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**An Agricultural Law Research Article**

**The War on GMOs: A Report from the Front**

by

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## **A National AgLaw Center Research Article**

# **The War on GMOs: A Report from the Front**

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According to the Union of Concerned Scientists (UCS), more than two-thirds of the seed supply of three primary crops in the United States (corn, canola, and soybeans) is now “contaminated” with genetically modified material.<sup>1</sup> Here is one scenario for how this happened. A corn seed production field is located downwind from a field growing pharmaceutical corn plants. Pharmaceutical plants are plants that have been genetically engineered to produce materials used to manufacture drugs. A wind blows pollen from the pharmaceutical field into the conventional seed cornfield, pollinating corn silks in that field. Some kernels of the ears of the seed corn thus contain DNA for drugs and even the drugs themselves. The seed corn producer harvests the seed and sends it to a processing facility where it is bagged and distributed into the seed corn market. An organic corn farmer buys some of this seed, unaware that it contains pharmaceutical DNA. She sells her crop to a maker of organic breakfast cereal. Consumers of that product then unknowingly “serve[ ] their kids drug-laced corn flakes.”<sup>2</sup> This scenario is not a product of the UCS’s imagination, fertile as it may be.

In 2003, a test-crop of corn engineered to produce pharmaceuticals invaded a crop of soybeans grown for human and animal consumption. In that instance, the agent was not pollen drift but the intermixing of volunteer corn plants with the soybeans. The contamination was discovered before the soybeans reached the market, but nearly 500,000 bushels of soybeans were effectively tainted. The federal Animal Plant and Inspection Service (APHIS) fined the corn producer, ProdiGene Inc., \$250,000 and made it reimburse the government’s cost of destroying the soybeans and cleaning the grain elevator where the contaminated beans were stored.<sup>3</sup>

Even before this incident, APHIS had responded to a growing concern about pharmaceutical plants by proposing to tighten permitting guidelines for field testing plant-made pharmaceuticals (PMPs). Among other changes, the agency proposed that experimental PMPs must be grown further away from conventional crops, that no food crops could be grown in the same field in the following planting season (the scenario in the ProdiGene case), that dedicated equipment would be used for PMP crops, and that

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<sup>1</sup> See UNION OF CONCERNED SCIENTISTS, GONE TO SEED: TRANSGENIC CONTAMINANTS IN THE TRADITIONAL FOOD SUPPLY (2004), *available at* <http://www.ucsus.org/documents/seedreport>.

<sup>2</sup> UNION OF CONCERNED SCIENTISTS, HOW DOES SEED CONTAMINATION OCCUR?, *available at* [http://www.ucsus.org/food\\_and\\_environment/biotechnology](http://www.ucsus.org/food_and_environment/biotechnology).

<sup>3</sup> PEW INITIATIVE ON FOOD AND BIOTECHNOLOGY, PHARMING REAPS REGULATORY CHANGES, *available at* <http://www.pewagbiotech.org/buzz/display.php3?StoryID=101>.

special grain cleaning protocols would be implemented.<sup>4</sup> In the wake of ProdiGene, APHIS has given notice of its intention to draft an Environmental Impact Statement addressing, among other things, the potential impact of pharmaceuticals on other forms of farming.<sup>5</sup> Some conventional food and grain producers support these federal regulatory initiatives. As the president of the National Corn Growers Association put it, “I never thought I’d be one to ask for more requirements, but we did. We don’t want to see an AIDs vaccine show up in a box of cornflakes. And with these regulations, that will never happen. If we don’t do it right, we won’t have this technology.”<sup>6</sup> Let us hope he is correct.

Not all producers, however, share the National Corn Growers Association’s faith that the federal government will or can effectively regulate agricultural biotechnology. Their concerns go far beyond the problem of pharmaceutical plants to an array of public health, environmental, and even ethical issues. These issues include the creation of resistant weeds and pests, reduction of agricultural biodiversity, increasing food allergenicity and toxicity, harm to non-toxic species like butterflies and native plants, and the very notion of human manipulation of species by crossing genes between different organisms. Increasingly, opponents of genetically engineered organisms (GMOs) are taking their concerns to state legislatures and local governments. And they are beginning to see results. In April 2004, the Vermont legislature became the first in the nation to require manufacturers of genetically modified seeds to label and register their products. The proponents of this statute narrowly missed passing a companion bill that would have imposed liability for economic losses caused by genetic contamination on seed manufacturers, rather than neighboring farmers who grow genetically modified plants in their fields.<sup>7</sup> In March 2004, the residents of Mendocino County, California, went even further by enacting an outright ban on genetically modified plants.<sup>8</sup> Following Mendocino County’s lead, voters in a dozen other California counties are considering initiatives that would ban genetically modified crops.<sup>9</sup>

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<sup>4</sup> Field Testing of Plants Engineered to Produce Pharmaceutical and Industrial Compounds, 68 Fed. Reg. 11337-01 (proposed March 10, 2003) (to be codified at 7 C.F.R. Part 340).

<sup>5</sup> Environmental Impact Statement; Introduction of Genetically Engineered Organisms, 69 Fed. Reg. 3271-01 (proposed January 23, 2004) (to be codified at 7 C.F.R. Part 340).

<sup>6</sup> PEW INITIATIVE ON FOOD AND BIOTECHNOLOGY, *supra* note 3 (quoting Fred Yoder, president, National Corn Growers Association).

<sup>7</sup> The Vermont Senate passed the manufacturer-liability bill twice unanimously, but the House Agriculture Committee did not take it up. See Darren M. Allen, *Douglas Signs Nation’s First GMO Labeling Law*, RUTLAND HERALD, Apr. 27, 2004, available at <http://www.rutlandherald.com>.

<sup>8</sup> Mike Geniella, *Mendocino County Voters Ban Biotech Crops: First County in the U.S. to Bar Gene-Altered Farming*, SANTA ROSA PRESS DEMOCRAT, Mar. 3, 2004, available at <http://www.pressdemocrat.com>. According to the Press Democrat, CropLife America, an industry association that represents biotech companies, shattered the local election spending record by putting more than \$500,000 into a “vote no on Measure H” campaign. See Mike Geniella, *Biotech Backers Pile on Cash in Mendocino*, SANTA ROSA PRESS DEMOCRAT, Mar. 2, 2004, available at <http://www.pressdemocrat.com>.

<sup>9</sup> See Glenda Anderson, *Altered Crop Bans Growing in Popularity*, SANTA ROSA PRESS DEMOCRAT, May 4, 2004, available at <http://www.pressdemocrat.com>.

One commonality between Mendocino County and Vermont is that both have a thriving and expanding organic agriculture. In both places, producers of organic grapes and wine, corn, milk, maple syrup, vegetables, wheat, and other commodities are counting on a market niche that provides them a premium above the prices of non-organic products.<sup>10</sup> And they are concerned that contamination by genetically modified materials will close and seal that niche. Under APHIS's organic rules, genetic contamination would not deprive the producer of organic certification.<sup>11</sup> But organic markets are rejecting contaminated organic products regardless of the producer's certification status. Grain mills that buy organic grain, for example, test for evidence of genetically modified material and, if they find it, they reject the entire load because the companies to whom they sell processed grain tolerate no genetic contamination. So despite their regulatory status under APHIS's rules, organic farmers face market-driven rejection of their contaminated products.<sup>12</sup> For this reason, organic producers in Vermont and Mendocino County were strong supporters of the regulations that legislators and voters approved.<sup>13</sup>

This article does not explore the pros and cons of GMOs. That debate is already lengthy—and barbed—and it is likely to continue for a while. Rather, this article analyzes the Mendocino County ban and the Vermont labeling and registration statute<sup>14</sup> with respect to their constitutionality. Sponsors of both measures anticipate legal challenges. In fact, the biotechnology industry has hinted strongly that these challenges will arrive soon.<sup>15</sup> And, quite clearly, both measures raise interesting issues under two related constitutional law doctrines: the dormant commerce clause and the concept of federal preemption. Because Mendocino County Measure H and Vermont H. 352 are so different in effect, analysis of their respective constitutionality, or lack of it, especially under the dormant commerce clause, is going to be very different too. Accordingly, Part

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<sup>10</sup> For information on organic agriculture in Vermont and Mendocino County, see Vermont Organic Milk Producers, available at <http://www.organicmilk.org>, Northeast Organic Farmers Association-Vermont, <http://www.nofavt.org>, Fetzer Vineyards, <http://www.fetzer.com>, and Frey Vineyards, <http://freywine.com>. In Vermont, the number of organic dairies is increasing while the number of conventional dairies is declining. Mendocino County has more pesticide free vineyard acreage than any other county in California. Fetzer Vineyards is one of the largest organic vineyards in the world.

<sup>11</sup> ANIMAL PLANT AND INSPECTION SERVICE, THE NATIONAL ORGANIC PROGRAM, QUESTIONS AND ANSWERS, available at <http://www.ams.usda.gov/nop>.

<sup>12</sup> Correspondence with John Cleary, Certification Administrator, Northeast Organic Farmers Association-Vermont, Apr. 5, 2004.

<sup>13</sup> Indeed, the lead sponsor of genetically modified organism legislation in Vermont, Representative David Zuckerman, is an organic vegetable farmer himself. One of his concerns about GMOs is the potential economic losses resulting from genetic contamination. Interview with Rep. David Zuckerman, Apr. 10, 2004.

<sup>14</sup> Vermont H. 352 is available at <http://www.state.vt.us>.

<sup>15</sup> See, e.g., *Mendocino Ban on Biotechnology has a Ripple Effect*, SACRAMENTO BEE, Mar. 7, 2004, available at <http://www.sacbee.com> (quoting Allen Noe, spokesman for CropLife America) (“I don't think we can afford to let it stand.”).

A of this article provides an introduction to these related constitutional doctrines. Part B briefly sets forth the principal concerns of GMO opponents. Part C explores the application of the dormant commerce clause to the Mendocino County ban and the Vermont labeling and registration statute. Part D explores the application of the doctrine of federal preemption to these same measures.

## **A. The Relationship Between Federal and State Power to Regulate Interstate Commerce**

### **1. The Dormant Commerce Clause**

The United States Constitution grants Congress the power to regulate commerce.<sup>16</sup> Without a doubt, trade in GMOs is commerce for purposes of this power. Articles of commerce are such even though they are valueless in themselves or harmful.<sup>17</sup> Congress's commerce power is not always exclusive, however, for states and localities retain their own power to regulate commerce to some extent.<sup>18</sup> But the boundary of that "extent" has never been precisely fixed, nor can it be. For example, what if Congress has *not* enacted a law requiring that genetically modified seeds traded in commerce be labeled and registered? May the state enact such a law? These questions are at the heart of the dormant commerce clause doctrine. Congress's power to enact such a law is dormant or unexercised. In the Congressional silence, may the state step in and act? The answer is sometimes yes and sometimes no. In other words, in some instances Congress's power is exclusive, but in others it is not.<sup>19</sup> The purpose of the commerce clause is to create a common market within the United States. State and local measures that interfere with the operation of this common market may be impermissible under the dormant commerce clause.<sup>20</sup>

The most commonly cited formulation of the test for determining whether a state or local measure is impermissible is set forth in *Pike v. Bruce Church, Inc.*<sup>21</sup> According to the Court:

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<sup>16</sup> U.S. Const. arts. 1 & 8, cl. 3.

<sup>17</sup> See, e.g., *Philadelphia v. New Jersey*, 437 U.S. 617, 621-23 (1978) (holding that solid waste is an article of commerce).

<sup>18</sup> The seminal case is *Gibbons v. Ogden*, 22 U.S. (9 Wheat) 1 (1824) in which the Court held that Congress's commerce power is compatible with concurrent regulation by the states. The Court found that the state's powers emanate from their "police powers"—a concept that does not actually appear in the Constitution.

<sup>19</sup> For a thorough introduction to the dormant commerce clause, see John E. Nowak & Ronald D. Rotunda, *CONSTITUTIONAL LAW 308 et seq* (6<sup>th</sup> ed. 2000). The seminal case for the notion of *selective* exclusivity is *Cooley v. Board of Wardens*, 53 U.S. (12 How.) 299 (1851).

<sup>20</sup> Nowak & Rotunda, *supra* note 19, at 310.

<sup>21</sup> 397 U.S. 137 (1979).

Where the [state's] statute regulates evenhandedly to effectuate a legitimate local public interest, and its effects on interstate commerce are only incidental, it will be upheld unless the burden imposed on such commerce is clearly excessive in relation to the putative local benefits. If a legitimate local purpose is found, then the question becomes one of degree. And the extent of the burden that will be tolerated will of course depend on the nature of the local interest involved, and on whether it could be promoted as well with a lesser impact on interstate activities.<sup>22</sup>

In short, the Court employs a balancing test. But note that there are four elements to the *Pike* test:

1. Is the statute evenhanded or does it discriminate against persons outside the state?
2. What are the putative local benefits and is their promotion legitimate under the state's police powers?
3. What is the extent of the burden placed on interstate commerce? and
4. Could the state have promoted its legitimate interests through a less burdensome or nondiscriminatory alternative?

Considering these questions in the context of the Mendocino County GMO ban and the Vermont labeling and registration statute, it is clear immediately that Measure H would be less likely to survive.<sup>23</sup>

## 2. The Doctrine of Federal Preemption

In a sense, the doctrine of federal preemption is the mirror image of the dormant commerce clause because the backdrop is not that Congress is silent but that it has spoken. Laws of Congress, and rules of federal agencies based on laws of Congress, preempt state and local measures by virtue of the Constitution's Supremacy Clause.<sup>24</sup> The Supremacy Clause provides that federal law prevails in any conflict with state law. For example, if Congress were to enact a statute prohibiting the labeling and registration of genetically modified seeds, Vermont's statute would be invalidated.<sup>25</sup> Congress could also explicitly preempt an entire field of regulation. It could simply say that Congressional regulation of GMOs would be exclusive. Preemption cases, however, do not arise in these straightforward circumstances. Congress rarely announces its intention to preempt the field, and the typical case involves a conflict between federal and state law that is more or less implicit. On the other hand, perhaps Congress has implicitly preempted the field without directly saying so.<sup>26</sup>

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<sup>22</sup> *Id.* at 142.

<sup>23</sup> *Infra* notes 61-78 and accompanying text.

<sup>24</sup> U.S. Const. art. VI, cl. 2.

<sup>25</sup> See *Jones v. Rath Packing Co.*, 430 U.S. 519 (1977) (a state may not enact a food labeling law that prohibits "reasonable variations" in accuracy if federal regulations allow such variations).

<sup>26</sup> For a thorough introduction to the preemption doctrine, see Nowak & Rotunda, *supra* note 19, at 347 *et seq.*

The test for whether the preemption doctrine applies is set forth in *Pennsylvania v. Nelson*.<sup>27</sup> According to *Nelson*, we must ask three questions:

1. Is the federal regulatory scheme in question pervasive?
2. Is federal occupation of the regulatory field required by the need for national uniformity? and
3. What is the burden of conflict between the federal and state regulatory programs?

The judicial balancing these questions demand is similar to the balancing that courts undertake in applying the dormant commerce clause. And there is another way in which the analysis is similar. Courts usually show more deference to state regulation of matters that are traditional state concerns under their police powers, primarily public health and safety. And, as with the dormant commerce clause, “each case turns on its own facts.”<sup>28</sup>

Essentially, in preemption cases, the courts are trying to divine Congressional intent. In determining Congressional intent, the Court has said that Congress must “manifest its intention clearly [because] [t]he exercise of federal supremacy is not lightly to be presumed.”<sup>29</sup> Instead, the Court looks for

a scheme of federal regulation so pervasive as to make reasonable the inference that Congress left no room to supplement it, because the Act of Congress may touch a field in which the federal interest is so dominant that the federal system will be assumed to preclude enforcement of state laws on the same subject . . . or where state law stands as an obstacle to the accomplishment and execution of the full purposes and objectives of Congress.<sup>30</sup>

To the extent that lower courts take this admonition seriously, proponents of federal preemption face a fairly high hurdle. Congress has, of course legislated in the field of GMOs,<sup>31</sup> and federal agencies have implemented that legislation through a series of regulations.<sup>32</sup> But if the biotech industry were to leap this hurdle, neither Mendocino

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<sup>27</sup> 350 U.S. 497 (1956).

<sup>28</sup> Nowak & Rotunda, *supra* note 19, at 349.

<sup>29</sup> *New York State Department of Social Services v. Dublino*, 413 U.S. 405, 413 (1973).

<sup>30</sup> *Pacific Gas & Electric Co. v. State Energy Resources Conservation & Dev. Comm’n*, 461 U.S. 190, 203-04 (1983) (internal quotations and citations omitted).

<sup>31</sup> See, e.g., The Plant Protection Act, 7 U.S.C. §§ 7701-7722 (2003) (authorizing the Secretary of the Department of Agriculture to regulate the movement of plants and plant parts, such as seeds, in interstate commerce).

<sup>32</sup> See, e.g., Field Testing of Plants Engineered to Produce Pharmaceutical and Industrial Compounds, *supra* note 4.

County Measure H nor Vermont H. 352 would survive scrutiny under the preemption doctrine.<sup>33</sup>

## **B. The “Perils” of Genetically Modified Organisms**

The stated purposes of Mendocino County Measure H and Vermont H. 252 are disarmingly vague. According to Measure H, the people of Mendocino County simply want “to protect the county’s agriculture, environment, and private property from genetic pollution by genetically modified organisms.”<sup>34</sup> The purposes section of Vermont H. 252 is narrower, since the statute is confined to labeling, but it is equally vague. According to H. 252, the purpose of labeling is “to help avoid adverse effects on the potential benefits of genetic engineering technologies and on the conservation and sustainable use of biological diversity through the use of such seeds.”<sup>35</sup> The more specific concerns behind these general claims have been explored in an extensive literature.<sup>36</sup> Part B briefly explains the major concerns in order to set the stage for discussion of the legitimacy of state and local regulation for purposes of dormant commerce clause and federal preemption analysis. Again, this article does not take sides on these issues. But the concerns must be sufficiently concrete to support state and local regulation in the face of constitutional challenge.

### 1. Genetically Engineered Organisms

For centuries agriculture has been marked by genetic manipulation of plants by selective plant breeding to increase yields, hardiness, and other attributes significant to agricultural production. Indeed, because of plant breeding, we are no longer hunters and gatherers.<sup>37</sup> Our familiar domestic corn (or maize), for example, evolved over centuries of plant breeding by Native American farmers from an ancestral wild grass called teosinte. Teosinte looks nothing like the corn on our tables today. The kernels of teosinte are very small and are not fused together like those on a husked ear of modern corn.<sup>38</sup> But the breeding techniques that have given us beans, squashes, melons, and root plants like potatoes and Jerusalem artichokes—other foods with Native American origins—are quite different from genetic engineering. Genetic engineering allows

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<sup>33</sup> *Infra* notes 79-102 and accompanying text.

<sup>34</sup> See Measure H, § 1 (Appendix A).

<sup>35</sup> See H. 252, § 1 (Appendix A).

<sup>36</sup> For some reason, the year 2002 produced a particularly plentiful vintage. See, e.g., MARK L. WINSTON, TRAVELS IN THE GENETICALLY MODIFIED ZONE (2002); KATHLEEN HART, EATING IN THE DARK: AMERICA’S EXPERIMENT WITH GENETICALLY ENGINEERED FOOD (2002); ENGINEERING THE FARM: THE SOCIAL AND ETHICAL ASPECTS OF AGRICULTURAL BIOTECHNOLOGY (Britt Bailey & Marc Lappe eds. 2002); GENETICALLY MODIFIED FOODS: DEBATING BIOTECHNOLOGY (Michael Ruse & David Castle eds. 2002).

<sup>37</sup> See FORAGING AND FARMING: THE EVOLUTION OF PLANT EXPLOITATION (David R. Harris & Gordon C. Hillman eds. 1989).

<sup>38</sup> NATIVETECH, NATIVE HISTORY OF MODERN CORN, *available at* <http://www.nativetech.org>.



biotechnology scientists to insert DNA from one species directly into the genome of an unrelated species or even phyla at the cellular level. Thus researchers have introduced fish genes (specifically flounder DNA) into tomatoes so the latter can be grown and stored at lower temperatures.<sup>39</sup> Now researchers are interested in introducing teosinte DNA into its evolutionary cousin—modern corn—in order to increase the latter's resistance to several viral diseases.<sup>40</sup>

While proponents of biotechnology point out that genetically modified foods have been around since agriculture's beginnings, opponents list a number of concerns that derive from the basic difference between traditional plant breeding and gene splicing.<sup>41</sup> The concerns are primarily health-related, socioeconomic, and environmental.

## 2. Claims of Health-Related Risks

### A. Allergic Reactions

At least sixty percent of the processed foods in the United States contain genetically modified material. And over seventy million acres of farmland have been planted with genetically modified crops.<sup>42</sup> For persons susceptible to food allergies, these numbers are troubling. Increased food allergenicity has been tied to genetic engineering in at least two ways. First, it can transfer proteins from foods to which people know they are allergic to those that they think are safe. And without food labels indicating the presence of genetically modified material, people will not know they are unsafe. For example, Brazil nut allergens, which can be dangerously allergenic, have been found in genetically modified soybeans.<sup>43</sup> Second, it could create new allergic responses to novel proteins that have never been in the human diet. GMO opponents warn<sup>44</sup> that without long-term allergenicity testing of new genetically modified products, millions of people could be exposed to serious health risks.

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<sup>39</sup> Singe Waller, *Have Some Flounder in Your Organic Tomatoes? No Thanks, I Think I'll Pass*, EMAGAZINE, available at <http://www.zmag.org>.

<sup>40</sup> UNIVERSITY OF CALIFORNIA MUSEUM OF PALEONTOLOGY, CORN AND ITS UNTAMED COUSINS: WILD GENES IN DOMESTIC CROPS, available at <http://www.evolution.berkeley.edu>.

<sup>41</sup> For a good introduction of the techniques of biotechnology, see SUSAN ALDRIDGE, *THE THREAD OF LIFE: THE STORY OF GENES AND GENETIC ENGINEERING* (1996). Basically, to put flounder DNA into a tomato the researcher must break through the seed cell wall and implant the fish gene. The "vector" for crossing the wall and carrying the fish cell is usually a bacterium. To determine whether the foreign gene made it into the cell, an "antibiotic resistance marker system" is added. Plant tissue is flooded with bacteria. If the antibiotic reacts, the researcher knows she has succeeded. But, if the new cell fails to express the foreign gene strongly enough to produce the desired traits, "viral promoters" are used to stimulate the introduced DNA.

<sup>42</sup> Joseph Mendelson III, *Untested, Unlabeled, and You're Eating It: The Health and Environmental Hazards of Genetically Engineered Food*, in *FATAL HARVEST: THE TRAGEDY OF INDUSTRIAL AGRICULTURE* 209, 209 (Andrew Kimbrell ed. 2002). Mendelson provides a succinct summary of the concerns of GMO opponents.

<sup>43</sup> *Id.* at 211. For a discussion of the Brazil nut study, see J.A. Nordlee et al, *Identification of a Brazil Nut Allergen in Transgenic Soybeans*, 334(11) *NEW ENG. J. MED.* 688 (1996).

<sup>44</sup> Mendelson, *supra* note 42, at 211.

## B. Toxicity

The result of inserting the DNA, bacteria, antibiotic resistance markers, viral promoters, and other elements of the “cassette” into the receiving plant cell is unpredictable. Researchers do not really know where the “cassette” will end up in the host plant’s genome, whether that place will be a safe and effective location or not. This uncertainty also troubles GMO opponents. There is fear, for example, that new, previously unknown toxicants could be produced, that levels of known, naturally occurring toxicants could be increased, and that crops could become capable of concentrating known toxicants from the environment, like pesticides. Consequently, GMO opponents call for long-term toxicological-testing before the marketing of products containing genetically modified material. And to make their case for better toxicological testing, they point to the fact that testing the first GMO food on the market, the Calgene Flavr Savr™ tomato, showed that consumption of the product produced stomach lesions in laboratory animals.<sup>45</sup>

## C. Antibiotic Resistance

The antibiotic resistance markers used to determine whether foreign genes are present are actually transferred to the target food. Many people fear that the widespread use of these markers could increase human resistance to important medical antibiotics. For example, an engineered field corn now on the market in the United States contains an ampicillin-resistant gene. Ampicillin is widely used to fight a number of infections. Several countries in Europe, including Great Britain, have banned the cultivation of this corn on the ground that it could move into the food chain and greatly reduce ampicillin’s efficacy. In 2000, the British Medical Association went so far as to call for “a ban on the use of antibiotic resistance marker genes in GE food, as the risk to human health from antibiotic resistance developing in microorganisms is one of the major public health threats that will be faced in the 21<sup>st</sup> century.”<sup>46</sup>

## D. Immunosuppression

Here, GMO opponents refer to a study showing that consumption of potatoes containing the biopesticide *Bacillus thuringiensis* (Bt) detrimentally affected immune system function, body metabolism, and organ development in laboratory animals.<sup>47</sup> Several crops, such as canola, have been engineered to produce their own pesticides and herbicides. The biotechnology industry has questioned the validity of the Bt study, but GMO opponents assert that the industry has been unable to produce its own peer-reviewed study to refute the findings.<sup>48</sup> This debate is destined to continue until

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<sup>45</sup> *Id.*

<sup>46</sup> *Id.* at 213 (quoting a resolution of the British Medical Association).

<sup>47</sup> *Id.* For the Bt study, see S.W.B. Ewen & A. Pustazi, *Effects of Diets Containing Genetically Modified Potatoes Expressing Galanthus novalis Lectin on Rat Small Intestines*, 354 THE LANCET 1359 (1999b).

<sup>48</sup> Mendelson, *supra* note 42, at 213.

additional and conclusive peer-reviewed studies are conducted. Unfortunately, there are few animal studies on the health effects of consuming genetically modified foods and even fewer human clinical studies.<sup>49</sup>

### 3. Socio-Economic Concerns

In addition to the potential threat to organic producers discussed above, GMO opponents point to several other socio-economic dislocations that will result from the widespread introduction of GMO crops. These include the domination of agriculture by a few multinational corporations, the inability of farmers to save seeds from year-to-year because of GM plant, and the loss of traditional plant varieties accompanied by the increasing rise of monocultures. Indeed, the trend toward monoculture threatens the vast storehouse of biological diversity that has characterized agriculture throughout human history.<sup>50</sup> Here is a representative statement predicting the results of widespread conversion to GMO agriculture: "Family and indigenous farmers will be driven off the land, and consumers' food choices will be dictated by a cartel of transnational corporations. Rural communities will be devastated. Hundreds of millions of farmers and agricultural workers worldwide will lose their livelihoods."<sup>51</sup> Understandably, this sort of rhetoric may create concerns among the family-based, organic dairy farmers and winemakers of Vermont and Mendocino County. And while it is overblown, it is matched by claims of the industry that only biotechnology can prevent recurrent famines around the globe.<sup>52</sup> In the rhetorical war on GMOs, combatants take no prisoners.

### 4. Claims of Environmental Risk

#### A. Biological Pollution

Bio-pollution is the term used to describe genetic contamination of organic farm fields. Wind is the major vector of this contamination, but insect pollinators and rain are also factors. Many such incidents have already occurred in the United States and organic farmers are justifiably concerned.<sup>53</sup> But GMO opponents identify other forms of bio-pollution on the horizon. Most of these are analogous to the problem of introducing an "exotic" species into a functioning ecosystem. GMO opponents fear, for example, that the release of genetically engineered "exotics" could have unforeseeable impacts no less serious than those caused by chestnut blight and Dutch elm disease. For proof, they cite a study by Cornell University researchers in the late 1990s finding that pollen from Bt-engineered corn poisoned the larvae of monarch butterflies. Subsequent

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<sup>49</sup> See J.L. Domingo, *Health Risks of Genetically Modified Foods: Many Opinions but Few Data*, 288 SCIENCE 1748 (2000).

<sup>50</sup> See VANDANA SHIVA, *MONOCULTURES OF THE MIND: PERSPECTIVES ON BIODIVERSITY AND BIOTECHNOLOGY* (1993).

<sup>51</sup> Mendelson, *supra* note 42, at 216.

<sup>52</sup> See, e.g., Amy Bakker & Monsanto, *Biotechnology: A Solution to Hunger and Starvation*, available at <http://www.monsanto.co.uk>.

<sup>53</sup> Correspondence with John Cleary, Certification Administrator, Northeast Organic Farmers Association-Vermont, April 5, 2004.

studies have concluded that GMO crops harm beneficial insects, like ladybugs and lacewings, and beneficial soil microorganisms.<sup>54</sup> These studies have also been challenged by the biotechnology industry, and it is fair to say the jury is still out on these and other questions.<sup>55</sup> But the fear is not altogether misplaced. Genetically altered plants are “exotic” in the sense that they are new organisms deliberately or accidentally introduced into ecosystems where they have never been before. And their impacts are difficult to predict.

## B. Superweeds and Superpests

Canola, a multibillion-dollar crop in the Canadian prairies, is now a superweed. Varieties genetically engineered to resist pesticides have crossbred with each other and with cousins like wild mustard, to form plants even more resistant than their parents. They then escaped into wheat fields as volunteers almost entirely resistant to most herbicides. The concept behind pesticide-resistant canola was that farmers would plant it and then spray the field with the particular herbicide the crop was engineered to resist. But a farming method designed to help farmers get rid of weeds has produced a superweed that farmers cannot kill without powerful broad-spectrum herbicides, such as 2,4-D, that farmers have been trying to avoid.<sup>56</sup> Similarly, researchers have discovered that cotton genetically designed to resist the pink bollworm can evolve bollworms resistant to pesticides.<sup>57</sup> To delay the appearance of Bt resistant bollworms in their fields, farmers now interplant with non-Bt cotton, the theory being that non-resistant bollworms living in these refuges will mate with resistant bollworms and produce non-resistant pests.<sup>58</sup>

Meanwhile, the next generation of GMOs, featuring resistance to frost and drought, presents the same potential problem of evolving superplants that out-compete their neighbors. These are matters the biotechnology companies recognize and take seriously, perhaps because they threaten to undermine a major promise of genetically modified crops: that farmers can easily defeat weeds and other threats. Monsanto, for example, is working in collaboration with research centers around the world to develop

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<sup>54</sup> Mendelson, *supra* note 42, at 215. For the butterfly study, see J.O. Losey et al., *Transgenic Pollen Harms Monarch Butterfly Larvae*, 399 NATURE 214 (1999).

<sup>55</sup> See, e.g., COUNCIL FOR BIOTECHNOLOGY INFORMATION, BT CORN AND THE MONARCH BUTTERFLY, available at <http://www.whybiotech.com> (asserting that Bt targets only harmful insects and that it does not persist in the environment).

<sup>56</sup> Tom Spears, *Superweeds Invade Farm Fields, Canola Plants are almost Pesticide-Proof Experts Say*, THE OTTAWA CITIZEN, Feb. 6, 2001, available at <http://www.mindfully.org> (writing about a report by the Royal Society of Canada).

<sup>57</sup> Eleanor Lawrence, *Beating the Bt Resistant Bollworm*, NATURE, 5 Aug. 1999, available at <http://www.nature.com/NSU/990805/990805-5.html>.

<sup>58</sup> *Id.* According to the rules of Mendelian genetics, the hybrid offspring of a Bt resistant bollworm due to a recessive gene and a non-resistant bollworm will be non-resistant itself. This is because two copies of a recessive gene must be present for the genetic trait to be expressed. These hybrid bollworm moths receive one copy of the resistance gene and one copy of a “normal” gene. As a result, they are not resistant to Bt.

data on cross pollination and gene flows between Roundup Ready® canola and common weeds. Monsanto and its research partners claim that successful hybridization between Roundup Ready® canola and weeds like wild radish occurs at low frequencies. But the company also promotes “stewardship” guidelines based on research showing that the amount of gene flow decreases as the distance from the genetically modified pollen source and weeds and non-resistant crops increases.<sup>59</sup> In other words, to delay the advent of superweeds, Monsanto suggests (ironically) that canola farmers adopt an approach similar to what organic farmers have been asking conventional farmers to do all along—maintain GMO-free buffer zones around their organic farms.<sup>60</sup>

### C. Application of the Dormant Commerce Clause

Dormant commerce clause jurisprudence has two distinct branches. One bars state and local governments from enacting measures that discriminate against commerce outside the jurisdiction of the enacting body. The second bars them from passing legislation that places an unacceptably heavy burden on interstate commerce. The distinction between these two branches is important because in recent decades the Supreme Court has looked skeptically on discriminatory statutes and much more generously on those that simply burden interstate commerce.<sup>61</sup> The most recent example of the first branch is *C and A Carbone, Inc. v. Clarkstown* in which the Court struck down an ordinance requiring the deposit of all solid waste generated within the town at a specific waste transfer station, also within the town’s borders.<sup>62</sup> The “formality” of a geographic boundary in the ordinance was a crucial element in the Court’s reasoning.<sup>63</sup> The Clarkstown statute discriminated on its face against transfer stations located outside the town’s jurisdiction, and that single fact was the deciding factor in the Court’s decision. To find a decision striking down a non-discriminatory statute because it imposed an excessive burden on interstate commerce, one must go back more than twenty years to *Edgar v. MITE Corp.*<sup>64</sup>

In short, the balancing test set forth in *Pike v. Bruce Church* is still the governing standard for evaluating non-discriminatory statutes, but the Court rarely employs it. In fact, the only recent invocation of *Pike* for the proposition that a local statute imposed an excessive burden on interstate commerce was Justice O’Connor’s concurring opinion in

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<sup>59</sup> MONSANTO, ROUNDUP READY® CANOLA AND CROSS POLLINATION, *available at* <http://www.monsanto.com.au>.

<sup>60</sup> Interview with John Cleary, Certification Administrator, Northeast Organic Farmers Association-Vermont, Apr. 5, 2004.

<sup>61</sup> MARK TUSHNET, *THE NEW CONSTITUTIONAL ORDER* 229 (2003).

<sup>62</sup> 511 U.S. 383 (1994).

<sup>63</sup> Tushnet, *supra* note 61.

<sup>64</sup> 457 U.S. 624 (1982) (striking down an Illinois statute regulating and in some circumstances prohibiting interstate corporate tender offers). This is the most recent excessive burden case cited by LAURENCE H. TRIBE, *AMERICAN CONSTITUTIONAL LAW* 1099 (3<sup>rd</sup> ed. 1999).

*Carbone*, a case involving a clearly discriminatory statute. This is the background that against which Measure H and H. 352 must be measured. The Court's apparent reluctance to strike down state and local statutes on "excessive burden" grounds alone is significant because both Mendocino County Measure H and Vermont H. 352 are facially neutral. Neither seeks to give an advantage to local merchants or consumers, so neither undermines the essential purpose of the dormant commerce clause—to ensure that the states do not impose economic protectionism.<sup>65</sup> The Court is far more likely to endorse state regulatory measures that treat residents and non-residents equally than those that disproportionately burden non-residents because "in the former situation an inner political check is operative that lessens the need for an active judicial review."<sup>66</sup>

But this is not the end of the story. It is typically said that the power of the states to regulate commerce, even in the national market, rests on the "police power"—though this term is found nowhere in the Constitution. And it is frequently asserted that the police power is most legitimately exercised when the benefits of state regulation include public health and safety. If the benefit to public health and safety is greater than the burden on interstate commerce, and the regulation is non-discriminatory, the Court will uphold the regulation.<sup>67</sup> And, of course, proponents of Mendocino County Measure H and Vermont H. 352 claim that many of the putative benefits of regulating genetically modified organisms are directly related to public health and safety.<sup>68</sup> The mere fact that a statute purports to protect public health and safety, however, does not automatically insulate it from dormant commerce clause challenge. If that were true, "states could avoid the restrictions of the dormant commerce clause by superficial changes in the language of the law."<sup>69</sup> The Court looks for a legitimate state objective that cannot be obtained in a way that is less burdensome on interstate commerce. But it also considers the direct and indirect effects of the regulation, and not just its stated purposes.

Clearly, between Mendocino County Measure H and Vermont H. 352, the less burdensome regulation is the latter. Registration and labeling of genetically modified seeds is substantially less burdensome on interstate commerce than an outright ban. Given the concerns expressed by the sponsors of H. 352 regarding public health and safety, environmental protection, and security for organic producers,<sup>70</sup> the balance would appear to favor the statute. Assuming that the putative benefits of registration and labeling are provable, H. 352 would probably survive a dormant commerce clause challenge rather easily. Of course, this assumption may prove to be inaccurate. The reviewing court will not simply accept the state's factual assertions of safety and other concerns on their face. Instead, it will weigh and evaluate the evidence. As the Supreme Court said in *Southern Pacific Co. v. Arizona*, promoting the interests of interstate commerce is "not to be avoided by 'simply invoking the convenient apologetics

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<sup>65</sup> Nowak and Rotunda, *supra* note 19, at 310.

<sup>66</sup> *Id.* at 317.

<sup>67</sup> *Id.* at 312.

<sup>68</sup> See *supra* notes 16-23 and accompanying text.

<sup>69</sup> Nowak and Rotunda, *supra* note 19, at 317.

<sup>70</sup> Interview with Rep. David Zuckerman, Apr. 10, 2004 (principal sponsor of Vermont H. 352).

of the police power.”<sup>71</sup> The Court held that the Arizona statute prescribing the maximum length of passenger and freight trains violated the dormant commerce clause because the regulation bore no reasonable relation to safety.<sup>72</sup> Still, let us suppose that Vermont can show that registration and labeling is reasonably related its safety, environmental, and agricultural concerns. In that case, H. 352 would likely survive because it does not favor in-state commerce and the burden it places on interstate commerce is relatively light.

One cannot say the same of Mendocino County Measure H, however, even though it is also non-discriminatory. This is in part because the burden of a ban on commerce is absolute. And in part because there may be less burdensome alternatives to a ban, including a registration and labeling requirement like Vermont’s. Measure H may run afoul of the dormant commerce clause even if Mendocino County can show that it is reasonably related to valid safety concerns. A state or local regulation affecting the national market, even if justifiable on public health and safety concerns, would be invalid under the dormant commerce clause if there is less burdensome alternative. In *Dean Milk Co. v. Madison*, for example, the Court invalidated a city ordinance that made it illegal to sell pasteurized milk that was not processed at an approved pasteurization plant within the city. The Court found that there were reasonable available alternatives to the regulation “adequate to conserve legitimate local interests.”<sup>73</sup> For example, public safety officers could travel to distant processing plants and charge the cost of inspection to importing merchants.<sup>74</sup> Indeed, the Court has made it clear that a ban on importation of a product may be unconstitutional even if the regulated material is admittedly harmful. Even harmful materials—such as solid and liquid wastes—are matters of commerce.<sup>75</sup>

Finally, however, Mendocino County Measure H must be viewed from a perspective noted above, namely that the Supreme Court has not struck down a *non-discriminatory* regulation that burdens interstate commerce in more than twenty years.<sup>76</sup>

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<sup>71</sup> 325 U.S. 761, 780 (1945) (quoting *Kansas City Southern Ry. Co. v. Kaw Valley Drainage District*, 233 U.S. 75, 79 (1914)).

<sup>72</sup> *Id.* at 775-76 (“The decisive question [is whether] the total effect of the law as a safety measure in reducing accidents and casualties is so slight or problematical as not to outweigh the national interest in keeping interstate commerce free from interferences which seriously impede it and subject it to local regulation which does not have a uniform effect on the interstate train journey which it interrupts.”). Compare *South Carolina State Highway Department v. Barnwell Brothers, Inc.*, 303 U.S. 177 (1938). There the Court evaluated evidence of safety putatively supporting regulation of the width and loaded weight of trucks on South Carolina highways. The Court concluded that the relationship between safety concerns and the regulations was reasonable. *Id.* at 191-96.

<sup>73</sup> 340 U.S. 349, 354 (1951).

<sup>74</sup> *Id.* at 356.

<sup>75</sup> *Carbone*, 511 U.S. 383 (1994).

<sup>76</sup> See *supra* notes 16-23 and accompanying text. In *Carbone*, the regulation under review was discriminatory in that it distinguished waste generated out-of-state from waste generated in-state. 511 U.S. at 383. The Court has also invalidated a less burdensome alternative to an importation ban in a case involving a waste disposal fee on hazardous waste generated out-of-state. See

The Court's stress on discriminatory enactments is important. Measure H does more than ban the importation of genetically modified organisms into Mendocino County. It would also ban the manufacture of GMOs within Mendocino County. The Court has upheld a ban on importation of a concededly harmful article of commerce in a non-discrimination case but only when the material's value in interstate commerce was "far outweighed" by the dangers of the article's movement in commerce.<sup>77</sup> Ultimately, a reviewing court might conclude that Measure H goes too far. But the recent history of the dormant commerce clause appears to be on Mendocino County's side. In fact, one constitutional law scholar has argued that the dormant clause is a piece of judicial fiction, anti-democratic, contrary to the spirit of the Constitution, and should be discarded.<sup>78</sup>

#### **D. Application of the Preemption Doctrine**

Every preemption case is a matter of statutory interpretation of Congressional intent in order to avoid state and local interference with Congressional objectives.<sup>79</sup> Congress can explicitly express its intent to occupy an entire regulatory field and thus prohibit state and local regulation. But preemption challenges do not occur in this context. They arise when Congress has not explicitly stated its intentions one way or another—that is, it has neither expressly proscribed nor accommodated state and local regulation. So the courts must deduce Congressional intent from suggestions and intimations. And that would be the case with respect to genetically modified organisms because Congress has expressed no intent to occupy the regulatory field. Courts tend to construe Congressional intent by posing a set of questions that are—on their face—relatively simple: 1) Is federal regulation so pervasive that it can be reasonably inferred that Congress does intend to preempt the field?; 2) Is there something about the regulated conduct that requires nationally uniform rules?; and 3) What is the burden of potential conflicts between federal and state rules? This is the inquiry laid out in *Pennsylvania v. Nelson*.<sup>80</sup> To explore the first of these questions, we will look at what conduct Congress has regulated (and how), as well as the conduct Congress has left unregulated.<sup>81</sup>

##### 1. Federal Regulation of Conduct in the Field of Genetically Modified Organisms

At first glance, federal regulation of genetically modified organisms seems pervasive indeed, if only because conduct in the field is regulated by three separate

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Chemical Waste Management, Inc. v. Hunt, 504 U.S. 334 (1992). Again, however, the case involved a discriminatory statute.

<sup>77</sup> Philadelphia v. New Jersey, 437 U.S. 617, 622 (1978) (upholding a New Jersey statute prohibiting the importation of most liquid and solid wastes originating out-of-state).

<sup>78</sup> See generally MARTIN H. REDISH, THE CONSTITUTION AS POLITICAL STRUCTURE (1995).

<sup>79</sup> Nowak and Rotunda, *supra* note 19, at 348.

<sup>80</sup> 350 U.S. at 502-05. See note 27 *supra* and accompanying text.

<sup>81</sup> I will focus on the first question, which is relatively matter-of-fact, and leave the others, which are more value-laden, to the litigants.



federal agencies, the Environmental Protection Agency, the Food and Drug Administration, and the Department of Agriculture, under a dozen different statutes. On a second look, however, the federal regulatory scheme seems diffuse and incomplete.<sup>82</sup>

#### A. The Food and Drug Administration

The Food and Drug Administration (FDA), through regulations promulgated pursuant to the Federal Food, Drug, and Cosmetic Act (FFDCA),<sup>83</sup> attempts to ensure that food products—except meat and poultry—are safe to consume. FFDCA Section 409 authorizes the FDA to regulate additives that become constituents of food or affect their makeup in some way. The FDA must approve a food additive before use unless it is considered “generally recognized as safe” (GRAS).<sup>84</sup> The FDA recognizes that a foreign gene inserted into a food plant like corn is an “additive” and thus subject to regulation under the FFDCA. But the agency has determined that the genetic modification will almost always be GRAS because the genetic material will be similar to common proteins, fats, and carbohydrates.<sup>85</sup> The main exceptions are cases in which genetic modification could cause allergic reactions and increase toxicity—safety risks the agency believes are “very low.”<sup>86</sup> The result is that the FDA’s regulatory approach to food safety is essentially voluntary because it is the food additive producer, rather than the FDA, who determines that an additive is GRAS.<sup>87</sup>

#### B. The Department of Agriculture

The United States Department of Agriculture (USDA) regulates field trials of genetically modified plants and their movement in interstate commerce under the Plant Protection Act.<sup>88</sup> The regulatory process provides the basic mechanism through which

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<sup>82</sup> As far as I know, the only comprehensive exploration of federal regulation of genetically modified organisms is Gregory N. Mandel, *Gaps, Inexperience, Inconsistencies, and Overlaps: Crisis in the Regulation of Genetically Modified Plants and Animals*, 45 WM. & MARY L. REV. 2167 (2004). The author’s title suggests his conclusions regarding the pervasiveness of federal regulation.

<sup>83</sup> 21 U.S.C. §§ 301-399 (2003). Meat and poultry safety is the responsibility of the Food Safety and Inspection Service of the United States Department of Agriculture under the Federal Meat Inspection Act and the Poultry Products Inspection Act, 21 U.S.C. §§ 451, 601, 1031 (2003).

<sup>84</sup> 21 U.S.C. §§ 321(s), 348 (2003).

<sup>85</sup> Statement of Policy: Foods Derived from New Plant Varieties, 57 Fed. Reg. 22,984, 22,989 (May 29, 1992).

<sup>86</sup> *Id.* at 22,886, 22,993.

<sup>87</sup> *Id.* at 22,989. The FDA also has regulatory authority over pharmaceuticals grown in genetically modified plants under the Public Health Service Act. 42 U.S.C. §§ 262, 262a (2003). The regulatory scheme follows the same approach as that designed for food safety, focusing on genetically modified plants that could have higher levels of allergenicity or toxicity. See DRAFT GUIDANCE FOR INDUSTRY: DRUGS, BIOLOGICS, AND MEDICAL DEVICES DERIVED FROM BIOENGINEERED PLANTS FOR USE IN HUMANS AND ANIMALS (Sept. 2002), available at <http://www.fda.gov/cber/gdlns/bioplant.pdf>.

<sup>88</sup> 7 U.S.C. §§ 7701-7772 (2003).

genetically modified plants are developed and placed in commercial markets. Prior to conducting a field trial, the developer must determine whether the genetically modified plant may be a “plant pest” and then notify the USDA’s Animal and Plant Health Inspection Service (APHIS) of the field trial.<sup>89</sup> Similarly, a distributor of genetically modified plant materials must provide notice before distribution in interstate commerce. An actual AHPIS permit for field-testing or distributing genetically modified plant materials is required only for plants deemed to be “regulated articles”—mainly plants containing pharmaceuticals.<sup>90</sup> A developer or distributor can also apply for “non-regulated status” and plants granted such status are no longer subject to any APHIS regulation.<sup>91</sup> Finally, it is worth noting that the only risk evaluated in this process—with the exception of pharmaceuticals—is the risk of creating a plant pest.<sup>92</sup>

### C. The Environmental Protection Agency

The Environmental Protection Agency’s (EPA) authority to regulate genetically modified organisms derives from its responsibility to ensure the safety of pesticide use pursuant to the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA). The EPA regulates genetic materials inserted into transgenic plants that express themselves as pesticides.<sup>93</sup> Under FIFRA, every pesticide must be registered with EPA before market distribution or use. The registration requires the applicant to submit information on the potential effects of the pesticide on the environment and on human health.<sup>94</sup> And if it appears that the plant modified to express its own pesticide would yield pesticide residues in food products, the EPA can establish “tolerance” levels.<sup>95</sup> But this means, in short, that the EPA’s regulatory authority is circumscribed in a way that is similar to that of APHIS. APHIS focuses on plant pests; the EPA focuses on pesticides. Genetically modified organisms that are manipulated for ends other than the expression of pesticides fall outside of the EPA’s jurisdiction.

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<sup>89</sup> 7 C.F.R. § 340.3 (2003).

<sup>90</sup> 7 C.F.R. § 340.0 (2003).

<sup>91</sup> 7 C.F.R. § 340.6 (2003).

<sup>92</sup> A plant pest is simply an organism that directly or indirectly harms plants—such as the boll weevil or a natural-born superweed like kudzu. 7 C.F.R. § 340.1 (2003). Every home gardener must fear above all else that some mad scientist will insert the gene that causes kudzu to grow a mile-a-minute into zucchini.

<sup>93</sup> Regulations Under the Federal Insecticide, Fungicide, and Rodenticide Act for Plant Incorporated Protectants, 66 Fed. Reg. 37,772 (July 19, 2001) (to be codified at 40 C.F.R. pts. 152, 174).

<sup>94</sup> 7 U.S.C. § 136a(c)(2) (2000).

<sup>95</sup> 21 U.S.C. § 346a (2000).

## 2. Missing Links in the Federal Regulatory Scheme<sup>96</sup>

### A. Environmental Protection

The EPA is the primary federal agency charged with ensuring environmental protection, but it has no oversight authority with respect to most genetically modified organisms. These organisms include animals, fish, and many plants that are engineered for purposes other than expressing pesticides. As a result, the EPA does not regulate field trials and ultimate market distribution of plants engineered to express herbicide and disease resistance, drought and temperature tolerance, or pharmaceutical and industrial compounds. This list makes up a majority of the genetically modified plants in use today, and it is probably going to be the future of the industry. These organisms could have significant environmental effects, and the EPA would be the logical locus of any regulatory program designed to mitigate these effects.<sup>97</sup> Nor do the other agencies cover the gaps. APHIS and the FDA do consider the potential environmental impacts of plants and animals designed to produce pharmaceuticals, but it is far from clear that they do so adequately. The National Research Council reports that APHIS and the FDA may lack the expertise and capacity to ensure that environmental reviews are sufficiently rigorous.<sup>98</sup> But in their defense, APHIS and the FDA—unlike the EPA—are not generally in the business of environmental review.

### B. Post-market Regulation: Beyond Testing and Distribution

Much of the impetus behind Mendocino County Measure H and Vermont H. 352 was based on concerns about the actual use of GMOs in production agriculture. For instance, the concern that pollen from a pest-protected plant could drift into the fields of an organic farmer was a major force behind the passage of Vermont H 352.<sup>99</sup> But when it comes to the GMO crops in the field, the agencies have limited regulatory authority. APHIS, for example, “deregulates” most crops as soon as field trials are complete.<sup>100</sup> The EPA has extensive authority to regulate pre-market testing of pest-protected plants, and it can impose post-market rules such as planting restrictions to protect the environment. But the EPA interprets its statutory authority in a way that prevents the

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<sup>96</sup> I will focus on the most glaring gaps in the regulatory scheme. For a more comprehensive treatment, see generally Mandel, *supra* note 82.

<sup>97</sup> *Id.* at 2231.

<sup>98</sup> NAT’L RESEARCH COUNCIL, GENETICALLY MODIFIED PEST-PROTECTED PLANTS: SCIENCE AND REGULATION 148 (2002); NAT’L RESEARCH COUNCIL, ANIMAL BIOTECHNOLOGY: SCIENCE-BASED CONCERNS 114-15 (2002).

<sup>99</sup> See *supra* notes 10-13 and accompanying text. Agency rules that pertain to the release of transgenic plants, for example, do not deal with pollen drift. See GENETICALLY MODIFIED PEST-PROTECTED PLANTS: SCIENCE AND REGULATION, *supra* note 98, at 109.

<sup>100</sup> MICHAEL R. TAYLOR & JODY S. TICK, POST-MARKET OVERSIGHT OF BIOTECH FOODS: IS THE SYSTEM PREPARED? 4 (2003), available at Resources for the Future, <http://www.rff.org/rff/Documents>.

agency from imposing liability on farmers who fail to adhere to planting restrictions.<sup>101</sup> The FDA appears to have extensive post-market regulatory authority in the field of food safety, but to date it has not focused on biotech foods from a public health perspective. Currently, the agency has no post-market inspection or compliance program.<sup>102</sup> In short, the federal regulatory scheme stops short of farmers' fields and grocers' shelves.

## E. Conclusion

Justice Oliver Wendell Holmes famously said that the primary business of being a lawyer is to predict what the courts will do.<sup>103</sup> But every commerce clause and federal preemption case is basically *sui generis*—and that makes prophesy perilous. Cases involving state and local regulation of genetically modified organisms will require judges to interpret complex statutory and regulation programs and, more importantly, read the sometimes inscrutable mind of Congress. This article has raised most of the factual, legal, and even political issues that would arise in such a case. But given the one-of-a-kind nature of the dormant commerce clause and federal preemption litigation, predicting what the courts will do is like forecasting the weather with nothing but last year's farmers' almanac. The only safe thing to say at this point is that these cases are coming, perhaps soon, to a courthouse near you.

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<sup>101</sup> The EPA's main planting restriction is designed to minimize the development of Bt resistance in insects. See *supra* note 47 and accompanying text. The EPA relies on seed distributors to implement planting compliance programs. It is unclear what the farmers' compliance rates actually are. *Id.*

<sup>102</sup> *Id.* at 5.

<sup>103</sup> Oliver Wendell Holmes, *The Path of the Law*, 10 HARV. L. REV. 457, 461 (1897).