

NOTE

FINDING A COMPROMISE IN THE DEBATE OVER GENETICALLY MODIFIED FOOD: AN INTRODUCTION TO A MODEL STATE CONSUMER RIGHT-TO-KNOW ACT

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I. INTRODUCTION	
II. HISTORY OF GMO LABELING ISSUES.....	
A. <i>The FDA Rejects a Mandatory Labeling Approach</i>	
B. <i>Courts have Upheld Challenges to the FDA's Rejection of Mandatory Labels</i>	
C. <i>Constitutional Challenges to State GMO Statutes Emerge Under the Commerce Clause and the First Amendment</i>	
D. <i>Federal Law May Preempt State GMO Labeling Requirements</i>	
III. THE CONSUMER RIGHT-TO-KNOW MOVEMENT ADVANCES MORE THAN CURIOSITY	
IV. A MODEL STATE CONSUMER RIGHT-TO-KNOW ACT.....	
A. <i>The Right-To-Know Act's Proposed Statutory Scheme</i>	
1. Section (1) Defines Important Terms.....	
a. <i>Foods Containing GMOs</i>	
b. <i>Persons Who Should Register GMO Products</i>	
c. <i>GMO Database Information and Accessibility</i>	
2. Section (2) Directs the Appropriate Person to Register Required Information.....	
3. Section (3) Directs the State Agency in Discharging its Responsibilities	
4. Section (4) Outlines Enforcement; Liability; and Defense Provisions	
B. <i>The Compromise: What the Right-To-Know Act Can Do for Producers and Consumers</i>	
V. CONSTITUTIONAL CHALLENGES REVISITED: COURTS SHOULD UPHOLD THE RIGHT-TO-KNOW ACT	
A. <i>The First Amendment Does Not Protect Producers Against Required Disclosures Under the Right-To-Know Act</i>	
B. <i>The Commerce Clause Allows Disclosures Under the Right-To-Know Act</i>	
C. <i>Federal Law Does Not Preempt the Right-To-Know Act</i>	
VI. CONCLUSION.....	

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I. INTRODUCTION

The public interest controversy surrounding genetically modified organisms (“GMOs”)¹ has become a hotly contested political issue. To date, only the Food and Drug Administration (“FDA”) and the federal courts have attempted to resolve this controversy. Central to the controversy is that people feel that they should have access to all information relevant to make informed decisions that comply with their personal and political beliefs. Specifically, some consumers believe they have a right-to-know whether they are purchasing genetically modified food so that they can live in what they believe is the healthiest and safest way.

Private consumer buying power and government action affect the economy. This intersection has turned the GMO controversy into a debate in political economics.² In the American capitalist marketplace, consumer demand based on informed decision making presumptively guides competitive forces to ensure the survival and improvement of optimal products.³ When it comes to GMOs however, consumers cannot make informed decisions and competitive forces stall because the government fails to require producers to disclose that

¹ “Genetically modified organisms (GMOs) . . . can be defined as organisms . . . in which the genetic material (DNA) has been altered in a way that does not occur naturally by mating or natural recombination.” Europa Web site, *Food Safety: From the Farm to the Fork, Genetically Modified Organisms*, available at http://europa.eu.int/comm/food/fs/gmo/gmo_index_en.html. (last visited Dec. 31, 2002); see also U.S. Food and Drug Administration, Center for Food Safety and Applied Nutrition, Office of Scientific Analysis and Support, *Report on Consumer Focus Groups on Biotechnology*, available at www.cfsan.fda.gov/~comm/biorpt.html (Oct. 20, 2002) (“There are a variety of terms that are in use to describe foods produced through bioengineering, such as ‘genetically engineered,’ ‘genetically modified,’ ‘genetically modified organism (GMO),’ ‘modern biotechnology,’ ‘foods derived through biotechnology,’ ‘bioengineered foods,’ and ‘food derived through recombinant DNA techniques.’”).

² See JOHN STUART MILL, *PRINCIPLES OF POLITICAL ECONOMY* (D. Appleton & Co. 1884) (discussing political economics in general); BENJAMIN J. TAYLOR & FRED WITNEY, *U.S. LABOR RELATIONS LAW HISTORICAL DEVELOPMENT* 65-79 (Prentice-Hall, Inc. 1992) (detailing an analogous historical example of political economy within the U.S. labor movement at the turn of the 20th century wherein the labor movement tried to secure employee protections through legislation, only to have the courts severely limit, if not strike down altogether, labor friendly statutes); John C. Reitz, *Centennial World Congress On Comparative Law: Political Economy as a Major Architectural Principle of Public Law*, 75 TUL. L. REV. 1121, 1123-24 (2001) (defining political economy to mean the intersection of state power and market power in the various forms that occur in comparative politics and economics).

³ Robert H. Lande, *Consumer Choice as the Ultimate Goal of Antitrust*, 62 U. PITT. L. REV. 503, 503 (2001) (explaining antitrust law as a mechanism to ensure that the economy responds to consumer demand, thereby leading to “the best product quality and variety,” among other benefits).

2003] *MODEL STATE CONSUMER RIGHT-TO-KNOW ACT*

they are selling GMO products.⁴ Consumers do not know whether they are purchasing GMOs or food containing traditionally bred ingredients and are, therefore, denied the opportunity to meaningfully participate in this marketplace.⁵ In response, the GMO controversy has swelled, as consumer advocate groups have tried, although unsuccessfully, to get the government of both the federal and state levels to mandate GMO disclosure.⁶

This note addresses the current controversy, which has focused largely on labeling requirements for GMOs. Part II outlines the history of the GMO labeling controversy, including the FDA's involvement, subsequent court battles and potentially threatening legal challenges. Part III will then discuss the largely underrepresented interests advanced by consumers, while Part IV will propose a statutory scheme entitled the Model State Consumer Right-To-Know Act (the "Right-To-Know Act"). Next, Part V will discuss and attempt to resolve potential legal challenges to the Right-To-Know Act. Finally, Part VI, concludes this Note by summarizing how the Right-To-Know Act can work to satisfy the needs of both consumers and GMO producers while avoiding the legal and political hurdles that have blocked proposed mandatory labeling schemes.

Generally, the proposed statutory scheme under the Right-To-Know Act envisions a state managed database compiling the names of food products containing GMOs. GMO producers would have a mandatory duty to disclose GMO information to the state agency managing the database. The Right-To-Know Act would serve a consumer's interest just as well as a labeling scheme. GMO producers would find it easy to comply with the Act, both in terms of cost and public relations. Further, the Right-To-Know Act would likely sidestep many of the controversial issues surrounding GMO labeling.

⁴ U.S. Food and Drug Administration, Center for Food Safety and Applied Nutrition, Office of Scientific Analysis and Support, *Report on Consumer Focus Groups on Biotechnology*, available at www.cfsan.fda.gov/~comm/biorpt.html (Oct, 20, 2000); also Fred H. Degan, *Biotechnology and the Food Label: A Legal Perspective*, 55 FOOD DRUG L.J. 301, 302 (2000) (explaining the five pieces of information that the FDA requires on food labels, none of which include GMO contents).

⁵ *Alliance for Bio-Integrity v. Shalala*, 116 F. Supp. 2d 166, 181 (D.C. 2000); see also U.S. Food and Drug Administration, *supra* note 4.

⁶ S. 2080, 106th Cong. (2000) (attempting unsuccessfully to amend several federal acts to require GMO disclosure on product labels); H.R. 3377, 106th Cong. (1999); *Int'l Dairy Foods Ass'n v. Amestoy*, 92 F.3d 67, 69 (2nd Cir. 1996) (granting preliminary injunction against a Vermont statute requiring disclosure at the place of purchase for milk produced with rBST); *Alliance for Bio-Integrity*, 116 F. Supp. 2d at 181 (upholding the FDA's decision to treat GMOs the same as traditionally bred foods with respect to labeling requirements); Statement of Policy: Foods Derived From New Plant Varieties; Notice, 57 Fed. Reg. 22991 (Dept. of Health & Human Serv. 1992) (announcing that the FDA would treat GMOs the same as traditionally bred foods with respect to labeling requirements).

II. HISTORY OF GMO LABELING ISSUES

A. *The FDA Rejects a Mandatory Labeling Approach*

The FDA has received immense pressure from consumer groups to require labels disclosing GMO content in food.⁷ In response, the FDA commissioned a report, which found that not only do consumers favor mandatory labeling, but that consumers were surprised and even outraged to learn that GMOs were already on the market.⁸ The report also concluded that consumers found GMO content disclosure necessary to make educated purchasing decisions.⁹ Despite the public pressure and the results of the report, the FDA does not require GMO content disclosure.¹⁰

Consumer groups targeted the FDA because the Food, Drug, and Cosmetics Act (“FDCA”) grants the FDA the limited authority to regulate labels.¹¹ When “a food is misbranded [because] its labeling is false or misleading,” the FDCA authorizes the FDA to adopt and enforce labeling requirements.¹² A label is misleading if it:

fails to reveal facts material in the light of such representations or material with respect to consequences which may result from the use of the 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.¹³

Whether genetic engineering constitutes a “material” change to food has become the focus of a legal controversy. Both in the past and present, the FDA has applied the “materiality” analysis to characteristics of the end product.¹⁴ The FDA will find labeling information “material” in three general

⁷ Degnan, *supra* note 4, at 307; Karen A. Goldman, *Labeling of Genetically Modified Foods: Legal and Scientific Issues*, 12 GEO. INT’L ENVTL. L. REV. 717, 720 (2000); Alicia T. Simpson, Note, *Buying and Eating in the Dark: Can the Food and Drug Administration Require Mandatory Labeling of Genetically Engineered Foods?*, 19 TEMP. ENVTL. L. & TECH. J. 225, 226 (2001).

⁸ U.S. Food and Drug Administration, *supra* note 4.

⁹ *Id.*

¹⁰ *Alliance for Bio-Integrity*, 116 F. Supp. 2d at 179; also Statement of Policy: Foods Derived From New Plant Varieties; Notice, 57 Fed. Reg. at 22991.

¹¹ 21 U.S.C. § 341 (2000).

¹² 21 U.S.C. §§ 321(n), 343(a)(1).

¹³ *Id.* § 321(n).

¹⁴ Food and Drug Administration, Center for Food Safety and Applied Nutrition Web site, *Draft Guidance for Industry: Voluntary Labeling Indicating Whether Foods Have or Have Not Been Developed Using Bioengineering; Availability* [“Voluntary Labeling”], at <http://www.cfsan.fda.gov/~dms/biolabgu.html> (Jan. 2001).

2003] *MODEL STATE CONSUMER RIGHT-TO-KNOW ACT*

circumstances.¹⁵ These circumstances apply when (1) the product poses “special health or environmental risks,” (2) the product label may mislead the consumer “in light of other statements made on the label,” or (3) the consumer is prone to think that because a certain food has certain similarities to another food that they are the same, when they are in fact not the same.¹⁶

In 1992, however, the FDA announced in a policy statement, that it would not require unique labeling of GMOs because they were not materially different from traditional foods.¹⁷ The FDA did, in accordance with the “materiality” analysis, still list four exceptions to this general policy which could bring it to require special labeling of GMOs.¹⁸ The first exception applies when a food is “significantly different from its traditional counterpart such that the common or usual name no longer adequately describes the new food.”¹⁹ In this situation, the FDA would require the producers to change the name to one that illustrates the variation.²⁰ The second exception applies when “an issue exists for the food or a constituent of the food regarding how the food is used or consequences of its use,” and then “a statement must be made on the label to describe the issue.”²¹ The third exception applies when a “bioengineered food has significantly different nutritional property,” and then “its label must reflect the difference.”²² The last exception applies “[i]f a new food includes an allergen that consumers would not expect to be present based on the name of the food,” and then “the presence of that allergen must be disclosed on the label.”²³ Only where the GMO contents of the food meets one of these four narrow exceptions, will the FDA promulgate mandatory GMO labeling requirements.²⁴ Where the GMO contents of the food do not meet an exception, the FDA imposes the same labeling requirements for the GMO product as it does for a traditional food.²⁵

GMO producers have several arguments to support the FDA’s policy. First, the FDA ensures that GMO foods, which are not subject to additional labeling requirements, are nutritionally equivalent to non-GMO foods.²⁶ Second, the

¹⁵ *Id.*

¹⁶ *Id.*

¹⁷ *Id.* (citing Statement of Policy: Foods Derived from New Plant Varieties; Notice, 57 Fed. Reg. 22984 (Dept. of Health & Human Serv. 1992)).

¹⁸ *Id.*

¹⁹ *Id.*

²⁰ *See id.* (explaining how the FDA responds when a food has been materially changed).

²¹ *Id.*

²² *Id.*

²³ *Id.*

²⁴ *Id.*

²⁵ *Id.* (stating that the FDA should apply the same labeling requirements for bioengineered and food in general where one of the exceptions is not met).

²⁶ Larry Thompson, *Are Bioengineered Foods Safe?*, FDA CONSUMER, at 23

FDA also ensures that GMO producers design GMO foods and consumers eat GMO foods in the same manner as traditional foods.²⁷ Third, consumers, generally, cannot distinguish GMO and non-GMO foods.²⁸ Fourth, much of the scientific community has not found that bioengineered food creates a significant health or environmental hazard.²⁹

The FDA may have also decided against labeling because it wanted to prevent the public from misunderstanding and subsequently stigmatizing GMO food. GMO food products are bioengineered and bioengineering is considered a continuation of traditional breeding practices employed in traditional foods.³⁰ The FDA worries that although GMOs and traditional foods are both the products of “breeding” practices, labels noting the existence of, or absence of, genetically modified contents will spur consumers to conclude that GMO food products are inferior to traditional food products.³¹

Yet, many consider new techniques employed in bioengineering GMOs as more advantageous than the traditional methods because scientists arguably have more control over the genetic changes and can effect this change in less time.³² With traditional practices, scientists change the genetic makeup of a plant to exhibit the desired trait by grafting and cross-pollinating plants with the desired traits.³³ With GMOs, scientists can engineer plants to have increased nutritional properties and resistances that allow farmers to use fewer pesticides.³⁴

Even voluntary disclosure of the presence or absence of GMOs on labels may violate FDA regulations, because “[a] label that implies a food is better than another because it was, or was not, bioengineered would be misleading.”³⁵

(interviewing Dr. Jane E. Henney), *available at* <http://vm.cfsan.fda.gov/~dms/fdbioeng.html> (Jan. - Feb. 2000).

²⁷ *See id.* (explaining why consumers should not fear eating GMO foods).

²⁸ Statement of Policy: Foods Derived From New Plant Varieties; Notice, 57 Fed. Reg. at 22991.

²⁹ *See* Voluntary Labeling, *supra* note 14 (finding no basis to conclude that bioengineered food “present[s] any different or greater safety concern than foods developed by traditional plant breeding”).

³⁰ *See* Thompson, *supra* note 26, at 23.

³¹ *Id.*

³² Richard Caplan & Ellen Hickey, *Weird Science: A Brave New World of Genetic Engineering*, [gefoodalert.org available at](http://www.pirg.org/ge/GE.asp?id2=4811&id3=ge&) <http://www.pirg.org/ge/GE.asp?id2=4811&id3=ge&> (Oct. 31, 2001).

³³ *Id.*; Michael K. Hansen, *Genetic Engineering Is Not an Extension of Conventional Plant Breeding; How genetic engineering differs from traditional plant breeding, hybridization, wide crosses and horizontal gene transfer*, CONSUMERS UNION (1998), *available at* <http://www.consumersunion.org/food/widecpi200.htm>.

³⁴ Lakshman D. Guruswamy, *Sustainable Agriculture: Do GMOS Imperil Biosafety?*, 9 IND. J. GLOBAL LEGAL STUD. 461, 469-474 (2002).

³⁵ Thompson, *supra* note 26, at 23.

2003] *MODEL STATE CONSUMER RIGHT-TO-KNOW ACT*

The issue here is when such an implication may be inferred. The FDA has given confusing signals regarding whether producers can voluntarily and legally use labels specifically noting they do not use GMO ingredients. On one hand, the FDA has suggested that statements such as “[w]e do not use ingredients that were produced using biotechnology,” “[t]his oil is made from soybeans that were not genetically engineered,” or “[o]ur tomato growers do not plant seeds developed using biotechnology” would minimize misleading implications.³⁶ On the other hand, the FDA “will evaluate the *entire* label and packaging in determining whether a label statement is in a context that implies that the food is superior.”³⁷

This issue remains unresolved in the courts. One federal district court has discussed superiority implications in the context of foreign versus domestic meats. In *Armour & Co. v. Nebraska*,³⁸ the Nebraska District Court found that under a Commerce Clause inquiry, a state-required label affixed to out-of-state meat with the statement “[t]his meat is of foreign origin” implied the superiority of domestic meat.³⁹ The court reasoned that consumers would draw this inference because the label lacked another explanation for the consumer warning.⁴⁰ The opinion was based on nothing more than the mandatory statement on the label, possible signs near the meat display cases, and recordkeeping of the meat’s origin.⁴¹ It did not involve a contextual analysis of the entire label itself, as suggested by the FDA for GMO labels.⁴² Arguably, the FDA could find a label misleading under a contextual analyses more easily than under such a commerce clause analysis because it adds more ways for the FDA to find implied superiority.

For example, consider a box of multi-grain breakfast flakes bearing “organic” and “all natural” labels, and which includes the statement, “we do not use ingredients that were produced using biotechnology.”⁴³ This statement would appear to run dangerously close to being contextually misleading, even though an “organic” label may not indicate superiority for the same concern of misleading consumers.⁴⁴ Even so, target consumers believe that organic foods are superior to conventional foods.⁴⁵

³⁶ Voluntary Labeling, *supra* note 14.

³⁷ *Id.* (emphasis added).

³⁸ 270 F. Supp. 941 (D. Neb. 1967).

³⁹ *Id.* at 945-946.

⁴⁰ *Id.*

⁴¹ *Id.* at 942-944.

⁴² *See* Voluntary Labeling, *supra* note 14.

⁴³ *Id.*

⁴⁴ *Id.*

⁴⁵ Organic Consumers Association, *Why Americans are Voting with Forks, Knives & Wallets*, available at <http://www.organicconsumers.org/newsletter/orgviewdec00.cfm#Why>. (Winter 2000-2001).

Health food producers may also try to affix statements in hopes of attracting consumers who believe that GMOs are inferior.⁴⁶ Finally, other non-GMO producers may attempt to appeal to sophisticated consumers by affixing to the label the statement “grown in accordance with European Union law” in reference to the European Union’s de facto ban on GMOs.⁴⁷ Until this issue is litigated, non-GMO food producers will increase their exposure to law suits by continuing to market products with labels referring to health or environmental issues and the absence of GMO ingredients.

B. Courts Have Upheld Challenges to the FDA's Rejection of Mandatory Labels

The Alliance for Bio-Integrity International Center for Technology Assessment (“The Alliance”) is one consumer advocate group which legally challenged the FDA’s decision to forgo mandatory labeling.⁴⁸ The Alliance claimed, among other things, that the FDA’s presumption about GMO safety, and its subsequent decision against requiring GMO labels was arbitrary and capricious.⁴⁹ The District Court held that the FDA’s interpretation of the FDCA and factual determinations regarding GMOs was reasonable.⁵⁰

Specifically with respect to labeling, the Court noted, “Congress has not squarely addressed whether materiality pertains only to safety concerns or whether it also includes consumer interest.”⁵¹ As a result, the court looked to the FDA,⁵² which interpreted the FDCA to authorize mandatory labeling only where there are “unique risks to consumer health or uniform changes to food derived through [genetic engineering].”⁵³ Further, the FDA would not consider consumer demand as it pertained to labeling requirements until it established materiality.⁵⁴ Based on this interpretation, the Alliance could not

⁴⁶ See, e.g., Michael Potter, *Eden Chairman and President on Genetically Modified Foods*, available at <http://www.edenfoods.com/info/02282001.html> (Feb. 28, 2001) (declaring Eden Foods does not support GMOs because they are dangerous and including a statement after Mr. Potter’s signature that “The EDEN brand means...no genetically engineered ingredients” among other things).

⁴⁷ Charles W. Smitherman, III, Comment, *World Trade Organization Adjudication of the European Union-United States Dispute Over the Moratorium on the Introduction of New Genetically Modified Foods to the European Common Market: A Hypothetical Opinion of the Dispute Panel*, 30 GA. J. INT’L & COMP. L. 475, 476 (2002).

⁴⁸ Alliance for Bio-Integrity v. Shalala, 116 F. Supp. 2d 166, 170 (D.D.C. 2000).

⁴⁹ *Id.*

⁵⁰ *Id.* at 178-79.

⁵¹ *Id.* at 178.

⁵² The court followed administrative law’s well-established principle that it should defer to agency action in cases involving scientific and technical issues. *Id.* at 176-77.

⁵³ *Id.* at 178-79.

⁵⁴ *Id.*

2003] *MODEL STATE CONSUMER RIGHT-TO-KNOW ACT*

successfully challenge the FDA's decision against requiring GMO labeling.

C. *Constitutional Challenges to State GMO Labeling Statutes Emerge Under the Commerce Clause and the First Amendment*

Some state legislatures have passed laws requiring GMO labeling despite the FDA's decision against labeling. In response, food producers have challenged these laws on Commerce Clause and First Amendment grounds. For example, the Vermont State Legislature attempted to require mandatory labeling of milk produced using the growth hormone rBST, which was sold within state boundaries.⁵⁵ In *International Dairy Foods Association v. Amestoy*,⁵⁶ the dairy producers brought suit in federal court challenging the law on the grounds that it violated both the First Amendment and the Commerce Clause.⁵⁷ On appeal, the Second Circuit sided with the dairy producers and reversed the lower court's denial of a preliminary injunction motion against enforcement of the Vermont labeling statute.⁵⁸

To secure a preliminary injunction, the dairy producers had to show irreparable harm and likely success on the merits at trial.⁵⁹ The court found that the dairy producers satisfied both prongs of this test under the First Amendment argument.⁶⁰ After finding for the dairy producers on their second claim under the First Amendment, the court failed to consider their first claim under the Commerce Clause.⁶¹

With respect to the first prong, "irreparable harm," preliminary injunction petitioners benefit by a First Amendment violation holding because it can apply to both state and federal laws. Additionally, a court might find it difficult for a petitioner to satisfy the "irreparable harm" prong under a Commerce Clause argument where the damage is primarily economic. The purpose of the Commerce Clause is to keep trade among the states free from tariffs and impediments.⁶² The First Amendment, on the other hand, advances rights that have intrinsic value, and prevents tyranny.⁶³ "[T]he loss of First Amendment freedoms, for even minimal periods of time, unquestionably

⁵⁵ VT. STAT. ANN. tit. 6, § 2754 (1994) (repealed on Mar. 30, 1998 pursuant to 1997, No. 61, § 272i). The rBST hormone neither genetically altered the milk nor the cow, but rather it stimulates milk production in the cow. See *Int'l Dairy Foods Ass'n v. Amestoy*, 92 F.3d 67, 69 (2d Cir. 1996).

⁵⁶ 898 F. Supp. 246 (D. Vt. 1995).

⁵⁷ *Id.*

⁵⁸ *Amestoy*, 92 F.3d at 69.

⁵⁹ *Id.* at 70.

⁶⁰ *Id.*

⁶¹ *Id.*

⁶² NORMAN REDLICH, ET AL., UNDERSTANDING CONSTITUTIONAL LAW, § 5.01 (2nd ed. 1999).

⁶³ *Amestoy*, 92 F.3d at 71.

constitutes irreparable harm.”⁶⁴ There is no similar per se argument under the Commerce Clause. For these reasons, the First Amendment analysis with regard to irreparable harm served the dairy producers’ interests more than a Commerce Clause analysis.

With respect to the second prong, “likely success on the merits at trial,” the court looked to the four-prong test for First Amendment protection of commercial speech set out in *Central Hudson Gas & Electric Corp. v. Pub. Serv. Comm’n of New York*.⁶⁵ The test includes: (1) the activity must be lawful and not misleading, (2) the government must assert a substantial interest, (3) the restriction must directly advance the substantial interest asserted, and (4) the restriction must be narrowly tailored.⁶⁶ The court found that the producers would likely prevail on the merits because Vermont failed to assert a substantial interest as required in prong two.⁶⁷ “Substantial interests” cannot be based on “mere speculation or conjecture,” but rather, they must be based on “real” harms to the public.⁶⁸ Here, Vermont’s assertion of “strong consumer interest” and the “public’s right to know,” did not identify real harms and were, therefore, not sufficient to establish a substantial interest.⁶⁹

The dissent took issue with the majority’s characterization of the interests Vermont asserted.⁷⁰ The dissent argued that district court had correctly identified four distinct and substantial state interests.⁷¹ These interests included that (1) Vermont citizens considered the use of rBST “unnatural,” (2) they feared its use would hurt small dairy farmers because increased production would lead to severe price competition, (3) they “believe[d] that rBST [was] harmful to cows and potentially harmful to humans,” and (4) they were concerned about the unknown long-term effects of its use.⁷² Unfortunately, neither the majority nor the dissent was proved correct because the Legislature subsequently repealed the labeling statute and the case never proceeded to trial.⁷³

D. Federal Law May Preempt State GMO Labeling Requirements

Courts have not addressed whether FDA regulations and policy, the FDCA,

⁶⁴ *Id.*

⁶⁵ 447 U.S. 557, 566 (1980) (listing the four prongs of a First Amendment analysis of commercial speech).

⁶⁶ *Id.*

⁶⁷ *Amestoy*, 92 F.3d at 73-74.

⁶⁸ *Id.* at 73 (citing *Edenfield v. Fane*, 507 U.S. 761, 770-71 (1993)).

⁶⁹ *Id.* at 73-74.

⁷⁰ *Id.* at 74-78 (Leval, J., dissenting) (detailing and examining the interests advanced by the state of Vermont).

⁷¹ *Id.* at 75-76 (citing *Amestoy*, 898 F. Supp. at 250).

⁷² *Id.*

⁷³ VT. STAT. ANN. tit. 6, § 2754 (1994) (noting the Vermont Act’s repeal).

2003] *MODEL STATE CONSUMER RIGHT-TO-KNOW ACT*

or the Nutrition Labeling and Education Act (“NLEA”) would preempt a state GMO labeling statute. Statutory preemption can be “conceptualized as marking out a continuum of conflict between state and federal regulations.”⁷⁴ At one end of the continuum the federal and state regulations unavoidably conflict and the federal regulation will preempt the state law.⁷⁵ At the other end of the continuum the federal and state regulations “operate independently,” and the state law remains valid.⁷⁶ Along the continuum lies “varying degrees of potential [conflict] between the federal and state interests.”⁷⁷ In this situation, courts declaring any preemption will consider local and national interests, “accommodating local interests wherever possible.”⁷⁸

In their preemption analysis, courts also look to Congressional intent.⁷⁹ Specifically, courts look at whether Congress expressly stated its intent to preempt state law.⁸⁰ If the court finds an express statement, it will then examine the scope of the preemption.⁸¹ If the state regulation operates outside the express reach of the federal regulation, it remains valid.⁸² Where there is no express statement to preempt, federal law may preempt state law where it is an obstacle to the federal law’s objective or purpose.⁸³ Federal law may also preempt state law where Congress has intended to occupy the field.⁸⁴

The NLEA’s provisions may preempt State GMO labeling regulations. Under the NLEA’s express preemption language, states may not regulate food labeling concerning nutritional content, health claims, standards of identity, misbranding related to common names, imitation foods, and misleading containers.⁸⁵ Congress did explicitly exempt any state regulation requiring label warnings relating to health and safety from NLEA preemption.⁸⁶ The NLEA, however, also expressly prohibits states from requiring any labeling “that is not identical to the common name requirement under the FDCA,” and where the “FDA has established a standard of identity and [the state

⁷⁴ Dan L. Burk, *The Milk Free Zone: Federal and Local Interests in Regulating Recombinant bST*, 22 COLUM. J. ENVTL. L. 227, 249 (1997) (citing Kenneth L. Hirsch, *Toward a New View of Federal Preemption*, 1972 U. ILL. L. REV. 515, 519 (1972)).

⁷⁵ *Id.*

⁷⁶ *Id.*

⁷⁷ *Id.*

⁷⁸ *Id.*

⁷⁹ *Id.* (citing *Cipollone v. Liggett Group, Inc.* 505 U.S. 504, 517 (1992)).

⁸⁰ *Id.* (explaining express preemption).

⁸¹ *Id.* at 250.

⁸² *Id.*

⁸³ JACK BEERMAN, ADMINISTRATIVE LAW 191 (Aspen Law & Business 2000).

⁸⁴ *Id.* (defining “field” preemption).

⁸⁵ Burk, *supra* note 74, at 259 (citing 21 U.S.C. § 343-1 (1993)).

⁸⁶ *Id.* at 260 (citing Pub. L. No 101-535, § 6(b), 104 Stat. at 2363-2364)).

regulation] does not conform to the FDA standard.”⁸⁷ Currently, the FDA does not consider GMO food dangerous to an individual’s health and safety.⁸⁸ Therefore, a State GMO labeling regulation may not conform to the FDA standard and GMO producers have a strong argument that the NLEA preempts the state regulation of GMO labeling.

However, an argument can be made that the NLEA should not preempt state labeling regulations where the state regulation complies with federal standards, but makes additional demands that do not convey nutritional value or differences.⁸⁹ If the NLEA’s purpose is to establish “uniform national standards for informing consumers of nutritional value of certain foods,” then labels designed to assist consumers in making “political or ethical assessment of the product” should not run afoul of congressional intent.⁹⁰ The problem remains, however, that even if this argument holds, consumer advocate groups still must worry that a state GMO labeling regulation may be unconstitutional under the First Amendment.⁹¹

Another argument against preemption is that a state’s traditional police powers encompass the regulatory power to require labels disclosing GMO content.⁹² Absent a “clear and manifest” congressional intent to preempt, a court will likely uphold a state statute regulating a field traditionally considered within a state’s police powers, such as health, safety, misrepresentation or fraud.⁹³ The problem with this argument is that the FDA, the courts, and the mainstream scientific community do not consider GMOs a health and safety hazard.⁹⁴ It is also unlikely that the sale of GMOs constitutes fraud because traditional and bioengineered food “do not differ in any meaningful or uniform way.”⁹⁵ Consumer advocate groups continue to argue that there is a material change in the food when, for example, a plant is bioengineered to have a gene from a different scientific kingdom.⁹⁶ Whether this constitutes “misleading the public” is discussed in Part V.

State regulatory agencies and the FDA have long operated concurrently over matters of consumer welfare and food safety, despite the FDCA’s

⁸⁷ Burk, *supra* note 74, at 260-61.

⁸⁸ Voluntary Labeling, *supra* note 14.

⁸⁹ Burk, *supra* note 74, at 263-64.

⁹⁰ *Id.* at 262-64.

⁹¹ See *supra* Part II.C. (discussing constitutionality of state GMO labeling regulations under the First Amendment).

⁹² Burk, *supra* note 74, at 251.

⁹³ *Id.*

⁹⁴ *Amestoy*, 92 F.3d at 71-73; *Alliance for Bio-Integrity*, 116 F. Supp. 2d at 176-77; see also Voluntary Labeling, *supra* note 14.

⁹⁵ Statement of Policy: Foods Derived From New Plant Varieties; Notice, 57 Fed. Reg. at 22991.

⁹⁶ Caplan & Hickey, *supra* note 32.

2003] *MODEL STATE CONSUMER RIGHT-TO-KNOW ACT*

comprehensive and pervasive system of regulations.⁹⁷ Consequently, the FDCA and the FDA are unlikely to block state action in these fields under a field preemption theory.⁹⁸ States, however, must still be mindful that the FDCA and the FDA may preempt state action in these fields where the state regulation acts as an obstacle to the purpose of the FDCA and the FDA.⁹⁹ The reasons for this are twofold. First, federal oversight is intended to eliminate unsafe or hazardous food from the American marketplace.¹⁰⁰ Second, and equally important, federal oversight is designed to promote safe and nutritious food in the American marketplace.¹⁰¹ GMO producers have a strong argument that where the FDA has found foods containing GMOs safe and nutritious, and scientific evidence cannot prove otherwise, state regulations finding to the contrary would frustrate the second purpose of federal oversight.¹⁰²

III. THE CONSUMER RIGHT-TO-KNOW MOVEMENT ADVANCES MORE THAN CURIOSITY

Refuting the FDA, consumer advocate groups argue that GMOs are “materially” different because they contain a hybrid of genetic material, which was never thought possible.¹⁰³ The Genetically Engineered Food Alert Campaign (the “Campaign”) denies that genetic engineering is an extension of traditional plant breeding.¹⁰⁴ Traditional methods use two of the same or closely related species to breed plants and therefore, the desired trait is already a part of the species genetic makeup.¹⁰⁵ Genetic engineering represents a radical departure from traditional methods because scientists now “breed” between different species, families or kingdoms.¹⁰⁶ For example, scientists have inserted chicken genes into apples, human genes into corn, rice and potatoes, and cow genes into soybeans and sugarcane.¹⁰⁷

Consumer advocate groups deny the opinion commonly asserted by GMO supporters, producers, and the FDA that genetic engineering is more precise

⁹⁷ Burk, *supra* note 74, at 266.

⁹⁸ *Id.*

⁹⁹ *Id.* at 267.

¹⁰⁰ *Id.*

¹⁰¹ *Id.*

¹⁰² *Id.*

¹⁰³ Caplan & Hickey, *supra* note 32, at 3.

¹⁰⁴ *Id.* (refuting the claims of the FDA and some private corporations who are involved in GMO production that bio-engineering food is a natural extension of traditional plant breeding).

¹⁰⁵ Thompson, *supra* note 26, at 23.

¹⁰⁶ Caplan & Hickey, *supra* note 32, at 2-3 (explaining that bio-engineering creates combinations that are too radical to be considered a natural extension of traditional plant breeding methods).

¹⁰⁷ *Id.* at 5.

and, therefore, safer than traditional methods.¹⁰⁸ Techniques, such as directly inserting genes using a “gene gun” or transferring DNA through bacteria, do not provide great control over where the genetic material is inserted.¹⁰⁹ In the 1990s, farmers in Mississippi, Arkansas, Tennessee, Missouri and Texas experienced crop failures of genetically engineered cotton.¹¹⁰ In 1997, Monsanto, the largest developer of GMOs, had to recall approximately 60,000 bags of canola, which it had mistakenly inserted with an unapproved gene.¹¹¹ Again, in May 2000, Monsanto disclosed that their soybeans contained unapproved genetic material accidentally inserted.¹¹² Monsanto’s genetically engineered soybeans have also not measured up to traditional soybeans, growing less in height and showing increased splitting in the stems.¹¹³

Consumer advocate groups point out that genetic engineers use marker genes and gene promoters that could pose serious risks to human health and the environment.¹¹⁴ Scientists insert marker genes with the gene controlling the desired trait to help determine if the insertion was successful.¹¹⁵ A commonly used marker gene is a bacterial gene for antibiotic resistance.¹¹⁶ These bacterial genes could pose problems for antibiotic resistance in humans and animals, or could find their way to disease causing bacteria to form new antibiotic-resistant diseases.¹¹⁷ In addition, scientists insert gene promoters to maximize the likelihood that the GMO food expresses the desired trait.¹¹⁸ The effects of this procedure vary depending on where the promoter gene is inserted, something over which scientists do not have precise control.¹¹⁹ Specifically, some scientists are concerned that the use of a common gene promoter from the Cauliflower mosaic virus “may result in a major source of new viruses arising from recombination.”¹²⁰

Consumer groups have also expressed concern over the potential for GMOs

¹⁰⁸ See *id.* at 3 (challenging the assertion that gene insertion, a form of bio-engineering, can be done with great accuracy).

¹⁰⁹ *Id.*

¹¹⁰ *Id.* at 4.

¹¹¹ *Id.* at 3 (providing specific examples where gene insertion, a form of bioengineering, has not proven to be as reliable as represented by GMO supporters).

¹¹² *Id.*

¹¹³ *Id.*

¹¹⁴ *Id.* at 3 (explaining how marker genes are used and why some scientists and the British Medical Association have serious concerns about the risks they pose to human health).

¹¹⁵ *Id.*

¹¹⁶ *Id.*

¹¹⁷ *Id.* (explaining that the primary concern with marker genes is the human immune system’s ability to defend itself from viruses).

¹¹⁸ *Id.* at 4.

¹¹⁹ *Id.*

¹²⁰ *Id.*

2003] *MODEL STATE CONSUMER RIGHT-TO-KNOW ACT*

to cross-pollinate with traditionally bred or wild plants.¹²¹ Cross-pollination could “change the basic nature of a plant” and possibly disrupt entire ecosystems.¹²² In a study comparing three lines of a mustard family plant (two genetically engineered and one traditionally bred), scientists found that the genetically engineered lines were 4 to 36 times more likely to cross-pollinate than the line using traditional methods.¹²³

While consumer advocate groups raise legitimate concerns, GMO supporters assert that these groups are really fearful of the unknown health and environmental hazards of GMOs.¹²⁴ The FDA and GMO supporters argue that there has never been a showing, or even a single report, verifying hazards caused by GMOs or presenting evidence in support of consumer fears.¹²⁵ Studies do show, however, a serious potential for health and safety hazards, even if consumer groups cannot document an actual catastrophe to date.¹²⁶ The FDA’s position ignores this potential threat; a threat which if proved true could cause irreparable damage.¹²⁷ The United States Public Interest Research Group characterizes the United States Department of Agriculture’s current field tests as using the environment for “a laboratory for widespread experimentation of genetically engineered organisms with profound risks that, once released, can never be recalled.”¹²⁸ Undoubtedly, it is precisely the unknown that concerns some consumer advocate groups.

Aside from health and environmental safety concerns, consumer advocate groups are also concerned about a consumer’s choice to exercise one’s conscience through purchasing power.¹²⁹ Consumers may also want to avoid GMOs because of religious or dietary restrictions, or because of philosophical objections to what they perceive as inappropriate interference with nature.¹³⁰ Lastly, consumers may want the simple ability to choose what they eat,

¹²¹ *Id.* (detailing a study in which bio-engineered plants had an unexpectedly high rate of cross-pollination).

¹²² *Id.*

¹²³ *Id.*

¹²⁴ Kelly A. Leggio, Comment, *Limitations on the Consumer's Right to Know: Settling the Debate Over Labeling of Genetically Modified Foods in the United States*, 38 SAN DIEGO L. REV. 893, 907 (2001).

¹²⁵ *Id.* at 906; see also Thompson, *supra* note 26, at 20.

¹²⁶ Caplan & Hickey, *supra* note 32.

¹²⁷ Richard Caplan, *Raising Risk: Field Testing of Genetically Engineered Crops in the U.S.*, p. v., PIRG.org, available at <http://www.pirg.org/ge/GE.asp?id2=4802&id3=ge&> (June 2001).

¹²⁸ *Id.* at vi.

¹²⁹ U.S. Food and Drug Administration, *supra* note 4.

¹³⁰ *Id.*; see also *Alliance for Bio-Integrity*, 116 F.Supp. 2d at 179-180; Mary Jane Angelo, *Genetically Engineered Plant Pesticides: Recent Developments in the EPA's Regulations of Biotechnology*, 7 U. FLA. J.L. & PUB. POL'Y 257, 288 (1996).

irrespective of any environmental or health risks involved.¹³¹

IV. A MODEL STATE CONSUMER RIGHT-TO-KNOW ACT

A. *The Right-To-Know Act's Proposed Statutory Scheme*

The Right-To-Know Act's basic scheme envisions the appropriate person along the food distribution food chain registering the names of all products containing GMOs with an appropriate state agency, whereby consumers can access the information from a database maintained by the state agency. The following discussion is an introduction to the substance of the Right-To-Know Act.

1. Section (1) Defines Important Terms

Section (1) of the Right-To-Know Act should define the terms contained therein. Several of the terms and concepts will play a definitive role in the scope of the Right-To-Know Act. This discussion defines only the most critical terms.

a. *Foods Containing GMOs*

First, the Act must define what constitutes "containing GMOs." If something contains GMOs a producer will need to register the food product with the appropriate state agency. Two recently proposed congressional bills, each entitled "The Genetically Engineered Food Right-to-Know Act," provide guidance.¹³² The proposed Act divides "containing GMOs" into two main definitions. One definition, termed "genetically engineered material," would cover products like the milk produced with rBST in *Amestoy* where the final product is not a GMO, but the manufacturing process uses GMOs. The proposed Act defines "genetically engineered material" as:

material derived from any part of a genetically engineered organism, without regard to whether the altered molecular or cellular characteristics of the organism are detectable in the material.¹³³

The second definition, termed "genetically engineered organism," would cover products like corn where the end product itself has been genetically altered. The proposed Act defines "genetically engineered organism" as:

- a) An organism that has been altered at the molecular or cellular level by means that are not possible under natural conditions or processes (including but not limited to recombinant DNA and RNA techniques,

¹³¹ *Id.*

¹³² H.R. 3377, 106th Cong. (1999) (proposing a labeling scheme to override the FDA's determinations); *see also* S. 2080, 106th Cong. (2000).

¹³³ *Id.*

2003] *MODEL STATE CONSUMER RIGHT-TO-KNOW ACT*

cell fusion, microencapsulation, macroencapsulation, gene deletion and doubling, introducing a foreign gene, and changing the positions of genes), other than a means consisting exclusively of breeding, conjugation, fermentation, hybridization, in vitro fertilization, or tissue culture, and

- b) An organism made through sexual or asexual reproduction (or both) involving an organism described in subsection (a), if possessing any of the altered molecular or cellular characteristics of the organism so described.¹³⁴

This bifurcation of the GMO definition is useful to consumers because it identifies either food which is genetically altered or food which is derived from a process utilizing genetically altered material. Consumers are usually concerned about both these types of foods.¹³⁵ Any Right-to-Know Act should include both categories of GMOs.

The definition of “containing GMOs” should also include products which *may* contain GMOs. Many times producers store food products indiscriminately, mixing traditional and bioengineered foods together.¹³⁶ This is especially true for corn producers.¹³⁷ If there is even a possibility that a food product contains GMOs, then the food producer must register the product.

b. Persons Who Should Register GMO Products

The Right-to-Know Act should also define who in the food distribution chain has the responsibility to register “containing GMO” information with the appropriate state agency. For purposes of this definition, the “appropriate person” required to register should include individual people, sole proprietors, and corporations. The responsibility to register should also lie with one party to avoid multiple and inefficient registering. The person at the beginning of the food distribution chain is least likely to know if the end product contains GMOs. For example, a corn producer may not know all of the food products its corn will go into. The person at the end of the food distribution chain is most likely to know which ingredients contain GMOs. In response, the Right-To-Know Act should require the person most likely to know whether the food product contains GMOs to register. Under this standard, the person already required by the FDA to put its name and contact information on the label,

¹³⁴ *Id.*

¹³⁵ U.S. Food and Drug Administration, *supra* note 4 (detailing consumer interests to include fear of unknown long-term health affects and the ability “to support or not support the dissemination of the technology” through purchasing power).

¹³⁶ Shirley A. Coffield, *The Management and Resolution of Cross Border Disputes as Canada/U.S. Enter the 21st Century: Biotechnology, Food, and Agriculture Disputes or Food Safety and International Trade*, 26 CAN.-U.S. L.J. 233, 237 (2000).

¹³⁷ *Id.*

should also be the person who has to register under the Act.¹³⁸ This person must already claim responsibility for the product to the consumer, so requiring that person to disclose GMO information under the Right-to-Know Act would be a reasonable extension of that existing duty. This standard is also preferable because it clearly and unambiguously defines who has the registering responsibly.

c. GMO Database Information and Accessibility

The Right-To-Know Act should identify what information a state agency needs to collect from a person to put into a database. This database should include only the most basic information about GMO food products. The purpose of the database is simply to identify those products that are GMOs, contain GMO ingredients, or were manufactured using GMOs. The database will not divulge sensitive information that a person could use to gain an unfair competitive advantage. Specifically, The Right-To-Know Act should define “registration information” to require the appropriate person to register the “name of the product” and the appropriate person’s “name”, “address” and “phone number.”

The Act should define “name of the product” to mean the product’s title as it appears on the final packaging for purchase by the end consumer. This definition of “name of the product” is preferable because it best informs a consumer’s purchasing decision.¹³⁹ The Act should define the appropriate person’s “name” to mean the name of that person as it will appear on the final packaging, and as required by the FDA.¹⁴⁰ The Act should define the person’s “address” to mean the address of that person’s headquarters, or where that person receives correspondence, whichever better facilitates communication. The Act should define the appropriate person’s “phone number” to mean the phone number at that person’s headquarters, or where consumers receive the most responsive customer service, whichever better facilitates communication.

The Right-to-Know Act would require the appropriate person to register GMO information defined above with an “appropriate state agency.” State legislatures have the responsibility of deciding which is the “appropriate state agency.” State legislatures should require those state agencies with which businesses already interact to store Right-to-Know Act information in a database. Using these agencies makes it easier for the appropriate person to comply with the Act. For purposes of the Act, “consumer” does not include

¹³⁸ See Degnan, *supra* note 4, at 302 (explaining that from its inception in 1938, the FDCA has required that labels display “the name and address of the manufacturer or responsible party involved in the marketing of the food”).

¹³⁹ See U.S. Food and Drug Administration, *supra* note 4.

¹⁴⁰ Degnan, *supra* note 4, at 302 (explaining that the FDCA has required from its inception in 1938 that labels display “the name and address of the manufacturer or responsible party involved in the marketing of the food”).

2003] *MODEL STATE CONSUMER RIGHT-TO-KNOW ACT*

wholesalers, distributors, or manufacturers. The purpose of the Act is to inform the consumer selecting food from the grocery store shelf, and therefore, “consumer” encompasses this class of individuals.

2. Section (2) Directs the Appropriate Person to Register Required Information

Section (2) of the Right-To-Know Act directs the appropriate person in their mandatory disclosure duty.¹⁴¹ This section simply directs the appropriate person to register certain information with the appropriate state agency. It reads:

All appropriate people responsible for the in-state sale of foods that are genetically engineered material or genetically engineered organisms shall register with the appropriate state agency. The registration information shall include:

- a) Name of the Product; and
- b) The Appropriate Person's Name, Address, and Phone Number.

3. Section (3) Directs the State Agency In Discharging Its Responsibilities

Section (3) of the Right-to-Know Act should outline the appropriate state agency's responsibilities. The state agency must construct, format, and maintain a database containing the registered information. State legislatures can decide how to construct, format and maintain its GMO database. Each legislature must conform, however, to certain accessibility standards because the easier a consumer can access and understand the database information, the more effective the Right-To-Know Act will be. The state agency must provide free access to the database, via the Internet, in a format which facilitates easy browsing. The database should allow consumers to search the database using various categories. These categories would include the four types of registered information (name of the product and the appropriate person's name, address and phone number), and different food subjects, such as “fruit,” “dairy,” “poultry,” and “cereal.”

The state agency is also responsible for satisfying consumer information requests. Not every consumer is comfortable using the Internet and may prefer to deal directly with the state agency. Specifically, the state agency would have to respond in writing with an answer to a consumer request for relevant information. State legislatures should set a response time period, such as 30 days, from when it receives the request. This section reads:

The appropriate state agency shall

- a) Receive the registrations made by persons pursuant to Section (2);

¹⁴¹ See *id.*

- b) Maintain a database of the registration information received; and
- c) Respond to a written request for information
 - i) Provided that the request is within the scope of the database; and
 - ii) Within 30 days from the date of receipt of the request.

Should the consumer request information outside of the scope of the database, the appropriate state agency shall:

- a) Respond to only the portion of the request that pertains to information maintained in the database; and
- b) Explain in its written response which portions of the request it was not able to respond to because that information is outside the scope of Section (2).

4. Section (4) Outlines Enforcement; Liability; and Defense Provisions

Section (4) of the Right-to-Know Act should cover administrative and judicial procedures, including enforcement mechanisms, liabilities imposed, and available defenses. The Act would make a failure to register a civil offense subject to penalty of a fine.¹⁴² State legislatures should use their discretion in determining the fine amount. In making that determination, legislatures should set the fine at an amount which provides people with an incentive to register. Similarly, legislatures should increase the fine each day the person fails to register.

The Right-to-Know Act should entrust private citizens and consumer groups, in addition to state agencies, with the responsibility of ensuring compliance. The administrative cost associated with having a state agency enforce the Act's provisions may prove too burdensome. Therefore, granting prudential standing to citizens to litigate compliance will better ensure enactment and enforcement. Private citizens and consumer groups could sue a person alleged to have failed to register, provided they can show constitutional standing to bring the case.¹⁴³ Upon successful adjudication, courts should direct a liable person to pay the fine and attorney's fees directly to the private citizen or consumer group bringing the suit. The burden to prove a failure to register will rest with the private citizen or consumer group in order to avoid an onslaught of Right-to-Know Act litigation.

If the private citizen or consumer group satisfies its initial burden, then the defending party can assert appropriate defenses. The proposed "Genetically

¹⁴² See, e.g., H.R. 3377, § 3(b) (detailing civil fines appropriate as a model for the Consumer Act); S. 2080, § 3(d).

¹⁴³ Dash T. Douglas, *Standing on Shaky Ground: Standing Under the Fair Housing Act*, 34 AKRON L. REV. 613, 614-615 (2001) (explaining constitutional limits under Article III to essentially require "actual" or "imminent" injury which is a "concrete and particularized" interference with a "judicially cognizable" right "fairly traceable to the challenged action of the defendant," commonly referred to in short hand as "injury-in-fact" (quoting *Lujan v. Defenders of Wildlife*, 504 U.S. 555, 560-561 (1992)).

2003] *MODEL STATE CONSUMER RIGHT-TO-KNOW ACT*

Engineered Food Right-to-Know Act” currently provides some guidance on appropriate defenses.¹⁴⁴ It provides a limited set of circumstances where a person is free from liability.¹⁴⁵ The Right-to-Know Act should use the same defense provisions so as to prevent it from becoming a strict liability scheme. Strict liability should only be applied to the most dangerous of business undertakings for specific policy reasons which are not applicable here.¹⁴⁶ Instead, the Right-To-Know Act should employ a negligence standard.¹⁴⁷ Therefore, a court could not hold a person liable if it negligently sells GMO food. Specifically, the negligence standard is set within a defense provision reading:

No person shall be subject to the penalties . . . or violation . . . involving the misbranding of food . . . if:

- a) Such person is an agricultural producer and the violation occurs because food that is grown, raised, or otherwise produced by such producer, which food does not contain a genetically engineered material and was not produced with genetically engineered material, is contaminated with a food that contains a genetically engineered material or was produced with a genetically engineered material (including contamination by mingling the two); and
- b) The agricultural producer does not intend such contamination.

The above Section does not apply to an agricultural producer to the extent that the contamination occurs as a result of the negligence of the producer.¹⁴⁸

The Right-to-Know Act will also allow a person to escape liability if the person signed a guaranty that the food is not contaminated with GMOs. This subsection states that:

No person shall be subject to the penalties...for a violation...involving the misbranding of food...if such person (referred to in this paragraph as the ‘recipient’) establishes a guaranty or undertaking signed by, and containing the name and address of, the person residing in the United States from whom the recipient received in good faith the food (including the receipt of seeds to grow raw agricultural commodities), to the effect

¹⁴⁴ H.R. 3377, § 3(c)-(d) (outlining where liability would not attach); S. 2080, § 3(b)-(c).

¹⁴⁵ *Id.*

¹⁴⁶ *See* *Indiana Harbor Belt R.R. Co. v. American Cyanamid Co.*, 916 F.2d 1174, 1177 (7th Cir. 1990) (discussing a paradigmatic case for strict liability and outlining a multi-factor analysis); *see also* Stephan A. Evans, Comment, *Using the Abnormally Dangerous Activity Doctrine to Hold Principles Vicariously Liable for the Acts of Toll Manufacturers*, 21 B.C. ENVTL. AFF. L. REV. 587, 602-614 (1994) (detailing the history and modern application of the “Abnormally Dangerous Activity Doctrine” justifying strict liability).

¹⁴⁷ *See id.*

¹⁴⁸ H.R. 3377, § 3(d); S. 2080, § 3(c).

that the food does not contain a genetically engineered material or was not produced with a genetically engineered material.

In the case of a recipient who with respect to a food establishes a guaranty or undertaking in accordance with [the above paragraph], the exclusion under [the above paragraph] from being subject to penalties applies to the recipient without regard to the use of the food by the recipient, including

- a) Processing the food;
- b) Using the food as an ingredient in a food product;
- c) Repacking the food; or
- d) Growing, raising, or otherwise producing food.¹⁴⁹

This Note proposes the above provisions of the Right-To-Know Act as an alternative to a labeling requirement, which has been the center of the controversy over GMOs and the consumer's right-to-know. By requiring simple disclosure, the Act's basic scheme strives to respond to consumer demands without unnecessarily burdening GMO producers. The advantages of the Right-To-Know Act, both legal and practical, are discussed below.

B. The Compromise: What The Right-To-Know Act Can Do For Producers And Consumers

The Right-To-Know Act effectively balances GMO producer and consumer interests, because it prevents GMO food from being stigmatized, while accommodating a consumer's right to know that he or she is purchasing GMO food. With consumers, their bottom line is that they want to know which foods contain or are produced with GMOs so they can make informed, educated purchasing decisions.¹⁵⁰ Consumers fear the effects that bioengineered food can have on their health, the health of animals, and the environment.¹⁵¹ Scientists have yet to confirm these fears, but they have also failed to confirm that GMOs are safe.¹⁵² Even if scientists eventually prove GMOs are safe, many consumers still have ethical, religious, philosophical, dietary, or other

¹⁴⁹ H.R. 3377, § 3(c); S. 2080, § 3(b).

¹⁵⁰ See *supra* notes 3-5 and accompanying text.

¹⁵¹ See *supra* notes 114, 122, 126-128 and accompanying text; see also Caplan & Hickey, *supra* note 32.

¹⁵² See *supra* notes 125-127 and accompanying text; see also American Medical Association, *Featured CSA Report: Genetically Modified Crops and Foods* (December 2000) (acknowledging that long-term effects on human health are possible and that there is a continuing need to study possible risks to the environment because "substantial information about their actual effects on the environment and on biological diversity is lacking"), available at <http://www.ama-assn.org/ama/pub/article/2036-4030.html>; see also Caplan & Hickey, *supra* note 36 (detailing potential dangers of GMOs); but see Thompson, *supra* note 26 (finding "no evidence that the bioengineered foods now on the market pose any human health concerns").

2003] *MODEL STATE CONSUMER RIGHT-TO-KNOW ACT*

objections to bioengineered food that underscore the need for informational disclosure by GMO producers.¹⁵³ The Right-to-Know Act satisfies the consumer's disclosure request by giving them free access to a database listing GMO food products.

On the other side, GMO producers fear that consumers will unfairly stigmatize their GMO products if required to disclose GMO content on the product label.¹⁵⁴ Consumers might infer that bioengineered foods are inferior, without adequate evidence supporting this inference.¹⁵⁵ The Right-To-Know Act alleviates the producers' fear by taking the disclosure off the grocery store shelf and placing it in a database. By not requiring disclosure at the time and place of the purchasing decision, it is less likely that consumers will stigmatize certain foods with something akin to a scarlet letter. In addition, GMO producers need not worry about additional costs associated with new labels or different labels for different state requirements.

Besides satisfying consumer and producer interests, the Right-to-Know Act is a preferable solution to the GMO controversy because it operates on a state, not federal level. Consumer advocate groups' attempts to persuade Congress and the FDA for labeling regulations requiring GMO disclosure have not been successful.¹⁵⁶ Consumer advocate groups, however, have been able to rally support for labeling regulations at the state level, making it more likely that the Right-To-Know Act could pass on such a level. Still, a state-level Right-to-Know Act would have to withstand legal challenges, unlike other unsuccessful state labeling regulation which courts have struck down in the past.¹⁵⁷ As the following Part discusses, the Right-To-Know Act should survive legal challenges under the First Amendment, the Commerce Clause and a federal preemption analysis.

V. CONSTITUTIONAL CHALLENGES REVISITED: COURTS SHOULD UPHOLD THE RIGHT-TO-KNOW ACT

A. *The First Amendment Does Not Protect Producers Against Required Disclosures Under The Right-To-Know Act*

Governments regulate or limit commercial speech as a way to prevent misleading speech or to protect consumers from the dangers of incomplete information.¹⁵⁸ Recently, however, courts have entertained legal theories arguing that the First Amendment protects commercial speech against

¹⁵³ See *supra* notes 130-131 and accompanying text.

¹⁵⁴ See *supra* notes 30-31 and accompanying text.

¹⁵⁵ See *supra* notes 30-34 and accompanying text.

¹⁵⁶ See *supra* notes 6,10, 17 and accompanying text.

¹⁵⁷ See *supra* Part II.B-D.

¹⁵⁸ *Rubin v. Coors Brewing Co.*, 514 U.S. 476, 491-92 (1995) (Stevens, J., concurring).

overreaching government regulations and limitations.¹⁵⁹ Just as the First Amendment right to personal speech, the First Amendment right to commercial speech includes the right not to speak.¹⁶⁰ Courts afford less First Amendment protection to commercial speech than to personal speech, because commercial speech “is of less constitutional moment than other forms of speech,” and a failure to distinguish between the two could dilute, “simply by a leveling process,” the First Amendment’s force in protecting personal speech.¹⁶¹ The First Amendment’s primary function as it relates to commercial speech is to “advance truthful disclosure.”¹⁶²

In *Central Hudson*, the Supreme Court set out a four-prong test for First Amendment protection of commercial speech.¹⁶³ This test includes: (1) the commercial speech must not be misleading and must pertain to a lawful activity; (2) the government must assert a substantial interest; (3) the restrictions must directly advance the substantial interest asserted; and (4) the restrictions must be narrowly tailored.¹⁶⁴ This standard, although similar to the strict scrutiny standard, actually subjects commercial speech challenges “to a standard of lesser review” than non-commercial speech First Amendment challenges.¹⁶⁵ This relaxed standard is based on the premise that consumers “will perceive their own best interests if only they are well enough informed, and . . . the best means to that end is to open the channels of communication, rather than to close them.”¹⁶⁶

Courts have said very little about the constitutional limitations of commercial speech in the context of mandatory disclosure requirements of food product contents. Courts have commented on compelled commercial speech in the context of government regulations requiring growers, producers, manufacturers, and handlers of certain food products to subsidize generic

¹⁵⁹ Brett B. Coffee, Note, *Environmental Marketing After Association of National Advertisers v. Lungren: Still Searching For an Improved Regulatory Framework*, 6 FORDHAM ENVTL. L.J. 297, 312 (noting that until 1976, commercial speech was not considered to warrant First Amendment protection).

¹⁶⁰ *Central Hudson Gas & Elec. Corp.*, 447 U.S. at 563 (citing *Ohralik v. Ohio St. Bar Ass'n*, 436 U.S. 447, 456-457 (1978)).

¹⁶¹ *Id.* at 563 n. 5.

¹⁶² *Amestoy*, 92 F.3d at 80.

¹⁶³ *Central Hudson Gas & Elec. Corp.*, 447 U.S. at 566.

¹⁶⁴ *Id.*

¹⁶⁵ *Bd. of Trustees of State Univ. of N.Y. v. Fox*, 492 U.S. 469, 477 (1989) (noting that “[c]ommercial speech [enjoys] a limited measure of protection, commensurate with its subordinate position in the scale of First Amendment values,” and is subject to “modes of regulation that might be impermissible in the realm of noncommercial expression”) (quoting *Ohralik*, 436 U.S. at 456).

¹⁶⁶ *Central Hudson Gas & Electric Corp.*, 447 U.S. at 562 (quoting *Virginia Pharmacy Board v. Virginia Citizens Consumer Council*, 425 U.S. 748, 761-762 (1976)).

2003] *MODEL STATE CONSUMER RIGHT-TO-KNOW ACT*

product marketing campaigns.¹⁶⁷ Prior to 1997, state courts and lower federal courts split over whether these regulations were unconstitutional, but many courts upheld this compelled speech under a theory that stimulating economic activity within an industry was a substantial government interest.¹⁶⁸ In 1997, the Supreme Court resolved conflicts among the courts in *Glickman v. Wileman Brothers & Elliott, Inc.*,¹⁶⁹ by holding that a compelled marketing campaign did not implicate a First Amendment analysis because it was “a question of economic policy for Congress and the Executive to resolve.”¹⁷⁰ While informative, *Glickman* provides little guidance as to how the Supreme Court would evaluate a state’s substantial interest in passing a Right-To-Know Act.

A court would likely not consider the Right-To-Know Act a “question of economic policy” under a *Glickman* analysis, because the Act requires GMO producers to engage in actual speech, whereas government compelled marketing campaigns require food producers to pay for speech made by a regulatory body.¹⁷¹ In addition, the Right-To-Know Act is not susceptible to a freedom of association challenge like compelled marketing campaign regulations.¹⁷² Instead, courts will likely review the Right-To-Know Act under the *Central Hudson* four-prong test.¹⁷³ After *Amestoy*, the second prong, requiring a substantial state interest, would most likely be at issue in a First Amendment challenge.¹⁷⁴ The government interest served by the Vermont rBST labeling statute in *Amestoy* is similar in nature to the interest served by the Right-To-Know Act. Both are designed to serve the interests of consumers in demanding information about the GMO content of food.¹⁷⁵

Using the government interests as advanced in *Amestoy*, a court evaluating the Right-To-Know Act could uphold it just as easily as it could strike it down, because *Amestoy* left the question open as to what constituted a substantial interest for purposes of commercial speech regulation.¹⁷⁶ The majority expressly stated that an interest of “consumer curiosity” alone would not satisfy the “substantial” requirement.¹⁷⁷ The government could also not rely on “speculation or conjecture” to establish “real” harms required to justify

¹⁶⁷ P. CAMERON DEVORE ET AL., ADVERTISING AND COMMERCIAL SPEECH, A FIRST AMENDMENT GUIDE § 12:16 (2001).

¹⁶⁸ *Id.* at 12-63-12-64.

¹⁶⁹ 521 U.S. 457, 475-77 (1997).

¹⁷⁰ *Id.*

¹⁷¹ *See id.* at 469-70.

¹⁷² *See id.*

¹⁷³ *See Central Hudson Gas & Elec. Corp.*, 447 U.S. at 566.

¹⁷⁴ *See Amestoy*, 92 F.3d at 72-74.

¹⁷⁵ *See id.* at 75-76 (Leval, J., dissenting).

¹⁷⁶ *See id.*

¹⁷⁷ *Id.* at 74.

the regulation of commercial speech.¹⁷⁸ The dissent disagreed with the majority's assessment citing legitimate fears, ethical concerns, and economic interests.¹⁷⁹

Even with the uncertainty left by the *Amestoy* court, one can still find a substantial interest established through the Right-to-Know Act. If government regulation of commercial expression is most appropriate to protect consumers against producers who might mislead them, and the producers are in the best position to disclose relevant information, then the First Amendment may not protect GMO producers against mandatory disclosure under the Right-To-Know Act.¹⁸⁰ The FDA has shown that consumers are generally unaware that American grocery stores sell GMO products.¹⁸¹ In fact, many consumers were shocked to learn of the practice, and felt that knowing the GMO content of food was necessary to making informed purchasing decisions.¹⁸² Therefore, a state may have a substantial interest in protecting its consumers who already feel producers are misleading them by mixing traditional and bioengineered food on grocery store shelves.

Assuming that a state does have a substantial interest in affording protection against perceived “misleading” behavior, failure to disclose GMO content currently does not fit within the FDCA’s definition of “misleading” behavior.¹⁸³ The FDCA allows the FDA to regulate labels when there is evidence of a safety hazard or when there is a material change in the product which the consumer can perceive, either by a sensory organ or nutritionally by the body.¹⁸⁴ The FDA does not believe GMO foods satisfy either of these concerns.¹⁸⁵ Fortunately, state legislatures are not bound by the FDA's limited conception of “misleading” because, unlike the FDA, they do not derive their power from the FDCA. Similarly, state legislatures are not bound to accept the FDA requirement that a consumer must be able to perceive, either by a sensory organ or nutritionally by the body, material changes to products.

Subject to the limitations of federal preemption discussed below, a state legislature should be able to adopt a different conception of what constitutes a “material change” in food and when a GMO producer “misleads” a consumer. Under its definitions, it could then compel GMO producers to disclose the simple fact of whether their food products contain or were produced using GMOs. Courts should uphold the state’s interpretation of “material change”

¹⁷⁸ *Id.*

¹⁷⁹ *Id.* at 75-76 (Leval, J., dissenting).

¹⁸⁰ See *Rubin*, 514 U.S. at 491-92 (Stevens, J., concurring); see also *Central Hudson Gas & Elec. Corp.*, 447 U.S. at 564.

¹⁸¹ U.S. Food and Drug Administration, *supra* note 4.

¹⁸² *Id.*

¹⁸³ *Id.*; see also *supra* notes 12-16 and accompanying text.

¹⁸⁴ *Id.*

¹⁸⁵ *Id.*; see also *supra* note 17 and accompanying text.

2003] *MODEL STATE CONSUMER RIGHT-TO-KNOW ACT*

and “misleading,” along with the substantial interest of protecting consumers, in finding the Right-To-Know Act constitutional under the First Amendment.

B. The Commerce Clause Allows Disclosures Under The Right-To-Know Act

The Commerce Clause ensures “the maintenance of a national economic union unfettered by state-imposed limitations on interstate commerce” and fosters “political cohesion by inhibiting states from imposing reciprocal barriers that would divide rather than unite.”¹⁸⁶ Courts have construed the Commerce Clause to grant exclusive power to Congress to regulate interstate commerce.¹⁸⁷ States still retain the power to regulate commerce in furtherance of their traditional police powers to the extent that its regulation does not interfere with or discriminate against other out-of-state interests.¹⁸⁸ Courts review a Commerce Clause challenge to a state law to see whether the state law does, in fact, interfere with an out-of-state interest on its face, in its intent, or in its effect.¹⁸⁹

If a state statute expressly discriminates against out-of-state interests, it is per se unconstitutional.¹⁹⁰ Statutes that are facially neutral, although not per se unconstitutional, may suffer the same fate if it still discriminates by its intent or effect.¹⁹¹ Courts have adopted a “least restrictive alternative” test to determine when facially neutral laws may violate the Commerce Clause.¹⁹² A court will uphold a facially neutral statute if the state can show a legitimate purpose for its enactment and that there are no alternatives less constraining to interstate commerce.¹⁹³ Under this inquiry, if the court finds that the facially neutral statute’s local benefits outweigh the incidental burdens to interstate commerce, it will uphold the law.¹⁹⁴

A court will also assess whether any in-state interests vicariously represent any out-of-state interests.¹⁹⁵ For example, the Supreme Court upheld a state statute helping the in-state paper industry by requiring the sale of milk in only paper containers.¹⁹⁶ The court found that the in-state plastics industry, which also stood to lose under the statute, vicariously represented out-of-state interests.¹⁹⁷ This inquiry prevents state lawmakers from favoring their

¹⁸⁶ REDLICH ET AL., *supra* note 63, at § 5:01.

¹⁸⁷ *Id.*

¹⁸⁸ *Id.*; see also Burk, *supra* note 74, at 293.

¹⁸⁹ REDLICH ET AL., *supra* note 63, at § 5:04.

¹⁹⁰ *Id.*

¹⁹¹ *Id.*

¹⁹² *Id.*

¹⁹³ *Id.*

¹⁹⁴ *Id.* at § 5.05.

¹⁹⁵ *Id.* at § 5.06.

¹⁹⁶ *Id.* (citing *Minnesota v. Clover Leaf Creamery Co.*, 449 U.S. 456 (1981)).

¹⁹⁷ *Id.*

constituents at the expense of others who are not fairly represented in the state democratic process.¹⁹⁸

A state-enacted Right-To-Know Act falls within the bounds of the commerce clause because it regulates an area within the scope of traditional police powers.¹⁹⁹ As discussed in *supra* Part V.A, states should be able to adopt more expansive definitions of “material change” and “misleading” than the FDA, subject to federal preemption, and therefore have a right to regulate commerce in this area by requiring GMO content disclosure. A state-enacted Right-to-Know Act is also facially neutral because governments have a legitimate purpose in passing the Act and because there are no less constricting ways of doing so. Nothing in the Act differentiates between GMO producers residing within the relevant state borders and GMO producers residing outside the state. Indeed, the Act is not interested at all in the source of the food. The only relevant question is where the food is sold. Only if the food is sold within the state, is registration and disclosure required in order to legitimately protect consumers.

There are also no alternative means of achieving disclosure that would lessen the impact on interstate commerce. A competing proposal requiring disclosure on the product label has not been successfully implemented.²⁰⁰ Further, a state-labeling scheme is too burdensome to interstate commerce because it would require special labels for each relevant state. From a manufacturing, distribution, and marketing perspective, the Right-To-Know Act is preferable because it merely adds an administrative duty for GMO producers, while it does not address or alter food packaging and labeling. It also advances local interests by giving consumers the opportunity to educate themselves about GMO foods and make informed purchasing decisions. This limited administrative burden coupled with important local benefits, supports a conclusion that the benefits to local consumers far outweigh any burden to interstate commerce.

Lastly, under the Right-to-Know Act, in-state interests vicariously represent out-of-state interests. The bulk of the administrative burden falls equally on in-state and out-of-state GMO producers. It is possible, however, that a state may not actually have any GMO producers residing therein, but even under such circumstances courts should still uphold the Act because its intent is to give consumers a voice where the federal government has failed to act. Where GMO producers comprise only a small minority, courts should again uphold the Act because the overall GMO representation in the legislative process is sufficient to quash a Commerce Challenge alleging inadequate political participation by those negatively impacted.²⁰¹

¹⁹⁸ *Id.*

¹⁹⁹ See Burk, *supra* note 74, at 248.

²⁰⁰ See *supra* Part II.

²⁰¹ See REDLICH ET AL., *supra* note 63, at § 5:06.

2003] *MODEL STATE CONSUMER RIGHT-TO-KNOW ACT*

C. Federal Law Does Not Preempt The Right-To-Know Act

As discussed in *supra* Part II.D, several types of federal preemption can invalidate a state law. Most relevant to this analysis is *obstacle* preemption.²⁰² Express preemption is not relevant as it is with a labeling statute, because the Right-To-Know Act sidesteps the NLEA by not implicating packaging or labeling.²⁰³ Field preemption is also not relevant because it is widely recognized that the FDA and states may regulate concurrently.²⁰⁴ Obstacle preemption analysis is appropriate because, like a labeling statute, the Right-To-Know Act could be an obstacle to the FDA's regulatory scheme.²⁰⁵ That is, the Right-To-Know Act could be characterized as an obstacle to the FDCA and FDA's goal of promoting safe and nutritious food in the American marketplace because its findings run counter to FDA findings on GMOs.²⁰⁶

Despite this characterization, the Right-to-Know Act would likely still survive obstacle preemption analysis. First, the Act is unlike a labeling statute because the type of disclosure required under the Right-To-Know Act is different in nature than that required by labeling statutes. Second, the FDA did not consider a scheme similar to the Right-To-Know Act where it considered but rejected labeling requirements.²⁰⁷ Therefore, the states would not be adopting a scheme expressly rejected by the FDA. Third, the registration required in the Right-To-Know Act is less burdensome on GMO producers because it imposes only a minimal administrative cost and because it does not have the same stigmatizing risks associated with a labeling scheme.²⁰⁸ Fourth, the Right-To-Know Act does not interfere with interstate commerce the way a state-imposed labeling requirement would. If the state adopted a labeling disclosure scheme, then a package not containing the correct labels would be illegal within the state in question.²⁰⁹ The Right-To-Know Act focuses instead on the actions of the GMO producers and not on the product itself as it is manufactured, distributed, and sold.

For these reasons, the Right-To-Know Act does not obstruct the FDCA and FDA's goal of promoting safe and nutritious foods. In fact, the Right-To-Know Act seeks to promote similar goals by allowing consumers to decide for themselves what foods they find suitable for their tables. Courts, therefore, should allow the Right-to-Know Act to survive preemption analysis.

²⁰² See *supra* note 84 and accompanying text.

²⁰³ See *supra* notes 86-89 and accompanying text; see also Burk, *supra* note 74, at 258.

²⁰⁴ See *supra* note 99 and accompanying text; see also Burk, *supra* note 74, at 266.

²⁰⁵ Burk, *supra* note 74 at 267.

²⁰⁶ See *id.*

²⁰⁷ See Voluntary Labeling, *supra* note 14.

²⁰⁸ See *supra* notes 30-31, 200-201 and accompanying text.

²⁰⁹ See *Amestoy*, 92 F.3d at 69.

VI. CONCLUSION

At the bottom of the GMO controversy, which has raged for over a decade, consumers want the simple ability to voice their will through their purchasing power, something that a capitalist economy is designed to embrace. Consumers deserve the opportunity to meaningfully participate in the economy. The Right-To-Know Act provides this opportunity in the form of a compromise that will also ensure that GMO producer interests are satisfied.

Implementation of the Right-To-Know Act is the best way to respond to the consumer demand for disclosure of GMO content in foods. It would allow consumers to educate themselves about which foods contain GMOs, while narrowly impacting GMO producers and minimizing possible stigmatization of their GMO products. The Right-To-Know Act's disclosure requirement involves the simple administrative task of registering basic information about the presence of GMOs in a particular food product. The Act makes no demands with respect to the packaging, labeling or marketing of food products. The Act is also designed in a way that consumers will view GMO disclosures away from the place and time of purchase, thus avoiding the possibility that they will stigmatize GMO foods. The Right-To-Know Act is also advantageous because it will survive legal hurdles that have blocked labeling schemes thus far. The Act would survive legal challenges under the First Amendment, the Commerce Clause, and federal preemption analysis. At best, both sides of the GMO controversy could successfully settle on the Right-To-Know Act to protect their respective interests.