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*Prophylactic Preemption of State Laws for the Mandatory Labeling of Genetically Modified
Foods: An Argument for Paternalism*
by
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I. Introduction

Genetically modified (GM) foods have been at the forefront of our nation's consciousness for well over twenty years. The first genetically engineered crops began to be planted commercially in the late 1980's and early 1990's, and are now nearly ubiquitous across the farm fields of our nation's agricultural sector. It is estimated that as much as 80% of the food that we purchase contains some amount of material from biotech crops. However, this technological explosion has not been without its obstacles. What began for many of the early GMO pioneers as the next great promise in the evolution of agriculture, destined to be the vehicle necessary for farmer's to keep pace with a world population projected to hit 9.5 billion in the next fifty years, has become a lightning rod for controversy, viewed by many in the general public as something to be feared, a technology beset with environmental and health risks.

Regulation of GM crops and food products has tread a long and convoluted path. Many countries have imposed mandatory labeling for GM foods, and others have imposed outright bans on the planting of GM crops or the sale of food products derived thereof. The United States has, without doubt, taken a much more permissive stance toward the technology, not only creating a regulatory framework through which GM crops are able to be approved for commercial use, but allowing GM foods to go to market without requiring additional labeling and identification. Although both prongs of this regulatory scheme have been challenged in recent years, the most vociferous challenge to the nation's GMO policies has been directed at the lack of mandatory labeling of GM foods.

Recent polls estimate that as many as 80% of Americans think that GM foods should be labeled. Efforts have been launched in multiple states to pass laws mandating the

labeling of all foods containing GMO byproducts. Although none of these efforts have yet been met with success, the trajectory of the debate suggests that it is only a matter of time before GM labeling laws are on the books in more than a few states. Just last year a California ballot initiative that called for the mandatory labeling of GM foods was narrowly defeated by a 3-point margin. Clearly, state labeling advocates are on the cusp of victory.

Against this backdrop, it becomes essential that the federal government act to explicitly preempt state labeling requirements. As biotech foods become increasingly common and necessary in the nation's food supply, a patchwork of labeling laws could present numerous problems for interstate commerce. Therefore, it is necessary that Congress act to preempt these grassroots efforts and create uniformity within the field. If, indeed, the labeling of GM foods is a proper subject for federal preemption, the question becomes what such a law should look like.

I will argue that there are important scientific, legal, and policy-based reasons for Congress to act to prohibit the mandatory labeling of GM foods. Overwhelmingly, the scientific evidence concludes that GM foods are safe for consumers and pose no significant risks to human health or to the environment. If this is the case, there is an insufficient governmental interest to justify imposing a labeling requirement on growers and manufacturers. Thus, a mandatory labeling law would not pass constitutional muster since, by compelling commercial speech, it would violate the first amendment rights of these producers. Finally, the lack of consumer knowledge regarding the science behind genetic modification of plants is likely to result in consumer aversion that is not commensurate with the actual risk (or lack thereof) that such foods pose. As there are limited avenues through which consumers can become better educated with regard to the actual health and

safety implications of GM foods, paternalistic principles may actually demand that the federal government intervene by prohibiting labeling in order to protect consumers from the dangers of misinformation.

II. Current Regulation of GM Foods

There is little question that the United States' approach to the regulation of GM foods is much more permissive than many if not most other countries. In general, the US has adopted a regulatory framework that presumes low risk from genetic modification and reviews GM products using existing federal laws and standards, such as the Plant Protection Act, 7 U.S.C. § 7701 *et seq.*, the National Environmental Policy Act of 1969, etc.¹ Many other countries—including those in the European Union—have taken an approach to GM food regulation based on the precautionary principle, limiting GM food where there is “a lack of certainty about safety.”² This difference in approach can also be seen in the laws that the United States and other countries have adopted with regard to the labeling of GM foods.

a.) International Labeling Laws

i.) Content of Labeling Regulations

¹ Emily Marden, *Risk and Regulation: U.S. Regulatory Policy on Genetically Modified Food and Agriculture*, 44 B.C. L. REV. 733, 738-739 (2004). *See also* Center for Food Safety v. Vilsack, 636 F.3d 1166 (9th Cir. 2011); Monsanto Co. v. Geertson Seed Farms, 130 S.Ct. 2743 (2010).

² *Id.* at 735. *See also* Matthew Rich, Note, *The Debate Over Genetically Modified Crops in the United States: Reassessment of Notions of Harm, Difference, and Choice*, 54 CASE W. L. REV. 889, 901 (2004) (noting that “GMO critics have called for the United States to adopt the Precautionary Principle when dealing with genetically modified foods and their regulation”).

Since 2000, “over forty countries have adopted labeling regulations for GM food,”³ however, the labeling laws adopted by different countries have displayed a high degree of variance. In fact, “the only common feature [of the various regulations] is the requirement to label products derived from GM crops that are *not substantially equivalent* to their conventional counterparts.”⁴ Of course, there are a number of countries that require labeling of GM foods that are *substantially equivalent* to non-GM foods as well. In fact certain countries require labeling if there is a presence of *any* “detectable transgenic material.”⁵ For example, although the European Union and China both have adopted regulations that require mandatory labeling of GM foods, the EU has adopted labeling requirements for foods that have a threshold content of transgenic material of 0.9%, whereas China’s regulation contains no threshold level.⁶

In addition to differences with regard to what level of transgenic character gives rise to a duty to label, the various regulations also differ in the extent of coverage. Some

³ Guillaume P. Gruère, International Food Policy Research Institute, *Labeling Policies of Genetically Modified Food: Lessons from an International Review of Existing Approaches* (2008).

⁴ *Id.* (emphasis in original). Of those countries that have adopted regulations, at least 24 countries have opted for mandatory labeling of GM foods, though some require labeling for certain products, but provide for voluntary labeling of other products. Guillaume P. Gruère & S.R. Rao, *A Review of international labeling Policies of Genetically Modified Food to Evaluate India’s Proposed Rule*, *AgBioForum*, 10(1):51-64, 52-53 (2007). Those countries that have adopted mandatory labeling also differ in the level of enforcement of their labeling policies. *Id.* at 52.

⁵ Gruère, *supra* note 3.

⁶ Gruère, *supra* note 4 at 52. A tolerance level of 0% means that any food derived from GM crops must be labeled, even if it does not contain any trace amount of GM material, such as transgenic DNA or proteins. *Id.* See also Regulation 1829/2003, of the European Parliament and of the Council of 22 September 2003 on Genetically modified Food and Feed, 2003 O.J. (L 268) 1, 11 (EC) (exempting from labeling requirements those “foods containing material which contains, consists of or is produced from FMOs in a proportion no higher than [0.9] per cent of the [total] food ingredients...provided that this presence is adventitious or technically unavoidable).

countries require labeling of nearly all types of food products, whereas others have explicitly exempted certain categories such as meat, feed, processed products, or food served in restaurants.⁷ Additionally, certain countries target the “presence of GM [sic] in the finished product” whereas others regulate “GM technology as a production process.”⁸ Countries that take the latter approach would therefore require labeling of foods that are derived from GM products whether or not the final product actually contains traces of GM material.⁹

Finally, of those countries that have passed regulations pertaining to the labeling of GM foods, there have been differing levels of enforcement of the regulations. In developing countries, especially, there is a general lack of enforcement of the regulations.¹⁰ For example countries such as Brazil or Indonesia, which have both passed labeling laws, have either failed to implement those laws altogether, or have only partially done so.¹¹ In fact, as of 2008, the only developing country that had fully and effectively implemented its labeling law was China.¹²

ii.) Implications of International Labeling Laws

It is clear that international labeling laws have had a noticeable effect on the sale and purchase of GM foods in those countries that have implemented them. Although the primary objective of most labeling laws is to provide consumer information and to protect

⁷ Gruère, *supra* note 4, at 53.

⁸ *Id.* at 52. *See, e.g.* EU Regulation 1829/2003, *supra* note 6, at 22 (stating that “[t]he presence in food...of material which...is produced from GMOs” is to be labeled if such material is in a proportion higher than 0.5%).

⁹ Gruère, *supra* note 4, at 52.

¹⁰ *Id.* at 53.

¹¹ *Id.*

¹² *Id.*

consumer choice,¹³ Messrs. Gruère and Rao note that the overwhelming effect of these laws in countries that have implemented them is the loss of the choice to purchase and consume GM foods due to the “virtual disappearance of any labeled GM product on the food shelves.”¹⁴ These authors argue that this effect is the result of food processors and retailers in those countries avoiding GM ingredients because of the risk of losing sales due to perceived consumer aversion to GM food and because of the additional costs related to tracking and labeling all food products that contain or are derived from GMOs.¹⁵ Therefore, although the intent of these regulations was the protection of consumer choice, it is arguable that the result has actually been the opposite: the restriction of true choice due to GM foods being driven from the market.

There is also some question as to whether these laws violate international trade laws as unlawful restrictions on trade.¹⁶ The problem arises when countries that allow for the production of GM crops and do not themselves have stringent tracking or labeling requirements enter into trade agreements with other countries that implement mandatory

¹³ See Gruère, *supra* note 4, at 54; Arthur E. Appleton, Colloquium Article, *The Labeling of GMO Products Pursuant to International Trade Rules*, 8 N.Y.U. ENVTL. L.J. 566, 567 (2000); Greg Jaffe, *What You Need to Know About Genetically Engineered Food*, THE ATLANTIC, Feb. 7, 2013, <http://www.theatlantic.com/health/archive/2013/02/what-you-need-to-know-about-genetically-engineered-food/272931/>.

¹⁴ Gruère, *supra* note 4, at 54. See also, Valery Federici, Note, *Genetically Modified Food and Informed Consumer Choice: Comparing U.S. and E.U. Labeling Laws*, 35 Brok. J. Int’l L. 515, 531.

¹⁵ *Id.* With regard to cost: a study from the United Kingdom estimates that the per capita cost of implementing various labeling schemata runs between \$0.23 and \$3.89. *Id.* at 57. Other countries have estimated that implementation costs could be as high as \$9.75 per person. *Id.* at 56 (citing a report estimating the cost of the introduction of mandatory labeling in Australia). As Messrs. Gruère and Rao note, the cost of labeling is inextricably linked to the amount of GM crop production in the country at issue, and many of the countries that have been at the forefront of labeling are those that restrict the production of GM crops and therefore import the majority of those crops from other countries with more permissive laws. *Id.* at 57.

¹⁶ Appleton, *supra* note 13 at 570. See also Gruère, *supra* note 4, at 57-59,

labeling laws. Although the World Trade Organization (WTO) has yet to answer the question directly, a few countries (including the United States) have argued that GMO labeling laws implicate and violate the Agreement on the Application of Sanitary and Phytosanitary Measures (SPS Agreement) and the Agreement on Technical Barriers to Trade (TBT Agreement).¹⁷

The SPS Agreement, in particular, requires that a law that has the effect of restricting trade must have scientific justification, and that such justification cannot be a merely theoretical health risk.¹⁸ As will be discussed below, the question of whether GM foods pose a legitimate health risk is still imbued with some amount of uncertainty within the scientific community, but the overwhelming majority of evidence at this time indicates that there are no legitimate health risks posed by the consumption of GM foods.¹⁹ If this is the case, those countries imposing labeling laws may not be able to identify a sufficient scientific justification for the restriction on imports of GM crops and foods.

The TBT Agreement, on the other hand, covers labeling requirements not based on SPS criteria²⁰ and is likely to be the Agreement relied upon by countries with labeling laws, as “most countries justify labeling as a consumer regulation rather than a safety

¹⁷ Appleton, *supra* note 13 at 571.

¹⁸ *Id.* at 572.

¹⁹ See, e.g. Lucia Martinelli et al., *Science, Safety and Trust: the Case of Transgenic Food*, 54 *Croat. Med J.* 91, 92 (2013) (noting that “[a]ccording to comprehensive studies, in which the most accredited scientific papers on feeding trials have been analyzed on the basis of certified experimental and statistical parameters, no significant health risks were found”); Rosie Mestel, *Scientists Defend Safety of Genetically Modified Foods*, *Los Angeles Times*, Oct. 24, 2012, <http://articles.latimes.com/2012/oct/24/science/la-sci-gmo-food-safety-20121025> (reporting that “among scientists, there is widespread agreement that [GM] crops aren’t dangerous”); Jaffe, *supra* note 13 (noting that “[n]umerous scientific agencies, including the Food and Drug Administration (FDA) and National Academy of Sciences, have conducted reviews that did not identify any health concerns” associated with GM foods).

²⁰ Appleton, *supra* note 13 at 574.

regulation.”²¹ One provision of the TBT agreement requires that labeling regulations (which would properly be categorized as “technical regulations” under the agreement) must be no more restrictive than necessary “to fulfill a legitimate objective.”²² The WTO Appellate Body has not yet addressed the issue of whether the protection of consumer choice is a “legitimate objective” for purposes of the agreement, but from the list of examples of what *are* legitimate objectives in the text of the agreement (all of which address in one way or another questions of consumer or national safety or security²³), it could be argued that a consumer’s right to know is *alieni generis* and is therefore not a legitimate objective. Therefore, unless a country could identify a basis for its labeling law other than protection of consumer choice, such regulation may be found to violate the TBT Agreement.

b.) Labeling Laws in the United States

i.) Current Labeling Paradigm

In the United States today, the policy of the FDA with regard to the labeling of GM foods is mostly informed by Sections 201 and 403 of the Food, Drug, and Cosmetic Act (hereinafter “the Act”),²⁴ which address the misbranding of food. First, with regard to the labeling of food, the Act prohibits “the adulteration or misbranding of any food...in

²¹ Gruère, *supra* note 4, at 58.

²² Appleton, *supra* note 13 at 576.

²³ The TBT agreement includes the following non-exhaustive list of legitimate objectives: “national security requirements; the prevention of deceptive practices; protection of human health or safety, animal or plant life or health, or the environment.” *Id.*

²⁴ Food and Drug Administration, Draft Guidance, *Guidance for Industry: Voluntary Labeling Indicating Whether Foods Have or Have Not Been Developed Using Bioengineering* (Jan 2001) (draft) [hereinafter “Labeling Guidance”], available at <http://www.fda.gov/food/guidancecomplianceregulatoryinformation/guidancedocuments/foodlabelingnutrition/ucm059098.htm> (last visited March 21, 2013).

interstate commerce.”²⁵ Section 403 of the Act defines misbranding as “labeling [that] is false or misleading in any particular, or...its advertising is false or misleading in a material respect.”²⁶ Section 201(n) provides further direction for determining whether a food label is misleading:

If an article is alleged to be misbranded because the labeling or advertising is misleading, then in determining whether the labeling or advertising is misleading there shall be taken into account (among other things) not only representations made or suggested by statement, word, design, device, or any combination thereof, but also the extent to which the labeling or advertising fails to reveal *facts material* in the light of such representations *or material* with respect to consequences which may result from the use of the 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.²⁷

Although the Act does not define material and “there is little discussion of the word ‘material’” in the legislative history of the Act, the FDA has “interpreted the scope of the materiality concept to mean information about the attributes of the food itself.”²⁸ An FDA guidance document reveals that the agency has found a lack of information to be material when the exclusion of a particular piece of information may “pose special health or environmental risks...mislead the consumer in light of other statements...on the label,” or imply that a food has the same “nutritional, organoleptic, or functional characteristics of” another similar food, when in fact it does not.²⁹

Given this interpretative foundation, when approached with the question of whether biotech foods must be labeled as such under the Act, the agency determined that the Act could not support *mandatory* labeling, as transgenic material in food was not

²⁵ 21 U.S.C. § 331(b).

²⁶ *Id.* at § 343(a).

²⁷ *Id.* at § 321(n) (emphasis added).

²⁸ Labeling Guidance, *supra* note 24.

²⁹ *Id.*

material in the way that the agency construes materiality.³⁰ Additionally, the agency noted that labels indicating that a particular food is “GMO free” may actually be misleading under the current legal paradigm, and thereby prohibited.³¹ What was less clear were circumstances under which *voluntary* labeling of the presence of transgenic material would be acceptable. The agency determined that the inclusion of such information on labels is permissible under the Act, but that manufacturers must be careful that such information is not given in a manner that would lead consumers to believe that the presence of such material confers a benefit or presents a danger that it actually does not.³²

³⁰ *Id.* See also Marden, *supra* note 1, at 761-62. “In [the draft guidance] document, FDA reaffirmed the position that most GM foods were substantially equivalent to their conventional counterparts...[and] that the process of genetic modification was not itself a material difference in the food.” *Id.* at 761.

³¹ Labeling Guidance, *supra* note 24. The agency gave multiple justifications for its conclusion on this matter. First, the agency noted that “genetic modification” means nothing more than altering the genotype of an organism through any mean, including traditional methods wherein plants were bred to exhibit certain traits more or less than normal. *Id.* This gets at the heart of what this author deems to be the most problematic aspect of opposition to GM foods from a scientific perspective. Second, the agency discussed the fact that “GMO free” is misleading for most foods, as most foods do not contain actual organisms. *Id.* This seems to be the weakest argument of the agency. It may be true that many if not most foods do not contain whole organisms in their native state, but one would imagine that the vast majority of consumers would know that “GMO free” means that the food does not contain any amount of material from GM plants. Finally, the agency noted that the concept of “free” requires the creation of a threshold above which the term may not be used. *Id.* Absent a metric to ensure that this is the case, use of the term “free” may be misleading, as even “GMO free” foods may contain trace amounts of biogenic material from GM plants.

³² Labeling Guidance, *supra* note 24. For example, the FDA stated that the use of phrases such as “not genetically modified” or “GMO free” that use the term “modified” would be misleading unless used in a context that clearly refers to bioengineering technology as “‘genetic modification’ mean the alteration of the genotype of a plant using *any technique*, new or traditional.” *Id.* (emphasis added). Additionally, the agency stated that the use of the term “free” may be misleading as there is currently no defined threshold in the U.S. for how much transgenic material may be present for a product to technically be classified as “free.” *Id.* Finally, the FDA indicated that “[a] statement that a food was not bioengineered or does not contain bioengineered ingredients may be misleading if it implies that the labeled food is superior to foods that are not so labeled.” *Id.*

Though no legal challenge has been directed at the FDA’s GM food labeling guidance document, the courts did uphold the agency’s determination that genetic modification is not a “material fact” in 2000, when a coalition of groups challenged the FDA’s 1992 “Statement of Policy” about foods derived from GM plants.³³ The plaintiffs challenged the FDA’s policy, arguing—in part—that the determination that GM foods are generally recognized as safe (GRAS) and therefore not subject to regulation as food additives³⁴ was arbitrary and capricious,³⁵ and that its determination that the process of genetic modification is not a material fact mandating special labeling was likewise arbitrary and capricious.³⁶ The court first held that the agency’s determination that transgenic material is GRAS—and therefore need not be regulated as a food additive—was consistent with the statutory requirements, and was not an abuse of the agency’s discretion.³⁷ Second, and more important to this discussion, the court held that the FDA’s decision not to require labeling of GM foods due to a lack of “materiality” was ultimately “a matter of interpretation” which “should be left to the agency.”³⁸ The plaintiffs’ contention that the FDA was wrong in interpreting material so as *not* to take account of consumer interest was unavailing, and the court found that the agency’s interpretation was reasonable and was sufficiently supported by scientific evidence to render it not arbitrary and capricious.³⁹

³³ Alliance for Bio-Integrity v. Shalala, 116 F.Supp. 2d 166, 170 (D.C. Cir. 2000).

³⁴ See, 21 U.S.C. § 321(s). “The term ‘food additive’ means any substance...becoming a component or otherwise affecting the characteristics of any food...*if* such substance is not generally recognized, among experts qualified by scientific training and experience to evaluate its safety, as having been adequately shown through scientific procedures...to be safe under the conditions of its intended use.” *Id.* (emphasis added).

³⁵ Alliance for Bio-Integrity, 116 F.Supp. 2d at 175.

³⁶ *Id.* at 178.

³⁷ *Id.* at 175-77.

³⁸ *Id.* at 178.

³⁹ *Id.* at 178-79

At this point, it seems to at least be settled that the Agency views the mandatory labeling of GM foods as impermissible under the current federal labeling paradigm. Of course, the FDA could always change its mind and adopt a different definition of “material,” but there is no indication that the FDA is willing to move in this direction. If labeling advocates are to be successful, then, it appears as though the most viable option would be the introduction of a new law that unfetters labeling determinations from the current “materiality” requirement.

ii.) State and Federal Efforts to Introduce Mandatory Labeling

As current federal law not only appears to not *require* labeling of GM food, but may, in fact, actually prohibit certain forms of *voluntary* labeling, a grassroots movement has arisen in recent years at the state level, lobbying state legislatures—or the general public in the case of ballot initiatives—to pass mandatory labeling laws.⁴⁰ Although none of these attempts have yet resulted in the passage of a law, the increase in consumer and industry interest in mandatory labeling⁴¹ (and the growing antipathy among consumers toward the

⁴⁰ See, e.g. Stephanie Strom, *Genetic Changes to Food May Get Uniform Labeling*, N.Y. Times, (Jan. 31, 2013) (discussing the efforts of labeling advocacy groups such as “Just Label It,” and noting that “roughly 20 states are now considering labeling requirements”); Label GMOs.org, California’s Grassroots, <http://www.labelgmos.org> (an example of a grassroots organization from California that has been visible in the recent labeling debate, there).

⁴¹ See, *GMO Poll Finds Huge Majority Say Foods Should Be Labeled*, HUFFINGTON POST (Mar. 05, 2013), http://www.huffingtonpost.com/2013/03/04/gmo-poll_n_2807595.html [hereinafter HuffPost Poll] (finding that “82 percent of Americans think [that] GMO foods should be labeled, while only 9 percent say they should not”); Michelle Simon, *Will a Federal Compromise on GMO Labeling Trump State Law, Forever?*, FOOD SAFETY NEWS, (Feb. 5, 2013), available at <http://www.foodsafetynews.com/2013/02/will-a-federal-compromise-on-gmo-labeling-trump-state-law-forever/#.UU9wR1vcpm1> (reporting that “representatives of wal-Mart, General Mills, Pepsi-Frito Lay, Mars, Coca-Cola and others met with the FDA [in January, 2013] to lobby for a mandatory federal GMO labeling law”) (internal citations omitted); Stephanie Strom, *Genetic Changes to Food May Get Uniform Labeling*, N.Y. Times, (Jan. 31, 2013); Stephanie Strom, *supra* note 40 (reporting that over

technology itself)⁴² makes it likely only a matter of time before labeling advocates are successful in their efforts.

One of the most recent and highly publicized labeling efforts occurred in California, where an initiative was successfully placed on the ballot for the 2012 election that, if passed, would have required labeling of many GM foods sold within the State.⁴³ The proposal was ultimately defeated 51.4%-48.6%,⁴⁴ but the effort appears to have bolstered similar efforts in other states, as there are—allegedly—nearly 20 states that are moving toward the introduction of proposals for labeling requirements.⁴⁵ Not all of these efforts have been limited to voter approved ballot initiatives, however. In at least eight states—including Washington, Connecticut, Vermont, New Mexico, Missouri, Maryland, Iowa, New Mexico, and Minnesota— legislative proposals have been introduced.⁴⁶ Most notably, two bills were recently introduced in the Minnesota State Legislature (HF 850 and SF 821) that would render a food “misbranded if it is, or may have been, genetically engineered and

20 major food companies have recently attended meetings with advocacy groups that favor labeling).

⁴² The Huffington Post/YouGov poll cited *supra* note 41 found that thirty-five percent of respondents believe that GMO foods are dangerous to eat. HuffPost Poll, *supra* note 41. *See also*, Stephanie Strom, *supra* note 40 (reporting that “[i]mpending F.D.A. approval of a genetically modified salmon and the Agriculture Department’s consideration of genetically engineered apples” has “accelerated concerns” among consumers).

⁴³ *See* CALIFORNIA SECRETARY OF STATE, CALIFORNIA GENERAL ELECTION OFFICIAL VOTER INFORMATION GUIDE 110-112 (2012).

⁴⁴ CALIFORNIA SECRETARY OF STATE, STATEMENT OF VOTE 13 (Nov. 6, 2012).

⁴⁵ Stephanie Strom, *supra* note 40.

⁴⁶ *See Id.*; Abbie Fentress Swanson, *GMO Labeling Laws On Deck In Midwest*, Community Radio for Northern Colorado (Mar. 20, 2013); Dan Flynn, *GMO Labeling Bill Introduced in U.S. Congress*, FOOD SAFETY NEWS (Feb. 20, 2013) (reporting that “[a] GMO labeling bill was tabled fairly early in the current session of the New Mexico Legislature;” that “HB 0903 is getting a public hearing in Maryland;” that a labeling bill, “Senate File...194” has been introduced in the Iowa Senate, though it “hasn’t yet gone anywhere;” and that a Washington Initiative to the Legislature, “I-522, will go to the voters this fall if lawmakers do not act upon it first”).

such fact is not disclosed.”⁴⁷ The language of both bills is very similar to that which was used in California Proposition 37, insofar as the proposed law would exempt from the requirement “processed food that would be subject to [labeling] solely because one or more processing aids or enzymes were produced or derived with genetic engineering.”⁴⁸ As will be discussed, *infra*, this is a very significant exemption, and does dramatically reduce the scope of the proposed legislation.

Efforts to introduce mandatory labeling laws have not been restricted to the state level, either. In February, 2013, U.S. Representative Jared Polis from Colorado announced that he would be introducing a federal bill in Congress that would propose to make “the labeling of food containing genetic modified organisms” mandatory “in all 50 states.”⁴⁹ Given the current political climate in the House, it is unlikely that such a bill would be met with success, but even if it fails in the House, it is clear that proponents of mandatory labeling are serious about getting the legislative ball rolling.

Without question, efforts to pass laws making labeling of GM foods mandatory are unlikely to abate at any point in the near future. In fact, if anything it is likely that such efforts will actually increase as GM crops become more common and more integral to our nation’s food supply, thereby rendering the regulation of GM foods—including their labeling—a more prevalent issue in the nation’s consciousness. If this prediction is correct, it is reasonable to believe that it is only a matter of time before the efforts of labeling proponents are met with success and laws are enacted that mandate the labeling of these foods. If labeling laws are as inevitable as this author believes, the next section will argue

⁴⁷ H.F. 850, 88th Leg. (Minn. 2013); S.F. 821, 88th Leg. (Minn. 2013).

⁴⁸ *Id.*

⁴⁹ Dan Flynn, *supra* note 46.

that it is imperative that Congress take the lead in passing a federal law that will preempt state laws, in order to establish a consistent, nationwide labeling paradigm.

III.) The Necessity of a New Federal Labeling Law

It may be asked at the outset why a new federal law is necessary if the FDA has already determined that the FDC Act governs the labeling of GM foods. A new law is necessary because it is unclear whether the current Act would preempt state labeling laws. This is problematic primarily because a patchwork system of disjointed labeling laws at the state level is not commercially sustainable.

a.) Preemption Under the FDC Act

The question of federal preemption under the FDC Act does not yield an entirely simple answer, as the correct answer differs for every subcategory of material that the Act regulates.

In *Wyeth v. Levine*, the U.S. Supreme Court held that a state “failure to warn” claim was not preempted by the Act when the manufacturer of an antihistamine used to treat nausea did not include an adequate warning on the drug’s label about the dangers of using an IV-push method of administration.⁵⁰ The warnings that were included on the drug’s label had been deemed sufficient by the FDA under the requirements of the Act,⁵¹ but the plaintiff argued that the label was nevertheless “defective because it failed to instruct clinicians to use the IV-drip method...instead of the higher risk IV-push method.”⁵² The defendant argued that the plaintiff’s claim was preempted under the Federal Act, and that it was not required to include anything on the label beyond what the FDA had indicated was

⁵⁰ *Wyeth v. Levine*, 555 U.S. 555 (2009).

⁵¹ *Id.* at 558.

⁵² *Id.* at 560.

necessary.⁵³ The Court, however, held that the plaintiff’s claim was *not* preempted under the Act, either on a theory of express preemption or conflict preemption,⁵⁴ and that the state-law duty to provide a stronger warning in this case did not “obstruct the federal regulation of drug labeling.”⁵⁵

In its opinion, the Court noted that in the 1962 amendments to the Act Congress had expressly indicated that the Act would only preempt state law to the extent that the provisions expressly so stated.⁵⁶ In this case, there was no provision expressly preempting state laws with regard to prescription drug labels, and state law was therefore not expressly preempted.⁵⁷ In contrast, the Court drew attention to the provisions of the Act that were added in 1976—regulating medical devices—which did include a statement expressly preempting state laws as to that subject matter.⁵⁸ In addition, the Court found that the defendant could not prevail under a theory of conflict preemption because,

⁵³ *Id.* at 560, 563-65.

⁵⁴ *Id.* at 567, 573.

⁵⁵ *Wyeth*, 555 U.S. at 573-81.

⁵⁶ *Id.* at 567 (stating that “the 1962 amendments added a saving clause, indicating that a provision of state law would only be invalidated upon a ‘direct and positive conflict’ with the [Act]” (quoting § 202, 76 Stat. 781, 793)).

⁵⁷ *Id.* at 574.

⁵⁸ *Id.* at 567, 574 (citing § 521, 90 Stat. 574 (codified at 21 U.S.C. § 360k(a)). 21 U.S.C. § 360k(a) provides that:

Except as provided in subsection (b) of this section, no State or political subdivision of a State may establish or continue in effect with respect to a device intended for human use any requirement:

- (1) which is different from, or in addition to, any requirement applicable under this chapter to the device, and
- (2) which relates to the safety or effectiveness of the device or to any other matter included in a requirement applicable to the device under this chapter.

Subsection (b) goes on to provide that a State may apply to the FDA for an exemption for State regulations or requirements applicable to medical devices if the requirement “is more stringent than” the federal requirement or it “is required by compelling local conditions” and would not otherwise “cause the device to be in violation” of federal requirements. § 360k(b).

although the state was in essence imposing additional requirements to those of the Act, these requirements were not inconsistent with the Act’s labeling provisions.⁵⁹ The Court has ruled similarly in other cases.⁶⁰

It seems clear that, for the current Act to preempt state laws with regard to mandating the labeling of GM foods, Congress must have included a provision in the portion of the Act that regulates the labeling of food that expressly preempts such laws. Otherwise, it must be found impossible—on a case-by-case basis—for individuals to comply with the requirements of both the federal Act and the state law in question. Interestingly enough, in 1990, Congress did amend Subchapter IV (addressing food) of the FDC Act, adding (among other things) section 343-1, which expressly preempts certain state food labeling laws.⁶¹ Therefore, the question becomes whether this section would apply to laws requiring the labeling of GMOs as such.

Section 343-1 of the Act prohibits any “State or political subdivision of a State” to “directly or indirectly establish...as to any food in interstate commerce” any of the following:

- (1) any requirement for a food which is the subject of a standard of identity established under section 341 of this title that is not identical to such standard of identity or that is not identical to the requirement section 343(g) of this title...;
- (2) any requirement for the labeling of food of the type required by section 343(c), 343(e), 343(i)(2), 343(w), or 343(x) of this title that is not identical to the requirement of such section...;

⁵⁹ Wyeth, 555 U.S. at 581.

⁶⁰ See *Riegel v. Medtronic, Inc.*, 552 U.S. 312 (2008); *PLIVA, Inc. v. Mensing*, 131 S.Ct. 2567 (2011) (holding that State product liability action for inadequate warnings on a drug label, although not expressly preempted by the FDCA, was preempted under conflict preemption principals as it was impossible to comply with both federal and State requirements in this case).

⁶¹ Federal Food, Drug, and Cosmetic Act, ch. 9, sec. 6, § 343-1, 104 Stat. 2353, 2362-64 (1990).

(3) any requirement for the labeling of food of the type required by section 343(b), 343(d), 343(f), 343(h), 343(i)(1), or 343(k) of this title that is not identical to the requirement of such section⁶²

Although all three of these subsections could be used as a basis to argue that state GMO labeling laws are expressly preempted, none of them apply to section 343(a) of the Act, which, as stated above, is the section that prohibits materially false or misleading labels, and the section that the FDA relied upon when issuing its guidance on the labeling of GM foods.⁶³ Therefore, although state laws and regulations may be preempted with regard to other aspects of “misbranding,” states could make a strong argument that, in excluding section 343(a) from the list of subsections with preemptory power, Congress intended to allow states leeway in adopting different standards with regard to materiality. In this way, so long as it remained possible for an individual to comply with section 343(a) and the state law, a state could base its law requiring labeling of GM foods on an interpretation of “materiality” that is more stringent than the FDA’s interpretation without running afoul of the national uniform nutrition labeling section of the Act.

It could be argued that, even were a state to cite a materiality as the basis for a mandatory labeling law, it is possible that such law would still be preempted under section 343-1(a)(1). Subsection (a)(1) states that state laws are preempted with respect to “any requirement for a food which is the subject of a standard of identity established under section 341” of the Act.⁶⁴ Section 341 of the Act authorizes the Secretary to “promulgate regulations fixing and establishing for any food, under its common or usual name...a

⁶² 21 U.S.C. § 343-1(a)(1)-(3). Subsections (4) and (5) were excluded as they are unlikely to have any relevance to this discussion. Subsection (4) prohibits conflicting requirements for nutritional labeling, and subsection (5) prohibits conflicting requirements regarding claims on the label regarding nutrition levels and other health-related claims. *Id.* at (a)(4)-(5).

⁶³ *See, Id.* at § 343(a); Labeling Guidance, *supra* note 24.

⁶⁴ 21 U.S.C. § 343-1(a)(1).

reasonable standard of identity.”⁶⁵ Therefore, subsection (a)(1) of section 343-1 prohibits states from adopting regulations for the identification of a food that conflict with the standard identifications adopted by the Secretary. Although on its face, this does not appear to implicate GM food labeling, it could be argued that branding an identified food as containing GMOs is, in essence, an affirmative statement that the identity of the food has changed. In this manner, GM corn (for example) would have a separate and distinct identity from non-GM corn. If this is the case, then a state law which mandates GM labeling could be construed as a regulation regarding the *identification* of a food.

The FDA has implied, in the Labeling Guidance document, that it does not consider current GM foods to have separate and distinct identities from their non-GM counterparts.⁶⁶ Therefore, if a state labeling law were to be construed as implicating the identity of a food, it could be argued that it would be preempted by section 343-1(a)(1), as the state’s requirements for identification would differ from those established by the Secretary.

Although this is a compelling argument, it is unlikely that the courts would agree that GMO labeling laws necessarily implicate section 341 of the Act. First, it is questionable

⁶⁵ *Id.* at § 341.

⁶⁶ *See* Labeling Guidance, *supra* note 24. In discussing the need for food labels to disclose all material facts about a food, the agency then stated that “[i]f a bioengineered food is significantly different from its traditional counterpart such that the common or usual name no longer adequately describes the new food, the name must be changed to describe the difference.” *Id.* Therefore, the FDA appears to tie the need for a unique identifier for GM foods to its determination of materiality discussion. This raises the question of whether section 343-1(a)(1), in expressly preempting state laws regarding identification of foods *impliedly* preempts state laws that implicate the materiality standard of section 343(a). Although this is a perplexing argument, it is likely—as argued, *infra*—that a court would find the lack of an express reference to section 343(a) in the National Uniform Nutritional Labeling Clause of the Act to mean that Congress did not intend to preempt State laws that differ with regard to materiality requirements, notwithstanding that such laws, almost by default, implicate issues of identity as well.

whether the underlying premise of this argument—that merely indicating that a food contains transgenic material necessarily implies that the said food has a separate identity from its counterparts which are free of transgenic material—is true.⁶⁷ The laws that are currently being proposed do not call for the cessation of the use of common identifiers on GM foods, as though the foods have become a new, distinct species, any more than labels such as “vitamin D milk” or “organic lettuce” somehow implies entities so significantly different from other “milk” or “lettuce” that the common name no longer adequately describes them.⁶⁸ It is more accurate to view GMO labeling as the addition of a qualifier rather than the identification of a completely distinct entity.

Second, the argument that GMO labeling necessarily establishes a new identity for GM foods seems to improperly conflate the issues of materiality and identity. Granted, as the FDA itself seems to imply, certain ways of interpreting materiality may indeed implicate identity,⁶⁹ however, this is not always the case. For example, a state could adopt a different standard for “material” that took account of the method of production⁷⁰ or of

⁶⁷ Granted, this premise has been bolstered by the rhetoric that has been used in the historical fight over GM foods. The use of such terms as “frankenfoods” certainly implies the advent of some new monster so insidious and twisted that it no longer shares a fundamental identity with the organism that was teased and tortured to create it. See Mark Lynas, *Lecture to Oxford Farming Conference, 3 January 2013*, <http://www.marklynas.org/2013/01/lecture-to-oxford-farming-conference-3-january-2013/>. However, over-the-top public rhetoric should not be confused with what ought to be the actual aim and effect of regulation.

⁶⁸ Now, if a state law required that all GM foods be labeled as “franken-” foods (imagine going to the store and seeing corn with a label that read “franken-corn”) there is little question in this author’s mind that section 341 would absolutely be implicated.

⁶⁹ See Labeling Guidance, *supra* note 24.

⁷⁰ See Matthew Rich, *supra* note 2 at 903-904; Diane E. Hoffmann, *The Biotechnology Revolution and Its Regulatory Evolution*, 38 *DRAKE L. REV.* 471, 505-506 (1988-1989); Alliance for Bio-Integrity, 116 *F. Supp. 2d* at 179.

consumer preference,⁷¹ neither of which are factors that implicate the identity of the food. As discussed, *supra*, it is the agency's unwillingness to consider as material factors that do not fundamentally alter the identity of the food or lead to health and safety risks that labeling proponents find so problematic.⁷² It is clear, then, that if a state grounded its labeling law in a broader definition of "material" which considered factors such as production process or consumer demand, the law would not implicate identity, and would therefore not be expressly preempted under section 343-1(a)(1).

Finally, it is well established that when a preemption clause within a statute "is susceptible of more than one plausible reading, courts ordinarily 'accept the reading that disfavors pre-emption.'"⁷³ Therefore, in the case of section 343-1, the glaring absence of section 343(a) in the list of enumerated sections that have preemptory power, a court is likely to find that a state labeling law that is grounded in a divergent view of materiality is not preempted by section 343-1, notwithstanding the fact that another reading of those sections could serve to combine the concepts of materiality and identification and thereby require preemption under section 343-1(a)(1).

b.) The Potential Problems with a Patchwork of State Labeling Laws

This discussion of preemption under the current Act would be unimportant if there were not compelling reasons why a multiplicity of state laws would be problematic.

However, when one considers the commercial implication of a landscape filled with many

⁷¹ See Alliance for Bio-Integrity, 116 F.Supp. 2d at 178. See also, Dorothy Du, *Rethinking Risks: Should Socioeconomic and Ethical Considerations Be Incorporated Into The Regulation of Genetically Modified Crops?*, 26 HARVARD J. L. & TECH. 375, 383-86 (2012) (arguing for the consideration of consumer choice in decisions regarding materiality and labeling).

⁷² Alliance for Bio-Integrity, 116 F.Supp. 2d at 178-179.

⁷³ *Altria Group, Inc. v. Good*, 55 U.S. 70, 77 (2008) (quoting *Bates v. Dow Agrosciences LLC*, 544 U.S. 431, 449 (2005)).

and varied state laws—some states requiring labeling for certain categories of foods containing transgenic material, but not others, some requiring no labeling whatsoever, some potentially even passing laws to prevent the voluntary labeling of GM foods—it becomes clear that not only is a patchwork of laws unwise, it may actually be practically untenable. One can only imagine the assortment of issues that growers, packagers, and manufacturers who sell GM foods in interstate markets would be faced with as they attempted to comply with fifty different labeling laws. Would they have to create fifty different labels for their products based on final destination? If that were not enough, imagine the logistical nightmare of attempting to get the right packages with the correct labels to the correct state. Clearly, this is not a feasible regulatory paradigm, and to the best of my knowledge, I am unaware of any product in interstate commerce that is subject to such a maze of state regulations.

In light of this, it becomes essential that the federal government step in and proactively preempt state laws before this potentially damaging legal paradigm is established. Before Congress can act, however, it must be asked whether it has the authority to proactively preempt state laws in this manner.

There is no question Congress has the authority, within the power granted to it by the commerce clause,⁷⁴ to pass laws with respect to food labeling. Current regulation of labeling under the Food, Drug, and Cosmetic Act has never been legally challenged, and it is unlikely that it ever will be: it is difficult to conceive of a law that falls more squarely within Congress' enumerated powers. Second, there is also little question that Congress may act preemptively or after the fact when passing a law to preempt state laws and create a

⁷⁴ U.S. Const. art. I, § 8, cl. 3.

uniform legal paradigm in a given area. The question is not one of timing, but is instead whether the law was made “under the authority of the United States”⁷⁵ and whether a subsequent or prior state law conflicts with the federal law.⁷⁶

The question, then, is not so much *whether* Congress is able to pass a law preempting state GM food labeling laws, but what the content of such a law should be. First, Congress could give section 343(a) preemptory effect by amending section 343-1 of the existing Act to specifically preempt state interpretations of “material” as it relates to food labeling. In this way, states would be prohibited from passing mandatory labeling laws on materiality grounds, as the FDA currently interprets 343(a) to prohibit mandatory labeling.

The problem that I perceive with this approach is that it seems to give short shrift to an issue that the public is—with increasing concern—demanding a comprehensive legal answer to. Of course, this is not to say that an amendment to the current Act would not work as a temporary patch until a more direct GMO labeling law were passed, but it is unlikely that it would appease the public as a long-term solution. Therefore, it seems that the best solution would be the creation of a new GM labeling law to address the issue comprehensively.

If Congress decides to act in this way, the question then becomes what position it should adopt on the issue. Without question, the most vocal voices in the debate today appear to be coming from the pro-labeling camp, but as the 2012 election results in California demonstrate, the public is roughly split on whether or not labeling ought to be mandatory. In the next section, I will argue that Congress should act to prohibit mandatory labeling.

⁷⁵ U.S. Const. art. VI, cl. 2.

⁷⁶ *Altria Group*, 55 U.S. at 76.

IV. A Federal Prohibition of Mandatory Labeling

There are two primary reasons that Congress ought to consider passing a law to prohibit—rather than require—labeling for GM foods. First, a law that mandates labeling may violate the free speech rights of the producers of GM foods and therefore be found unconstitutional. Second, the lack of consumer understanding of the scientific consensus regarding the safety of GM foods is likely to result in a level of consumer aversion that is inconsistent with the low risk that such foods pose. However, there are limited avenues through which consumers can become better educated with regard to science-based health and safety implications of GM foods, and it is therefore necessary that the federal government intervene and prohibit mandatory labeling in order to prophylactically protect consumers from the dangers of misinformation, and to protect the agricultural industry from the “European effect” wherein transgenic crops are forced from the market by irrational decision-making.

a.) The Unconstitutionality of Mandatory Labeling

The current debate over GM labeling is not the first time that biologically “modified” organisms and the byproducts therefrom were targeted for labeling. In 1994, the State of Vermont passed a law that required the labeling of milk or milk products that came from dairy herds treated with recombinant Bovine Somatotropin (rBST), better known as recombinant Bovine Growth Hormone (rGBH), a growth hormone that increases milk production in cows.⁷⁷ The law was passed one year after the FDA had approved the use of rGBH *and* refused to require labeling of such products, finding that those “products derived from herds treated with rBST are indistinguishable from products derived from untreated

⁷⁷ See *Int’l Dairy Foods Ass’n v. Amestoy*, 92 F.3d 67, 69 (2d Cir. 1996).

herds.”⁷⁸ A group of dairy manufacturers challenged Vermont’s law in federal court, arguing that it was unconstitutional because it violated their first amendment rights and violated the Commerce Clause.⁷⁹

The court held that the statute did, indeed, violate the First Amendment rights of the plaintiff manufacturers, that the State did not have a compelling reason to abridge that right in this case, and that the mandate was therefore unconstitutional.⁸⁰ In so holding the court made more than a few points that are easily transcribed to the present debate about whether the current slate of GM foods provide grounds for mandatory labeling.

First, a statute that *mandates* otherwise involuntary speech is no different than a law that *prohibits* certain speech for First Amendment purposes.⁸¹ Second, the court reiterated the point that “the right *not* to speak inheres in political and commercial speech alike and extends to statements of fact as well as statements of opinion.”⁸² Therefore, even though the Vermont law purported to compel a factual statement on (arguably) purely commercial speech, this did not mean that it was free of constitutional error. Next, in order to determine whether a governmental restriction on commercial speech is permissible, it must pass the four-part test articulated by the Supreme Court in *Central Hudson*, meaning that the governmental interest at the heart of the regulation must be substantial.⁸³

⁷⁸ *Id.*

⁷⁹ *Id.*

⁸⁰ *Id.* at 74.

⁸¹ *Id.* at 71.

⁸² Int’l Dairy Foods Ass’n, 92 F.3d 67 at 71 (emphasis added) (internal citations omitted).

⁸³ *Id.* at 72. *See Central Hudson Gas & Elec. Corp. v. Pub. Serv. Comm’n of N.Y.*, 447 U.S. 557, 566 (holding that, “[i]n commercial speech cases...a four-part analysis has developed,” which entails a determination (1) of whether the express concerns lawful activity, (2) of whether the asserted governmental interest is substantial, (3) of “whether the regulation direction advance the [asserted] governmental interest, and (4) of whether the regulation “is not more extensive than is necessary to serve [the asserted] interest.”)

Applying the *Central Hudson* test, the court found that Vermont had “failed to establish the second prong of the...test” because the interest that asserted by the State to justify its abridgement of the corporations’ First Amendment rights was not substantial.⁸⁴ The State had not attempted to justify the regulation on health and safety grounds, but rather had argued that the law was defensible on the ground that it was consistent with a strong consumer interest in and demand for such labeling and because it protected the consumers’ “right to know.”⁸⁵ The court held that the (admittedly genuine) demand for this information by the general public, absent some underlying and “*reasonable* concern for human health or safety,” was inadequate grounds upon which to “permit the State...to compel the dairy manufacturers to speak against their will.”⁸⁶ In so holding, the court established the rule—which as of yet has not been overturned—that “consumer curiosity alone is not a strong enough state interest to sustain the compulsion of even an accurate, factual statement.”⁸⁷

This is, undeniably, a seminal case for analyzing the constitutionality of a mandatory labeling law. In order for a mandatory labeling law for GM food to pass Constitutional muster after this case, it is clear that it would have to be based on something more than

⁸⁴ Int’l Dairy Foods Ass’n, 92 F.3d 67 at 73.

⁸⁵ *Id.* at 73. As the court noted, it was understandable that Vermont chose not to defend the law on public health and safety grounds as “the FDA ha[d] concluded that rBST has no appreciable effect on the composition of milk produced by treated cows, and that there are no human safety or health concerns associated with food products derived from cows treated with rBST.” *Id.* (internal citations omitted). This particular point is important to keep in mind when discussing whether a State could base the mandatory labeling of GM foods on health and safety concerns.

⁸⁶ *Id.* at 73-74. The dissent, on the other hand, believed that Vermont’s stated interests, “including worries about rBST’s impact on human and cow health, fears for the survival of small dairy farms, and concerns about the manipulation of nature through biotechnology,” *did* provide sufficient grounds. *Id.* at 74 (Leval, J., dissenting).

⁸⁷ *Id.* at 74.

naked consumer interest or concern. However, as was the case in Vermont, consumer “right to know” continues to be one of if not *the* central argument for why a labeling law is justified.⁸⁸ This fact has led some experts in the field to believe that “the odds are good that the Supreme Court would...strike down a GMO labeling requirement” were one to be passed today.⁸⁹ Indeed, unless a state, or even the federal government, could ground a labeling law in something other than a consumer’s right to know, it is difficult to imagine a different outcome.

Of course, others have pointed out the fact that “the FDA and USDA [currently] permit certain other types of food labels that are unrelated to the nutritional safety profile of food” such as the “fair trade” label.⁹⁰ Though this may be true, there is one fundamental difference between the “fair trade” label (among others)⁹¹ and the GMO labeling laws that are being contemplated: the FDA and USDA have not *mandated* that producers use the fair trade label. Certainly, requiring a producer to label its food as containing transgenic material is conceptually different from permitting producers to indicate that their product

⁸⁸ See, e.g. Appleton, *supra* note 13 at 567 (stating that “[t]he most important argument in support of GMO labeling...is the ‘consumer’s right to know’”); Rich, *supra* note 2 at 904 (stating that “[t]he issue of labeling genetically modified foods is centered on the tension between a consumer’s right to know and the bioengineering industry’s interest in not labeling”); Du, *supra* note 71 at 384 (noting that as GMOs have become more prevalent and consumers were increasingly aware of their presence, “polls revealed that an unequivocal majority of consumers wanted GM foods labeled”); CALIFORNIA GENERAL ELECTION OFFICIAL VOTER INFORMATION GUIDE, *supra* note 43 at 110 (declaring that “California consumers have the right to know whether the foods they purchase were produced using genetic engineering”).

⁸⁹ Rosie Mestel, *Genetically modified foods: Who has to tell?*, Los Angeles Times, Feb. 23, 2013, available at <http://articles.latimes.com/2013/feb/23/science/la-sci-gmo-labeling-20130223> (quoting Hank Greely, director of the Stanford Center for Law and the Biosciences).

⁹⁰ Du, *supra* note 71 at 385.

⁹¹ The “organic” label is another example of voluntary labeling permitted by the FDA and USDA.

is certified fair trade or organic when the producer has put in the effort to obtain such certification.

If consumer interest alone is insufficient grounds for a mandatory labeling law, the question then becomes whether there are any other viable grounds that could form a defensible basis for such a law. The Second Circuit, of course, appeared to condone “reasonable” health and safety concerns as potentially sufficient grounds for such regulation.⁹² Could a GMO labeling law possibly be justified on “health and safety” grounds?

There is little question that the public debate over the safety (or lack thereof) of GMOs is far from resolved.⁹³ However, at this time, the scientific consensus is nearly unanimous that GM foods pose no significant health or safety risks.⁹⁴ Indeed, though GMO skeptics have been quick to pose hypothetical, unknown risks that GM foods could pose,⁹⁵ these fears appear to be largely baseless insofar as the scientific literature is concerned.⁹⁶ It

⁹² Int’l Dairy Foods Ass’n, 92 F.3d 67 at 73-74.

⁹³ See GMO Poll, *supra* note 41 (reporting that in a recent survey, 21% of respondents said that they think GMO foods are safe to eat, while 35% believe that they are dangerous).

⁹⁴ See, Lucia Martinelli et al., *Science, safety, and trust: the case of transgenic food*, 54 *Croat Med J.* 91, 91-92 (2013) (finding that “[o]n the whole, peer-reviewed studies on GM food safety do not note significant health risks” and again that “[a]ccording to comprehensive studies, in which the most accredited scientific papers on feeding trials have been analyzed...no significant health risks were found,” and noting that the few existing exceptions “have been disregarded by the scientific community, based on incorrect experimental designs and statistic analysis”); Rosie Mestel, *Scientists defend safety of genetically modified foods*, *Los Angeles Times*, Oct. 24, 2012, available at <http://articles.latimes.com/2012/oct/24/science/la-sci-gmo-food-safety-20121025> (reporting that “among scientists, there is widespread agreement that [GM] crops aren’t dangerous”).

⁹⁵ See, Stacy Malkan, *Massive Tumors in Rats Fed Monsanto’s Genetically Engineered Corn in First Long Term Study*, *Right to Know Blog*, Sept. 19, 2012, (demanding that the agricultural industry immediately release documents linking GM foods to health issues such as “tumors, kidney and liver damage, and premature death”).

⁹⁶ See Martinelli, *supra* note 94 at 91. There was one French study published by Food and Chemical Toxicology in 2012 that garnered quite a bit of press for its finding that severe health defects were manifested in rats that were fed a diet of GM maize sprayed with the

appears that the FDA has sufficient support for its finding that there is “no basis for concluding that bioengineered foods 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.”⁹⁷

Given this current weight of scientific evidence, it is unlikely that a state could successfully argue that GM foods pose a substantial health and safety concern. A state could argue that there are still hypothetical risks, especially long-term risks, that have not yet manifested and that future studies might demonstrate to be real and significant. Even were such studies to come to light in the future, it is unlikely that the Court would rule that the mere potentiality of such future findings amounts to a health and safety risk that is substantial enough to mandate labeling in the present. Aside from health and safety concerns, it is difficult to imagine another justification for a mandatory labeling law that would satisfy the second prong of the *Central Hudson* test.

b.) A Paternalistic Argument for a Prophylactic *Prohibition* on GMO Labeling

If a federal law mandating GMO labeling is constitutionally untenable, there are three remaining approaches that Congress could take. First, it could pass a law that is

weed killer, Roundup. See Michelle Castillo, *Study says genetically modified corn causes tumors, but other scientists skeptical about research*, CBS News, Sept. 21, 2012, available at http://www.cbsnews.com/8301-504763_162-57517377-10391704/study-says-genetically-modified-corn-causes-tumors-but-other-scientists-skeptical-about-research/. However, the study was subsequently lampooned and disavowed by the scientific community as being poorly conceived and executed, and therefore unreliable. See European Food Safety Authority, Press Release, *EFSA publishes initial review on GM maize and herbicide study*, Oct. 4, 2012 (reporting that the EFSA concluded that the French study was “of insufficient scientific quality to be considered as valid for risk assessment”).

⁹⁷ Labeling Guidance, *supra* note 24. See also Martinelli, *supra* note 94 at 92 (finding that “possible difference between transgenic feedings and their isogenic counterparts were considered of no biological or toxicological significance” by comprehensive feeding studies).

neutral with regard to labeling, but that would permit producers to label if they so desire. Second, it could pass a law that empowers the FDA to determine whether labeling is or is not required, thereby leaving the ultimate decision in the hands of the agency.⁹⁸ Third, it could pass a law explicitly prohibiting the labeling of GM foods, but granting authority to the FDA to require labeling in individual cases in which the transgenic food is not substantially similar to its conventional counterpart. Although the first and second options are inarguably more palatable (who doesn't like the idea of greater personal freedom?), the third option may actually be the one that is necessary from a public policy perspective, given an atmosphere of unjustified consumer bias toward GM food and the government's interest in protecting the use of GM crops.

A voluntary labeling law is attractive because it appears to grant consumers a choice without infringing upon the First Amendment rights of producers. Proponents of such a scheme are likely to argue that it will lead to an efficient outcome—as the amount of labeling that actually occurs will be consistent with how much labeling the market demands—while concomitantly protecting consumer choice. This argument assumes, however, that the probable market outcome in this case is the most desirable outcome. If market demand is based on uninformed and, thus, biased decision-making (as I will argue it is), the outcome will, in reality, not be as efficient as it could be. Even if GM crops are

⁹⁸ I will not discuss the second option in detail, as it would essentially look the same as what we have today under the FDCA. The FDA has already revealed its approach to GMO labeling, and unless a new law were to establish considerations for labeling other than materiality, the FDA's approach would likely not differ from what it is today. If Congress were to pass a new law, but granted the FDA authority to consider factors other than materiality (such as consumer demand), this would likely lead to a voluntary labeling scheme, which I discuss, *infra*.

more viable and less costly to grow,⁹⁹ farmers may avoid planting them if consumer opinion is adverse for fear that they would not be able to move a product in a hostile market. As mentioned in Part I, this effect has already been seen in European countries that have adopted labeling laws.¹⁰⁰ As noted, this could actually have the ironic result of decreasing certain consumer choice.

As stated, *supra*, current public attitude toward GM foods is at best uncertain, though it appears to be leaning toward skepticism and overt disfavor of the technology in general.¹⁰¹ However, as outlined in the previous section, this consumer aversion is not based upon scientific fact. In reality, it appears to be largely the product of a misunderstanding of the science behind the technology, carried along by the pure inertia of public opinion.¹⁰² When most consumers hear the term “genetically modified organism” the word that is likely to stick in their minds is “modified;”¹⁰³ conjuring images of an unholy tampering with nature, yielding unnatural and insidious results.¹⁰⁴ The potential

⁹⁹ Mark Lynas, *Lecture to Oxford Farming Conference, 3 January 2013*, <http://www.marklynas.org/2013/01/lecture-to-oxford-farming-conference-3-january-2013/>.

¹⁰⁰ See *supra* note 14 and accompanying text.

¹⁰¹ See *supra* notes 41 & 93 and corresponding text.

¹⁰² See DANIEL CHARLES, *LORDS OF THE HARVEST* 205-229 (Perseus Publishing 2001). In his book, Mr. Charles provides an interesting look into the genesis of the biotech movement and the forces opposed to it. The cited chapter contains a most insightful look into the motivations and efforts of Greenpeace and other groups opposed to the use of GMOs, and the success of that movement in beginning to sway the opinion of the general public toward skepticism. Scientists caught in the crossfire felt, understandably, frustrated by the tide of public opinion: “many...scientists involved in the controversy felt enraged, helpless and betrayed by their own culture. ‘This stuff is straight out of the Dark Ages,’ glowered one of them darkly.” *Id.* at 227-28.

¹⁰³ See Jaffe, *supra* note 13.

¹⁰⁴ *Id.* at 92-93. Mark Lynas, formerly an outspoken opponent of GMOs who changed his mind after researching the science behind the technology, had this to say about how he and others who opposed GMOs attempted to paint them in the public’s eye:

psychological reasons for this negative association are myriad, and would defy a comprehensive analysis in the space available in this paper. However, two factors that are likely at work to some degree are “bounded rationality”¹⁰⁵ and the oft-cited “confirmation bias.”¹⁰⁶

In general, the bounded rationality model is used to explain—in part—why consumer choices do not always accomplish the most rationally optimal outcome and why consumers’ choices may not align with what is best for their personal welfare.¹⁰⁷ Scholars who have written on the matter are quick to point out that bounded rationality is not the same as irrationality,¹⁰⁸ but is, instead, rationality limited by imperfect knowledge, incomplete information, and the natural cognitive limitations innate to all human beings.¹⁰⁹ This model appears to be particularly applicable in the case of GM foods, as it is reasonable to assume that most consumers simply do not understand the scientific process whereby these genetically modified organisms are created, and fail to realize that this process is

We employed a lot of imagery about scientists in their labs cackling demonically as they tinkered with the very building blocks of life. Hence the Frankenstein food tag—this absolutely was about deep-seated fears of scientific powers being used secretly for unnatural ends.

Lynas, *supra* note 98.

¹⁰⁵ Reinhard Selten, *What Is Bounded Rationality?*, in *BOUNDED RATIONALITY: THE ADAPTIVE TOOLBOX* 13, 15 (G. Gigerenzer & R. Selten eds., 2001) (referring to bounded rationality as “optimization under some cognitive bounds”); *see also* ALISTAIR MUNRO, *BOUNDED RATIONALITY AND PUBLIC POLICY: A PERSPECTIVE FROM BEHAVIOURAL ECONOMICS* 3 (2009) (defining bounded rationality as “the failure to have complete and consistent preferences”).

¹⁰⁶ Linda Heath & R. Scott Tindale, *Heuristics and Biases in Applied Settings: An Introduction*, in *APPLICATIONS OF HEURISTICS AND BIASES TO SOCIAL ISSUES* 1, 8 (Linda Heath et al. eds., 1994) (summarizing the confirmation bias as the tendency for pre-conceived categories to bias information search and interpretation in such a way that confirms those expectations).

¹⁰⁷ Alistair Munro, *supra* note 104 at 1-2.

¹⁰⁸ *See*, Gerd Gigerenzer and Reinhard Selten, *Rethinking Rationality*, in *BOUNDED RATIONALITY: THE ADAPTIVE TOOLBOX* 1, 4 (G. Gigerenzer & R. Selten eds., 2001) (noting that “[b]ounded rationality is neither optimization nor irrationality”).

¹⁰⁹ *See*, Reinhard Selten, *supra* note 104 at 14, 17.

largely analogous with what horticulturalists have been doing for hundreds—if not thousands—of years through conventional breeding and mutagenesis.¹¹⁰ Nor do most realize that most of the genes introduced by biochemists into transgenic plants are genes which code for proteins that, although not occurring naturally in that particular species, are present in other species that are already part of our diet.¹¹¹

This lack of basic scientific understanding is important because one's understanding of the underlying science will undoubtedly have ramifications on whether that person believes that labeling is or is not necessary; whether the presence of GMOs in our food is really of any material significance. A consumer who is ignorant regarding the scientific process undergirding the product is much more likely to be swayed by the mores of popular opinion, regardless of whether that opinion has scientific support or not. Therefore, such a consumer is likely to make choices that do not properly reflect the amount of actual risk.

Additionally, unless a consumer were to take it upon herself to research the scientific facts supporting GM foods, there are few other channels through which she could obtain this information. Contrast this to a product such as pharmaceuticals—which

¹¹⁰ See Lynas, *supra* note 98; CHARLES, *supra* note 101 at 106 (“such phenomena were not fundamentally new. Similar genetic processes had been occurring in the world’s fields and forests since the origins of plant life...So the risks posed by unexpected side effects of genetic engineering, though unpredictable, are still familiar); Mestel, *supra* note 94 (reporting that scientists believe that GM plants “are as safe as those generated for centuries by conventional breeding and...by irradiated plant material).

¹¹¹ See Lynas, *supra* note 100; Jaffe, *supra* note 13 (stating that “[t]he DNA inserted into GE seeds, and the protein it produces...are sometimes molecules that humans have already been exposed to); Mestel, *supra* note 94 (“‘There is not mystery here,’ [says] UCLA plant geneticist Bob Goldberg. ‘When you put a gene into a plant...it behaves exactly like any other gene’”). Jaffe also points out that even those proteins and genes that are not already part of our diets (for example, the protein produced by the *Bacillus thuringiensis* (bt) gene that was introduced into corn and soybeans, CHARLES, *supra* note 99 at 41-50) are more often than not denatured during the production process. Jaffe, *supra* note 13.

likewise contain warnings or listings of ingredients that most consumers without a background in biochemistry would not understand. In the case of a technical warning on a pharmaceutical drug that the consumer does not understand, she is able to approach her doctor or pharmacist and obtain expert information on the implications of the listed compounds and their potential side effects. The consumer is not left on her own. Where would a consumer who had a question about the safety of GMOs turn? Would she write the FDA to ask their opinion? Would such inquiry be given a satisfactory answer?

One could argue that the FDA could remedy this problem by creating a consumer information service to provide information regarding GM foods. However, even were the FDA able to establish, in conjunction with a voluntary labeling law, reliable outside channels through which one could obtain information regarding the actual health risk of GM foods, given the prevailing negative opinion that the public has developed toward the technology, it is possible that an overriding confirmation bias may render such efforts largely ineffective.

Confirmation bias explains why “it is difficult to change people’s minds about... risks once their minds are made up.”¹¹² As stated, *supra*, recent polls suggest that about 35% of people believe that GM foods are harmful;¹¹³ a number that cannot be justified by the scientific literature detailing the health risks of such foods. Whether rational or not, given that this has become the established *expectation* with regard to GM foods, one may reasonably ask whether educational efforts would succeed in swaying public opinion, or whether a significant portion of the population has irreversibly made up its mind that GM

¹¹² David R. Holtgrave et al., *Heuristics, Biases, and Environmental Health Risk Analysis, in APPLICATIONS OF HEURISTICS AND BIASES TO SOCIAL ISSUES* 259, 265 (Linda Heath et al. eds., 1994). *See also*, Alistair Munro, *supra* note 104 at 54-56.

¹¹³ GMO Poll, *supra* note 41.

foods pose a significant danger to consumer health and wellbeing and would not be swayed. Even though the aforementioned poll also indicated that nearly 50% of respondents indicated that they were at this time unsure as to whether GM foods did or did not present health and safety risks,¹¹⁴ it is conceivable that educational efforts may be ineffective at counteracting the negative rhetoric aimed at GM crops and foods. As the uptick in state grassroots labeling efforts demonstrate, the pro-labeling (and often time anti-GMO) groups have been very effective at capturing the public discourse on this issue. If educational efforts did fail, the inefficient market effects caused by bounded rationality would not be mitigated.

A federal prohibition of labeling, on the other hand, though it eschews consumer choice in the short run, has certain advantages over the voluntary model described above. Whereas a voluntary labeling paradigm may ultimately lead to the same market inefficiencies that have been observed with mandatory labeling schemes, a prohibitory labeling policy circumvents the inefficiencies caused by bounded rationality and consumer biases by never putting the decision to consumers in the first place. Without question, such approach is overtly paternalistic, and would not satisfy the public's desire to know, but it may, nevertheless, be justifiable from a policy perspective.

First, one can make the argument that prohibiting GMO labeling is necessary to promote the development of biotech crops, which in turn confers a social benefit since GM crop development appears at this time to be the most viably sustainable way for the global food supply to keep pace with an ever-increasing world population.¹¹⁵ GM crops are not a

¹¹⁴ *Id.*

¹¹⁵ *See* Lynas, *supra* note 100 (reporting that the world population is expected to increase to 9.5 billion people—from 6.9 billion, today—by the year 2050, and that, along with

mere convenience for farmers; they are likely to be one of the key tools in the belt of the global and domestic agricultural industry to keep pace with a quickly growing demand. Given this fact, the government has both a commercial and a public welfare justification for acting to prohibit labeling, as labeling laws are likely to have trickle-down effects on the use of such technology in the field.

Second, one could make the argument that the government has a duty to protect consumers from the inefficiencies and dangers of misinformation and their own “irrational” cognitive biases, and that the best way to do this with regard to the labeling of GM foods—given the aforementioned limitations on consumer education—is through an all-out prohibition of labeling for biotech foods that are substantially the same as their conventional counterparts. If a particular GM food is truly not materially different from the non-GMO variety, then any label indicating that the mere presence or absence of transgenic material makes the one product inferior (or superior) to the other must by definition be deceptive advertising, as it does not accord with scientific fact. Therefore, any law that sanctions such labeling—be it mandatory or voluntary—could be construed as a sanctioning of deceptive advertising practices. Surely, the federal government has an interest in protecting consumers from the provision of such misleading information, *especially* when those consumers do not have the knowledge base that is necessary to penetrate false statements and public biases in order to derive the truth.¹¹⁶

continually decreasing levels of global poverty, this will result in a global demand increase of over 100%).

¹¹⁶ In *BOUNDED RATIONALITY AND PUBLIC POLICY: A PERSPECTIVE FROM BEHAVIOURAL ECONOMICS*, Mr. Munro makes the argument that the so called “nanny state” (what I have here classified paternalism) may be necessary to counteract the effects of bounded rationality. Alistair Munro, *supra* note 104 at 148-49. However, he stops one step short of my proposal by claiming that paternalistic regulation may only be desirable to mitigate bounded rationality

Of course, a labeling prohibition may also prove to be untenable for various reasons. Chiefly, it could be argued that such prohibition violates the First Amendment rights of producers who wish to voluntarily designate their food as “GMO-free” as an unlawful prohibition on speech (rather than unlawfully compelled speech in the case of a mandatory labeling law). Although this argument has some merit, it is possible that aforementioned policy justifications would constitute a sufficiently substantial governmental interest to justify prohibiting this type of commercial speech. Additionally, as previously discussed, the FDA has *already* imposed limits under the FDCA (albeit in guidance) on certain forms of advertising that indicate that a food is GM free. Of course, this determination has never been challenged on constitutional grounds.

Assuming that a prohibitory labeling law would violate producers’ First Amendment rights, the government would have to show that it has a substantial interest to justify its action. To this end, the government could argue that the two interests described above create a sufficiently substantial basis. First, the government has an interest in protecting consumers from misleading advertising. In *Central Hudson* the Supreme Court noted that, before a state law even need be subjected to the “substantial interest” analysis, the speech in question must not be misleading.¹¹⁷ If, as I have argued, GM food labels are per se misleading, then the government would not have to identify a substantial interest in the first place. Even if a GM food labeling were found to be only potentially misleading, the government could argue that the FDCA similarly prohibits certain labels that would

when consumers are *aware* of their limited rationality and invite such regulation. *Id.* Although I agree that this (unlikely?) situation would merit state paternalism, I would hold that paternalistic lawmaking may also be justified in certain cases when consumers are unaware of their cognitive biases, but the stakes of the issue are particularly great.

¹¹⁷ *Central Hudson*, 447 U.S. at 563-564 (defining “misleading” communication as one that is “more likely to deceive the public than to inform it”).

constitute misbranding of food,¹¹⁸ yet there has never been any indication that the FDCA violates the rights of producers. Second, the government could argue that a prohibitory labeling law is reasonable as it promotes the general welfare by acting, albeit remotely, to prevent inefficient market forces from forcing from the market GM foods and crops that are necessary to maintain national food security. Whether these interests would be substantial enough to cut constitutional muster is debatable.

In addition to the constitutional argument, one could argue that a prohibitory law is inconsistent with the current permissive approach toward other non-material labels, such as “fair trade” or “organic.” Even assuming that these labels do not address material facts,¹¹⁹ this does not mean that the government is under any obligation to be equally as permissive when it comes to the labeling of all non-material information. Additionally, organic and fair-trade are fundamentally different from GM food in one important respect: whereas consumers have come to view GM as something to avoid, organic and fair trade products have come to be viewed largely as desirable. Therefore, the heuristics and cognitive biases that have created an aversion to GM foods are not at work in the same manner with organic and fair trade foods, and the government therefore has no need to adopt paternalistic laws to combat consumer biases in the case of those categories. Finally, organic and fair trade foods are not necessary to the nation’s food security in the same way that biotech foods are.

Lastly, proponents of labeling are likely to point out that government intrusions into consumer affairs for paternalistic reasons have, in the past, been met with negative

¹¹⁸ 21 U.S.C. §§ 331, 343.

¹¹⁹ Which I do not believe that they do.

results.¹²⁰ This argument ignores the fact that almost all regulation is in some respect inherently paternalistic. Paternalism certainly is not a popular theory (authors have already criticized the FDA’s current labeling policy as “paternalistic”),¹²¹ and it is almost assumed that paternalism is a great evil to be avoided at all costs. The assumption that paternalism is never justifiable, though, seems terribly myopic.

It may be true that none of us wants the government constantly looking over our shoulders to ensure that we are making choices that are efficient and best for society at large, but the consumer’s individual freedom to obtain the information that they want must constantly be weighed against the government’s legitimate interest in limiting a consumer’s exposure to deceptive or misleading information, especially when such exposure is likely to result in consumer choices that may very well force an essential technology from the market. When one considers the increased costs associated with labeling, the potentially adverse effects that labeling could have on the agricultural industry’s ability to adapt and advance in an ever-changing global landscape, and the danger of leaving uninformed consumers to fend for themselves in the face of misleading information, a prophylactic, paternalistic prohibition becomes an option that must at least be considered.

V. Conclusion

The conflict over labeling is not likely to abate until laws—either state or federal—are in place to address the issue directly. Each year, more and more GM crops are planted on the nation’s agricultural land, only piquing the fears of consumers who are largely

¹²⁰ The Prohibition Period immediately comes to mind.

¹²¹ See Du, *supra* note 71 at 384; Rich, *supra* note 2 at 906 (stating that “ignor[ing] mass public concern is irresponsible, and denotes a paternalistic approach to public policy.”)

unfamiliar with what is meant by scientists “genetically transforming” plants. Without question, consumers across the United States will continue to demand that the State and federal governments act to require labeling by producers of foods that contain transgenic material. If the federal government fails to act and instead leaves it up to states to address consumer demand, the result is likely to be a patchwork of state regulations, which could threaten to dramatically upset interstate commerce. What is needed, then, is a definitive federal law addressing the question of GM labeling head on; one that creates a uniform and predictable labeling paradigm that works to promote the safe and effective use of GM crops, that ensures our ability to continue to feed an ever-increasing population, and, possibly, one that protects consumers from their own biases. However Congress chooses to act, let us hope that it acts with prudence, and acts soon.