supply. The participants recognized that having this information about the genetically modified status of their food is a basic precondition both to their being able to make food decisions on an individual basis, as well as to their ability to monitor government regulation of these products.

Although scientists or regulators may dismiss citizens’ risk preferences and aversions as unscientific or unsubstantiated, in a democracy, laypeople must be allowed to express and act on those preferences. In fact, “democracy is by definition a system of rule by the inexpert.”⁴⁹⁸ Moreover, in many cases, the preferences dismissed by scientists as unscientific are not based on factual beliefs, but rather represent value judgments.

⁴⁹⁷It seems that this is why the FDA does nothing to discourage consumers from purchasing Ho-hos, Twinkies, and Ben and Jerry’s ice cream. Although there are clearly healthier alternatives on the market, consumers are free to make purchasing decisions that are strongly influenced by irrational and *unscientific* principles like taste and marketing.

⁴⁹⁸*Genetically Modified Government*, *ECONOMIST*, May 27, 1999, available at 1999 WL 7363327.

Such value judgments are precisely the kinds of issues to be resolved by the polity at large rather than a small cadre of technocrats. For instance, the aversion to risks that could harm future generations, children, or risk aversion generally, all represent important and socially constructive value judgments that common citizens should be able to express and have reflected through government policy and personal purchasing decisions. Moreover, Slovik's research strongly indicates that the risk assessments of scientists themselves are also shaped by their own personal world views, suggesting that scientists' conclusions are not necessarily more "rational" than public opinion.⁴⁹⁹

Although FDA's primary role is to protect the public health, it should not use its power in order to subvert the public's preferences in the name of protecting public health. Such a regulatory stance is at best paternalistic. This is perhaps why the FDA does not officially express this reasoning as a justification for refusing to label. Nevertheless, the FDA's stated justification for refusing to call for mandatory labeling: that information about genetic engineering is not material because scientific evidence does not indicate that it is material is ultimately unconvincing, particularly since so many scientists themselves have argued that the research data is not complete enough, and that no risk analysis has been done to date. Statutory analysis clearly indicates that the FDA has ample regulatory authority to regulate genetically modified foods much more stringently and to require labeling of these foods.

Ultimately, the decision whether or not to apply labels to foods containing genetically modified ingredients is a political one. Slovic has argued that "defining risk is . . . an exercise in power."⁵⁰⁰ Labeling decisions also represent an exercise in power. The labeling issue raises fundamental issues about the distribution of information between food producers and consumers. Although scientific data plays a role to play in determining the relevance of information, the ultimate decision over whether or not to require labeling essentially represents a political question. Scientists may be able to provide important information about the known

⁴⁹⁹ *Trust, Emotion, Sex, Politics*, *supra* note 393 at 83.

⁵⁰⁰ *Trust, Emotion, Sex, Politics*, *supra* note 393 at 95.

risks and benefits of a particular product, but science does not answer questions about what kinds of risks consumers should be aware of, or what kinds of preferences consumers should be allowed to express. These are issues of judgment that should properly be determined in the realm of public debate.

Even if the FDA is convinced that public judgments and risk preferences are irrelevant for purposes of labeling policy, the agency still has a strong vested interest in maintaining public trust in the agency. The FDA will be unable to carry out its mission of protecting public health if it loses the trust of the public. The EU-US Biotechnology Consultative Forum Final report noted that credibility of democratic institutions is often tied the “transparency of decision-making” and the participation of all relevant stakeholders.⁵⁰¹ In fact, the report noted that a “[l]ack of trust jumps across seemingly unrelated areas of regulation and policy.”⁵⁰²

Ultimately, scientific evidence and assurances cannot quell public concerns unless the public has faith in the science and agencies that produce and rely on such data.⁵⁰³ Moreover, “[i]n the absence of trust, science (and risk assessment) can only feed public concerns, by uncovering more bad news”⁵⁰⁴ Trust is an essential element of effective communication between the FDA and consumers. Moreover, this trust in an institution, once created, must be safeguarded vigilantly since it is difficult to establish, but very easily destroyed.⁵⁰⁵ In fact, the public is likely to view information that challenges their trust in an institution as more plausible than information that would reinforce confidence in the institution,⁵⁰⁶ and “distrust, once initiated, tends to reinforce and perpetuate distrust.”⁵⁰⁷ Without trust, no communication from the FDA will ever be effective.⁵⁰⁸ In fact, trying to counter concerns about risk with raw scientific data will often only serve

⁵⁰¹ *Final Report*, *supra* note 390 at 6.

⁵⁰² *Final Report*, *supra* note 390 at 6.

⁵⁰³ *See Trust Emotion, Sex, Politics*, *supra* note 393 at 88.

⁵⁰⁴ *Id.* at 93.

⁵⁰⁵ *Id.* at 88.

⁵⁰⁶ *Id.* at 91.

⁵⁰⁷ *Id.* at 92.

⁵⁰⁸ *Id.* at 88.

to “exacerbate conflict,” particularly when the key point of conflict is about a value judgment.⁵⁰⁹ Distrust in public institutions only serves to feed the perception that “risks are unacceptably high.”⁵¹⁰

Scientists, as well as other stakeholders, have acknowledged the need for public trust: “it behooves government—and industry—to build long-term public confidence by establishing strict rules to ensure safety and choice for consumers and to safeguard the environment.”⁵¹¹ Glickman also acknowledged the need to secure public confidence. He stated, “[n]ow, more than ever, with these technologies in their relative infancy, I think it’s important that, as we encourage the development of these new food production systems, we cannot blindly embrace their benefits. We have to ensure public confidence”⁵¹²

FDA is in an ideal position to serve in an “honest broker” role in the agricultural biotechnology debate. In fact, the United States is one of the few western democracies that has a trusted food and drug regulatory agency like the FDA.⁵¹³ And recent controversies notwithstanding, the public still has a great deal of trust in the agency.⁵¹⁴ However, the FDA’s ability to protect the public health is largely dependent on the public’s faith in the integrity and independence of the agency.⁵¹⁵ FDA’s position that its current policies are based solely on scientific evidence while critics are merely motivated by political, or unscientific concerns—contrary evidence notwithstanding—may ultimately further undermine trust in the agency.

Moreover, the FDA’s argument that its labeling policy is based purely on science is further undermined by

⁵⁰⁹*Id.* at 95.

⁵¹⁰*Id.* at 62.

⁵¹¹Jacobson, *supra* note 106.

⁵¹²*Glickman Address*, *supra* note 251.

⁵¹³*Food for Thought*, *supra* note 157. (“European governments have a distressingly bad record of suppressing ‘inconvenient’ scientific data, and when that does not work, of simply lying about food safety. With experiences as diverse as BST (mad-cow disease), bacterially contaminated meat and (most recently in Belgium) cancer causing dioxin in poultry, pork, and beef to draw on, consumers have developed a healthy skepticism about the things that officialdom tells them are or are not safe to eat”)

⁵¹⁴*Sticky Labels*, *supra* note 160. (“though Americans generally mistrust government meddling, they have great confidence in the country’s food and drug regulatory body, the FDA, to ensure that all food, genetically modified or not, is safe.”)

⁵¹⁵*Glickman Address*, *supra* note 251.

the fact that some scientists have recently advocated labeling for reasons other than simply assuring public safety. They argue that labeling of GM foods might be necessary to trace any long-term increases in allergies or diseases to GM foods.⁵¹⁶ These scientists caution that absent the ability to trace the health effects of GM foods through labeling requirements, “any unanticipated health impact” of GM food would be undetectable by any agency except in the case of a “monumental disaster.”⁵¹⁷ Thus, labeling could actually be a necessary step in studying the long-term health effects of genetically modified foods.

D. The Second Generation of Bioengineered Foods

In any case, recent developments in the agricultural biotechnology industry may make the current labeling debate moot. The biotech foods currently under development, deemed “second generation” bioengineered foods, are more likely to reflect the preferences of consumers.⁵¹⁸ Such consumer driven changes may improve the taste of a particular product, increase the products health benefits, or decrease the allergenic properties of the food.⁵¹⁹

The FDA has signaled that these “second-generation” products may be more likely to be subject to mandatory labeling requirements than the first generation counterparts, depending on their effects on nutrition.⁵²⁰ The fact that such bioengineered foods would be characterized by different nutritional qualities than their conventional counterparts may trigger mandatory labeling even under the FDA’s current materiality analysis.⁵²¹ Moreover, some scientists have suggested that functional foods may require the introduction of more complex genetic traits than those currently on the market, and may require more thorough safety review

⁵¹⁶Declan Butler & Tony Reichhardt, *Long-term Effect of GM Crops Serves up Food For Thought*, 398 NATURE 651, 651 (April 22, 1999).

⁵¹⁷*Id.*

⁵¹⁸*Next Generation Biotech Products Will Face Traditional Labeling Issues in U.S.*, FOOD CHEMICAL NEWS, July 13, 1998, available at 1998 WL 1098146

⁵¹⁹*Who’s Afraid*, *supra* note 438

⁵²⁰*Next Generation Biotech Products Will Face Traditional Labeling Issues in U.S.*, *supra* note 518.

⁵²¹*Next Generation Biotech Products Will Face Traditional Labeling Issues in U.S.*, *supra* note 518.

comparable to the kinds of testing required of new drugs entering the market.⁵²² Thus, the development of the technology to cater the biotech to consumers' preferences may itself bring about the labeling of those foods, and greater safety testing.

Moreover, as the foods themselves are designed to fulfill consumer needs and desires, producers will have built-in incentives to label them because the value of such foods for marketing purposes would depend on the manufacturer's ability to keep them separated from their traditional counterparts.⁵²³ Moreover, even some GM foods not explicitly designed to respond to consumer preferences may require identity labeling if, as in the case of the Flavr Savr Tomato, the product must be handled differently from conventionally grown products.⁵²⁴

Consumers are much more likely to be accepting of GM foods if they can directly reap benefits from those foods.⁵²⁵ Thus, if the second generation of genetically engineered foods truly offer the consumer benefits that the biotech companies are promising, the companies may be much more successful in convincing consumers to accept such foods.

Ultimately, the developing a strong and credible policy for GM foods requires both a commitment to strong scientific principles and an acknowledgment of the importance of the eating public's interests in a changing food supply. According to Dr. Peter Kareiva, senior ecologist for cumulative risk assessment at the National Oceanic and Atmospheric Administration, answers to the questions raised by biotechnology "will not come just from 'handing off a science answer like a stone tablet from the mountaintop.'" ⁵²⁶ He further argues that "any decision about what to do next will be determined not only by the magnitude of the risks and benefits, determined by scientists, but by the value placed on them by those making the decisions."⁵²⁷

⁵²²Butler & Reichhardt, *supra* note 516 at 651.

⁵²³*Sticky Labels*, *supra* note 160.

⁵²⁴Winn, *supra* note 342 at 685.

⁵²⁵*Trust, Emotion, Sex, Politics*, *supra* note 393 at 81.

⁵²⁶*What's Next for Biotech Crops?*, *supra* note 288.

⁵²⁷*What's Next for Biotech Crops?*, *supra* note 288.

FDA's current approach simply does not address the public's real concerns. The FDA's own consumer focus group study found that "[v]irtually all participants" favored labeling, and that "[v]irtually no one mentioned wanting to know the specific effects of bioengineering on the product as a reason for labeling. Instead, participants wanted to know whether the food was a product of biotechnology because they were concerned about the potential for unknown long-term effects of the technology."⁵²⁸ Moreover, FDA's assurances pointing to the absence of evidence proving that biotech foods are dangerous are not likely to truly address consumer concerns. As stated by Dr. Goldberg, "when you ask...[whether] these products [are] dangerous, I think you are asking the wrong question. Foods are not like pesticides. We don't ask are they dangerous; we ask are foods safe, and that is the question that the food and Drug Administration should be asking."⁵²⁹

Given the degree of scientific uncertainty about genetic engineering and the flexibility accorded to the FDA in the relevant labeling regulations, FDA's labeling policy represents a political calculation with political implications. While the FDA may consider the risk of consumer overreaction to a mandatory labeling regime to be unacceptably high, it should at least acknowledge that its labeling policy rests on these kinds of judgments, rather than on scientific evidence. Ultimately, labeling policy rests in large part on the discretion of the FDA. While scientific evidence about risks should inform the decisionmaking, such evidence ultimately cannot and should not determine such a discretionary decision.

⁵²⁸ *Consumer Focus Groups*, *supra* note 5 at 4.

⁵²⁹ *Biotechnology in the Year 2000 and Beyond*, *supra* note 22 at 121.