

## Next Verse, Same as the First: Inadequacies in the Government's Legal Approach Toward Biotechnology

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## Next Verse, Same as the First: Inadequacies in the Government's Legal Approach Toward Biotechnology

By Kimberly Righter\*

An old saying proclaims that fools rush in where angels fear to tread. The question for legislatures is whether they are fools or angels as they determine to what degree they will regulate biotechnology. Right now, many in the public perceive the growth of the biotechnology industry as a Faustian compromise of public and environmental safety, foreseeing promises of bread on every table disintegrating into a reality of ecological catastrophe. Meanwhile, supporters of biotechnology maintain that neither unsubstantiated suspicions nor accusations of immorality or “playing God” should interfere with scientific progress that could eliminate diseases and end hunger. The stakes involved and the extreme divergence of opinion demand that lawmakers intervene, setting standards for both agency review of biotechnology research and the level of industry accountability should a product cause harm.

Biotechnology is the science of manipulating the fundamental building blocks of life – genes – ideally to produce organisms with positive attributes, such as slow-ripening tomatoes with an extended shelf life. The issue of how to regulate bio-engineered foods has social, ethical, and political implications. By avoiding the reproductive limits of nature, scientists can design novel products with tangible social benefits

Policymakers must acknowledge that they confront more than a simple rivalry between those who support liberalizing markets and those who support the “precautionary principle,” a principle which requests that scientists look hard before they leap into gene manipulation which possibly threatens public health, biodiversity, and ecosystems. must determine: 1) how much industry should internalize the social costs of any harm that they create, 2) the extent of the government’s duty to provide for the security of its citizens and the environment, and 3) whether industry has a duty to label genetically modified products as a method of public disclosure.

### I. How the Science of Biotechnology Works.

The hype surrounding the biotechnology industry’s potential accomplishments sounds like a forecast of the miracles of the “Seventh Son” – healing diseases, increasing crop yields, cleaning up hazardous waste, and growing food without soil. The lack of venture capital initially retarded product development, since the research requires substantial upfront investments. For instance, one biotechnology company spent almost ten years and \$350 million preparing its drug for market.<sup>1</sup> Biotechnology, however, has arrived and is rapidly altering agricultural practices.

Before assessing the law pertaining to biotechnology, it is necessary to examine how biotechnology works. Understanding the ambiguities in the process accentuates the potential for both damages and benefits from future applications. Biotechnology can generate food products, commonly referred to by the European Commission as “genetically modified organisms,” through recombinant deoxyribonucleic acid (DNA) techniques, which modify DNA *in vitro* at

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<sup>1</sup> Julie A. Davies and Lawrence C. Levine, *Symposium: Biotechnology and the Law: Biotechnology's Challenge to the Law of Torts*, 32 McGeorge L. Rev. 221, 236 (2000).

the molecular level.<sup>2</sup> Proteins inside the plant influence its traits like color, texture, and life span, as well as its processes that may, for example, influence the flavor and quantity of its fruit. The DNA within the plant determines the production of these proteins.

The process of creating a genetically-engineered plant is complex. Scientists begin by isolating the genetic material linked to a trait or process that they want to change. Then, the scientists must extract from another organism the desired DNA segment, typically accomplished by using an enzyme, a biological catalyst. Determining how to integrate the desired DNA into the recipient's preexisting DNA is the next step. Scientists accomplish this task with a second enzyme, but still must select a method to insert the desired DNA into the recipient. They can attach the desired DNA to a chemically-treated "plasmid," which is a piece of bacterial DNA that contains biochemical signals that allow it to exist and replicate within a cell.<sup>3</sup> Another option is "Bioballistics," a method in which scientists paint DNA encoding on microscopic metal particles and, then, "fire" that DNA into the recipient's cells using a "gene gun."<sup>4</sup>

Scientists must not only isolate the genetic and chemical basis of the trait they want the new plant to display, but also find a way to get the foreign genetic material into the new plant precisely where the material is necessary, accounting for appropriate timing in the sequence of development and strength. They must accomplish this task without disrupting any of the other processes of the living plant. When even baker's yeast has 7,573 genes, such demands are formidable.<sup>5</sup> Researchers admit that in humans and other complex organisms, DNA does more than generate proteins. Scientists cannot yet identify, however, those responsibilities.<sup>6</sup> Taking into account the wide range of variables that influence the appearance and functioning of plants, miscalculations are possible. Ultimately, genes may simply fail to operate as expected in the recipient cell.<sup>7</sup>

Proponents of biotechnology defend its methods as a means to accelerate and fine tune traditional selective breeding techniques.<sup>8</sup> In the words of a research technician for Monsanto (the largest manufacturer of herbicide-resistant, genetically-engineered seeds) "what we do is the same as Mother Nature."<sup>9</sup> Opponents focus on the unnatural capacity of biotechnology to cross a rhinoceros with a standard garden tomato to get a leathery-skinned tomato. Biotechnology permits gene transfers across species boundaries, a distinctive and notable departure from the old routine.

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<sup>2</sup> See John Charles Kunich, *Mother Frankenstein, Doctor Nature, and the Environmental Law of Genetic Engineering*, 74 S Cal Law Rev 807, 809 (2001).

<sup>3</sup> See *id.*; Larry Thompson, *Are Bioengineered Foods Safe?: Methods for Genetically Engineering a Plant*, FDA Consumer, 18, 22 (Jan.-Feb. 2000).

<sup>4</sup> Kunich, *supra* note 2.

<sup>5</sup> *What's What in Biotechnology?*, 6 Briefing Paper 4 (European Federation of Biotechnology, Task Group on Perceptions of Biotechnology, 1997).

<sup>6</sup> Remarks, Lecture to Students at Celera, Rockville, MD (Nov. 16, 2001).

<sup>7</sup> Sophia Kolehmainen, *In Depth: Genetically Engineered Agriculture: Precaution Before Profits: An Overview of Issues in Genetically Engineered Foods and Crops*, 20 Va. Env'tl. L.J. 267, 272 (2001).

<sup>8</sup> See James H. Maryanski, Ph.D., Biotechnology Coordinator, Center for Food Safety and Applied Nutrition on behalf of Food and Drug Adminis. before the Committee on Science Subcommittee on Basic Research, U.S. House of Rep., (Oct. 19, 1999) <<http://www.fda.gov/ola/1999/plant2html>> Visited Sept. 25, 2001 [hereinafter "Maryanski Report to the House"] ("The new gene splicing techniques are being used to achieve many of the same goals and improvements that plant breeders have sought through more conventional methods.")

<sup>9</sup> cited in Julie Teel, *Student Article: Regulating Genetically Modified Products and Processes: An Overview of Approaches*, 8 N.Y.U. Env'tl. L.J. 649, 652 (2000).

## II. Agencies Inadequately Regulate Biotechnology Food Products.

In June 1986, federal agencies adopted the Coordinated Framework for Regulation of Biotechnology Products, which treats biotechnology products the same as products that result from traditional farming techniques.<sup>10</sup> The Framework was meant to avoid unreasonable risks, in light of the government's limited budget and the potential benefit to the country of innovations from biotechnology. The regulatory approach stitches together a number of existing statutes, emphasizing continuity in an agency's authority and experience.

The Framework cryptically encourages the agencies with oversight authority to adapt their guidelines as necessary, but, in emphasizing agency discretion, fails to identify what standards agencies should apply in assessing the safety of biotechnology products.<sup>11</sup> Despite scientists' suggestions, current governmental regulations do not require tests for toxicity to the immune system, developmental toxicity, or effects on the nervous system.<sup>12</sup> Significantly, the Framework is a policy statement and not a rule, adopted to "aid in the formulation of agency policy with respect to control of microorganisms developed by genetic engineering techniques."<sup>13</sup> Ultimately, the Framework fails to create an enforceable obligation. In terms of accountability, the courts' traditional deference to an agency's decision regarding its area of expertise, combined with the impromptu nature of the Framework, is likely to doom citizen suits filed against agencies for failing to implement safeguards regarding public safety and health under the Framework.<sup>14</sup>

### A. Agency Roles in Regulating Biotechnology are Poorly Defined.

#### *The Food and Drug Administration*

The Food and Drug Administration (FDA) is responsible under the Federal Food, Drug, and Cosmetic Act (FFDCA) and the Public Health Service Act for ensuring the safety of all domestic and imported foods intended for human or animal consumption, except for meat, poultry, and egg products.<sup>15</sup> In reviewing the safety of biotechnology foods, the FDA disregards the process of gene manipulation, accepting the premise that substances introduced to the food by scientists are "substantially equivalent" to "well-characterized proteins, fats, and carbohydrates."<sup>16</sup> The FDA has reached this conclusion even though studies, including some reporting "equivalence," demonstrate statistically significant differences in the compositions of genetically engineered and conventionally bred plants. One study of genetically engineered cotton revealed: "Several amino acids in cottonseed from lines 531 to 757 showed statistically significant differences when compared to the measured amino acid in cottonseed from the control line."<sup>17</sup>

<sup>10</sup> 51 Fed. Reg. 23302 (June 26, 1986).

<sup>11</sup> See *Exercise of Federal Oversight Within the Scope of Statutory Authority: Planned Introductions of Biotechnology Products into the Environment*, <<http://www.nbiap.vt.edu/othersrc/scope.fed.txt>> Visited Sept. 5, 2001 (Office of Science and Technology Policy, Executive Office of the President, 1992).

<sup>12</sup> EPA FIFRA SAP No. 2000-03, 9 (Sept. 28, 2000).

<sup>13</sup> *Foundation on Economic Trends v. Johnson*, 661 F. Supp. 107, 109 (D. D.C. 1986)

<sup>14</sup> See *Chevron U.S.A. Inc. v. Natural Resources Defense Council, Inc.*, 467 U.S. 837 (1984); *United States v. Mead Corp.*, 121 S. Ct. 2164 (2001).

<sup>15</sup> <<http://www.uvm.edu/nusc/nusc237/401-403.html#402>> Visited Nov. 7, 2001.

<sup>16</sup> See *Maryanski Report to the House*, *supra* note 8.

<sup>17</sup> *Genetically Engineered Food: Still Unlabeled, Still Untested*, (Greenpeace, Jan. 2001) <<http://www.greenpeaceusa.org/ge/geresourcetxt.htm>> Visited Nov. 7, 2001.

The fact that recombinant DNA fails to qualify as an “additive” reduces the FDA’s level of scrutiny of product safety and postpones the point in marketing at which a developer must obtain FDA approval of a product. According to § 402(a)(1) of the FFDCA, the FDA can remove food from the market that poses a risk to public health. This provision, however, only applies to “adulterated” food. Unless a substance has been added to the food – which, in the eyes of the FDA is not the case with bioengineering – the FFDCA defines “adulterated” food in terms of whether the *expected quantity* of “poisonous or deleterious substances” within the food will “render it injurious to health.”<sup>18</sup> For bioengineered foods, the definition is simply too narrow.

In the interest of public health, § 409 requires pre-market approval for all food products containing additives. Even if the FDA decided to regard recombinant DNA as an additive, as long as the substance is “generally recognized as safe”, then pre-market approval is not required. In 2000, over fifty environmental, consumer, and family farm groups jointly petitioned the FDA to reconsider its position on pre-market testing.<sup>19</sup> As a result of such pressure and with much publicity, the FDA began reviewing some bio-engineered foods prior to their commercial marketing, despite refusing to reclassify the recombinant DNA as an additive.<sup>20</sup>

### *The Environmental Protection Agency*

The Environmental Protection Agency (EPA) requires that developers either register a pesticide under the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA) or obtain a permit under the FFDCA. Under FIFRA, which is predominantly a procedural, not a substantive, statute, the EPA regulates the testing, sale, distribution, and use of pesticides.<sup>21</sup> Traditionally, FIFRA applies to chemicals and not to living organisms. Still, the statute broadly defines “pesticides” as “any substance or mixture of substances intended for preventing, destroying, repelling, or mitigating any pest...”<sup>22</sup> The EPA interprets FIFRA to cover genetically modified organisms that exhibit the characteristics of pesticides, even though, as indicated in 40 C.F.R. § 152.20, plants are typically exempt from FIFRA’s requirements. To register a “plant-pesticide,” a developer must provide the EPA with a risk-benefit assessment before marketing the product. Based on the information that the developer supplies, the EPA determines whether a pesticide will cause “unreasonable adverse effects on the environment” when used properly.<sup>23</sup> The burden of proving the product safe is on the developer.

Under the FFDCA, the EPA requires documentation with “sufficient data” to support the safety of a plant-pesticide<sup>24</sup> before issuing an Experimental Use Permit (EUP) for pre-

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<sup>18</sup> FFDCA § 402(a)(1).

<sup>19</sup> *Genetic Engineering: Government* (Greenpeace) <[www.greenpeaceusa.org/ge/governmenttext.htm](http://www.greenpeaceusa.org/ge/governmenttext.htm)> Visited Nov. 7, 2001.

<sup>20</sup> See <<http://www.uvm.edu/nusc/nusc237/401-403.html#402>> Visited Nov. 7, 2001.

<sup>21</sup> 7 U.S.C. §§ 136-136(y).

<sup>22</sup> FIFRA 2(u).

<sup>23</sup> 7 U.S.C. § 136a(c)(5)(D).

<sup>24</sup> FIFRA encourages information sharing to streamline the regulatory process. In Ruckleshaus v. Monsanto, the Supreme Court noted that although Monsanto paid considerable money developing health, safety, and environmental data to submit to the EPA, the data was for a government application and did not remain the property of Monsanto.<sup>24</sup> According to the Court, the agency had authority to eliminate the cost of duplicative research by allowing other companies to reuse the data and by disclosing the data publicly. Currently, according to 7 U.S.C. § 3(c)(1)(F)(i), with the permission of the company that submits data, another company may reuse the original data for registration in support of another permit application related to a “similar chemical.” To encourage such collective data use, FIFRA even includes a clause for arbitration in § 3(c)(1)(F)(iii) to overcome a company’s reluctance to share such information.

registration sale or distribution. Announcements appear in the Federal Register both when a company applies for an EUP<sup>25</sup> and when the EPA grants approval for an EUP. The public may object to an EUP for up to 60 days after the date of the EPA's approval.

The Federal Register, however, is not common reading material. Some environmental groups view the notice and comment process for the approval of plant-pesticides as merely a gesture on the part of the EPA, allowing the public to make a clamor without consequence, like a ghost rattling incorporeal chains.<sup>26</sup> Unsurprisingly, while public opinion polls show concern about genetically modified soybeans, the EPA did not receive a single comment to its Federal Register notices in the late 1990s regarding the applications for an EUP or the registration of the use of an herbicide-resistant soybean that was genetically engineered by Aventis.<sup>27</sup> In fairness to the EPA, it followed proper procedure and cannot reasonably be expected to hold a press conference and publicity campaign every time a researcher is ready to introduce a new chemical. The EPA maintains a public docket that allows people to inspect and copy a large number of documents, including safety reviews on individual pesticides.<sup>28</sup>

An EUP is not necessary for every new pesticide. Developers conducting small field tests of under 10-acres of land or 1-acre of water are not required to get an EUP to collect data.<sup>29</sup> In addition, a presumption exists that EUPs are not required for experiments in a contained facility, such as a laboratory.<sup>30</sup> The EPA may also grant lenient tolerance levels to permit some marketing of a pesticide or exempt an experimental design for the production of food for distribution in interstate commerce.<sup>31</sup> According to the statute, the EPA is supposed to base tolerance levels on toxicity data, focusing on the effect of the pesticide on humans and animals after being ingested and the effect on other organisms through exposure by air, soil, and water. Yet, scientists warn that current testing methods focusing on the purified protein from bacteria "will not generally help quantify other kinds of toxicity that may arise by chance from interactions of the heterologous protein with food material, nor will it increase the reliability of measures due to food gene disruption."<sup>32</sup> Instead, testing should mirror patterns of consumer use and test the *whole foods* for toxicity.<sup>33</sup>

#### *The United States Department of Agriculture*

The Plant and Protection Act (PPA) authorizes the United States Department of Agriculture (USDA) to:

[p]rohibit or restrict the importation, entry, exportation, or movement in interstate commerce of any plant, plant product, biological control organism, noxious weed, article, or means of conveyance, if the Secretary [of Agriculture] determines that the restriction is necessary to prevent the introduction into the United States or the dissemination of a plant pest or noxious weed within the United States.<sup>34</sup>

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<sup>25</sup> *Case Study III: Herbicide-Tolerant Soybean*, 31 (CEQ/OSTP, Jan. 2001) <<http://ostp.gov>> Visited Sept. 17, 2001 [hereinafter "*GMO Soybean*"].

<sup>26</sup> Interview with Craig Culp, Head of Greenpeace USA's Biotechnology Program, at Greenpeace, in Washington, D.C. (Nov. 8, 2001). [hereinafter "*Greenpeace Interview*"].

<sup>27</sup> *GMO Soybean*, *supra* note 25 at 32.

<sup>28</sup> *Id.*

<sup>29</sup> See 40 C.F.R. § 172.3(c)(1)(2000).

<sup>30</sup> *Id.* § 172.3(b)(1)(i)(2000).

<sup>31</sup> FFDCA § 408.

<sup>32</sup> EPA FIFRA SAP no. 2000-03, 12 (Sept. 28, 2000).

<sup>33</sup> See *id.*

<sup>34</sup> 7 U.S.C. § 7712(a).

A “plant pest” is an organism that could “directly or indirectly injure or cause disease or damage in or to any plants or parts thereof.” The USDA broadly defines “plant pest” to include genetically modified organisms and exercises its authority through the Animal and Plant Health Inspection Service (APHIS).<sup>35</sup>

In administering the PPA, APHIS is required to protect American agriculture against pests and diseases. To fulfill this duty, APHIS prohibits the “introduction,” meaning the “release into the environment” or movement through or into the United States, of a “regulated article”<sup>36</sup> without first obtaining approval from APHIS.<sup>37</sup> Realistically, the phrase “release into the environment” expands APHIS’s authority to include all environmental releases of a plant-pesticide, as long as the plant-pesticide poses a significant threat to a local ecosystem.

If a plant-pesticide requires an environmental impact statement under NEPA instead of just an environmental assessment, then APHIS requires developers to obtain a permit and to supply the agency with advanced notice more than 120 days before the scheduled release of regulated articles into the environment.<sup>38</sup> While the permit application requirements seemingly focus on the technique of gene manipulation, it is the product rather than the biotechnology process that remains central to APHIS. A recent policy statement by the agency demonstrates this position’s logical outgrowth: “Any new virus problem that might result from the use of a transgenic plant would be detected by farmers, seed producers, and scientists, as would any new plant virus or plant disease.”<sup>39</sup> In such thinking, APHIS fails to acknowledge the risks that the plant can pollinate or interact with other elements of a particular ecosystem. Obviously, detecting a virus does not necessarily mean stopping a virus, since some invasive plants are difficult, if not impossible, to contain. As with the EPA, APHIS requires in 7 C.F.R. § 340.4(b)10(i) that anyone handling the plant-pesticide “orally notif[y] APHIS immediately upon discovery and notif[y] APHIS in writing within 24 hours in the event of an accident or unauthorized release of the regulated article.” This obligation covers the unintentional release or inability to contain the plant due to such things as accidents of nature, vandalism, and vehicle collisions.

While APHIS defines its jurisdiction over plant-pesticides broadly, developers significantly can exempt certain regulated articles from the traditional permit requirements by notifying APHIS before they release the product into the environment.<sup>40</sup> APHIS will attempt to approve or deny the field trial within 30 days.<sup>41</sup> In 1997, APHIS increased the range of eligible genetic constructs that qualify for the exemption, originally only having allowed six standard crops. Now, similar to the guidelines that the FDA follows, APHIS asks the developers to guarantee that the plant-pesticide is “innocuous” in terms of their potential to spread disease.

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<sup>35</sup> 7 C.F.R. § 340.1.

<sup>36</sup> *Id.*

<sup>37</sup> *Id.* § 340.0

<sup>38</sup> *Id.* fnt. 6.

<sup>39</sup> *AIBS Transgenic Virus-Resistant Plants and New Plant Viruses* (USDA, Aug. 1995)

<<http://www.aphis.usda.gov/biotech/pubs.html>> Visited December 12, 2001. This report is from an American Institute of Biological Sciences Workshop Sponsored by APHIS and the Biotechnology Industry Organization, Inc.

<sup>40</sup> 7 U.S.C. § 340.3.

<sup>41</sup> *Id.* § 340.4(b).

## **B. Holes in the Regulatory Framework Pose a Risk to Public Safety and the Environment.**

In a recent interview, Craig Culp, the head of Greenpeace USA's biotechnology program, quipped that "the 'Coordinated Framework' does not seem very coordinated from a regulatory standpoint. Certain biotech products are under the purview of the EPA, some are under the purview of the FDA, some are under the purview of the USDA..." He criticized the "bizarre kind of rationality" that goes into categorizing an entire plant as a pesticide to provide the EPA with legal oversight.<sup>42</sup> The system undeniably is an ad hoc construct put in place to oversee incredibly complex scientific endeavors.

Folk wisdom suggests that too many cooks spoil the soup. The adage strikingly applies to the jumble of governmental regulations attempting to offer sufficient regulatory oversight of biotechnology products without carefully delineating the duties of agencies. The Coordinated Framework confers implicit authority to agencies to address new biotechnology issues using old statutes, which at times are simply insufficient.

Ultimately, some biotechnology products slip through loopholes in the net of regulations. The FFDCA, FIFRA, PPA, and the Public Health Safety Act are narrowly designed to cover products intended for commercial use, which poses serious limitations. For example, if a genetic experiment is undertaken without government funding to produce a transgenic fish for weed control, that fish, because of its position outside of the stream of commerce, could completely avoid the sweep of the government's net. The caveat is that the fish must not be used for food, although it may swim unregulated in United States waters.

The confusion in this half-baked regulatory approach is exacerbated by the government's decision to close its eyes to the potential for error that is intrinsic in the process of bio-engineering. Even scientists only issue "opinions," not definitive statements, as to the safety of particular biotechnology experiments, acknowledging that alternate theories and contradictory views may exist. Meanwhile, the government's regulatory approach concentrates on the biotechnology product's objective characteristics and intended use, ignoring the process.<sup>43</sup> By adhering to this strategy, the government brushes aside not only reasonable concerns about the potential risks arising from the application of molecular biology in the current context, but, significantly, also its obligation to public safety for biotechnology work that does not produce a product. Unless the project requires an EUP from the EPA or is conducted with government funding, a scientist can conduct any experiment they want, albeit possibly with the slight hassle of some reporting requirements.

Statutory exemptions allow many biotechnology products to avoid agency scrutiny. FIFRA exempts pesticides created solely for export to foreign nations from permit requirements, although some record-keeping duties remain.<sup>44</sup> Regardless of the product's intended use, FIFRA exempts plant-pesticides that act by affecting the plant so that the target insect has difficulty attaching itself or invading the plant tissue with toxins and substances that are coat proteins of viruses. Meanwhile, the scope of the FDA's mandate is alarmingly narrow – food safety for consumption by animals and humans – entirely neglecting the consequences of the release of a genetically modified organism on the environment.

Fundamentally, in treating genetically modified organisms as static products, agencies fail to take into account that living entities move, reproduce, cross-breed, evolve, and mutate.

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<sup>42</sup> Greenpeace Interview, *supra* note 26.

<sup>43</sup> See *Stauber v. Shalala*, 895 F. Supp. 1178 (W.D. Wis. 1995).

<sup>44</sup> 7 U.S.C. § 136(a); 40 C.F.R. § 152.30(d).

The laws inappropriately assume the viability of containment, even when the transgenic organism's location qualifies that organism for an exemption from agency review. The EPA has placed geographic boundaries on the planting of transgenic crops without fully calculating for the consequences of reseeding and pollen drift, as if a firm order of "stay" will fix the crops in place. Under FIFRA, the EPA may designate plant-pesticides bound for Mexico or Canada as statutorily exempt; FIFRA, however, fails to account for the potential of plants to emigrate back into the U.S. The EPA and APHIS both accept quarantine as a proper method of preventing the spread of particularly harmful chemicals. While this method may contain products that are issued from a can or drum, genetically modified plants in a field simply are more invasive and warrant a different approach.

FIFRA, in theory, has many labeling requirements. In practice, how can someone feasibly follow labeling requirements if plants cross-breed, transmitting the recombinant DNA of a transgenic plant to its wild relative? Who is responsible for labeling the offspring? A farmer may not only raise concerns about tangible infringements on his or her property rights when his organic crops are pollinated by genetically engineered neighbors, but may also deny any retroactive responsibility for labeling or safety requirements. Plus, who is responsible for compensating that farmer if he or she loses his crops due to such cross-breeding or from new plant viruses evolving from genetically engineered plants and then spreading? Current law neglects these questions.

To offer consistency, the government's policy encourages agencies to coordinate their definitions. Such an approach, however, may simply result in a "race to the bottom" in regulatory standards. For instance, as mentioned previously, APHIS recognized and mimicked the FDA's lax attitude toward the scope of regulatory coverage. While the agencies all have the goal of preventing harm, they apply different standards of review in determining product safety. In terms of policy, the idea that the EPA should look to its neighbor instead of to the risk to the public and the environment to establish an appropriate standard is unconscionable. At the same time, under the Coordinated Framework, agencies sometimes have overlapping jurisdictions. Companies may face different standards of review depending on which agency takes the lead.

In terms of the stringency of review, the EPA and APHIS both are supposed to prevent products that produce "unreasonable adverse effects" from getting on the market. Yet, these agencies are strapped for cash, time, and personnel, with uncertain prospects for additional resources. Industry, often with political support, pushes the agencies for quick product reviews. Lacking sufficient resources to conduct thorough scientific investigations and gain knowledge of the products independently, the agencies must rely on developer-provided information. Assembly-line review is inappropriate, however, for such a highly specialized science as biotechnology. Without the resources to hire employees with the exceptional, specific expertise to evaluate in sufficient depth the genetic stability of most biotechnology products, agencies lack a feasible, realistic alternative to remedy the current inadequacies of the review process.

### **C. The Public Faces Significant Obstacles to Successfully Challenging an Agency Action in Court.**

A court case protesting an agency action is unlikely to succeed. For example, in Foundation on Economic Trends v. Thomas, the court held that the EPA's issuance of an EUP for genetically engineered microbial pesticides was rational, noting that the EPA's actions occurred "within a substantive regulatory framework that emphasizes the quality of man's

environment,<sup>45</sup> and a procedural framework that provides ‘full opportunity for thorough consideration of the environmental issues and for ample judicial review.’”<sup>46</sup> Undoubtedly, the courts show respect for the routines of agencies in implementing statutes. As the Supreme Court indicated in United States v. Mead, in challenging an agency’s policies, the public must understand that the court will give “substantial respect” to an agency’s decisions, even when those decisions are merely policies and not rules.<sup>47</sup> The more consistency the agency shows in interpreting its obligations, the more deference the agency receives from the courts.<sup>48</sup>

Ripeness is another obstacle to success in causes of action against agencies in biotechnology cases, as seen in Alliance for Bio-Integrity v. Shalala, 116 F. Supp. 2d 166 (2000). According to Article III of the U.S. Constitution, federal courts require an actual, present controversy between parties and not a hypothetical or speculative problem. In a biotechnology case, this requirement is significant because the court will not become involved in disagreements over administrative policies, such as when the EPA announces a rebuttable presumption about genetic foods. The courts avoid interfering before an agency makes a formal, concrete decision. As seen in a number of cases, including Alliance for Bio-Integrity, the courts are likely to view a case as premature for adjudication and dismiss that case on summary judgment if the case is filed before an agency has reached a final determination.<sup>49</sup>

Even if a case is successful, relief may be elusive. The standard for issuing an injunction to stop testing or uproot a crop already in the soil is extremely high. A plaintiff must show that he or she faces “irreparable injury” without an injunction *at the time when* the plaintiff could receive injunctive relief.

### **III. The Government Should Respond to Warnings of Potential Problems.**

#### **A. The Government Should Learn from Lessons of the Past.**

Reacting to identifiable problems, Congress enacts legislation with a backward glance. The Coordinated Framework statutes bear the mark of their origins, being implemented based on past difficulties. The requirements of the statutes are applied prospectively, but may fail to sufficiently overcome the Framework’s lack of coherency and attention to the unique elements of biotechnology. Instead of reinforcing industry’s social responsibilities, these statutes adopt neither the constraints of command-and-control strategies nor the diligence of the Resource and Conservation Recovery Act’s (RCRA) cradle-to-the-grave management of hazardous waste.

A recent law review article drew an apt analogy between organic chemical technology in the 1940s and biotechnology now, describing both as being “unpredictable, risky, and capable of causing pollution and harm to health and the environment.”<sup>50</sup> In the author’s words:

From the 1940s until the mid-1960s, the nation was seemingly oblivious to its developing legacy of abandoned hazardous waste dumps, fields and by-ways wasted by excessive pesticides, fish and wildlife threatened by pesticides and fertilizers, and of a population exposed to unquantified, unevaluated, unstudied,

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<sup>45</sup> *Foundation on Economic Trends*, 637 F. Supp. 25, 29 (Dist. D.C. 1986).

<sup>46</sup> *EDF v. EPA*, 489 F.2d 1247, 1256 (D.C.Cir. 1973) cited in *id.* at 29.

<sup>47</sup> *Mead*, *supra* note 14.

<sup>48</sup> *Id.*

<sup>49</sup> *See id.*

<sup>50</sup> Joan M. Ferretti, *Looking for the Big Picture – Developing a Jurisprudence for a Biotechnological Age*, 10 *Pace Env’tl. L. Rev.* 711 (1993).

and unexplained risks of harm. In the heat of the World War II effort, a regulatory approach to organic chemicals was not a priority. Even after the war, it was still not a consideration... The nation's health care system, its taxpayers, its natural resources, and its citizen's health, enjoyment and prosperity have also paid the price for the lack of organic chemical foresight.<sup>51</sup>

As the War ended, consumer demand skyrocketed. New products, such as those now known as persistent organic pollutants, seemed in tune with the cultural shift to urban life and the refinement of the agricultural industry. In a rush to modernize, the country did not understand that these carcinogenic chemicals could linger in the environment for 100 years.

Fragmented statutes halfheartedly addressed the environment, failing to recognize and tackle the causes of ecological damage. With images of birds dying, rivers burning, and neighborhoods overrun by toxic soups on television screens across America, the government finally responded. In 1969, the National Environmental Policy Act (NEPA) was passed, followed by the creation of the EPA in 1970. The EPA gained momentum and definition through the passages of the Clean Air Act in 1970, FIFRA and the Federal Water Pollution Control Act in 1972, and RCRA and the Toxic Substances Control Act in 1976.<sup>52</sup> The U.S. again runs the risk of heralding a new technology without fully appreciating how extensively that technology could impact the environment.

## **B. Acknowledging Public Protests, the Novelty of the Science, and Industry “Accidents,” The Government Should Review the Safety of Bio-Engineered Food More Thoroughly.**

### *1. As Public Fears Regarding Biotechnology Increase, the Government is Denying the Public's Request for Better Notice of Bio-engineered Products.*

The level of current consumer wariness regarding biotechnology foods strikingly deviates from a reality in which these foods are increasingly a part of the American diet. The contrast between consumers' goals to avoid genetically modified organisms and purchasing habits implies a lack of informed decision making. In studies conducted by the Angus Reid Group, 45 percent of consumers expressed reservations about the sale of genetically engineered foods in 1998, while 51 percent of consumers expressed such a concern in 2000.<sup>53</sup> A 2001 USA Today Weekend Poll asked: “Should it be legal to sell genetically modified fruits and vegetables without special labels?” Seventy-nine percent of respondents categorically replied: “no.”<sup>54</sup> Yet, around 65 percent of the foods for sale in grocery stores contain ingredients derived from genetically engineered plants.<sup>55</sup> Such a discrepancy also surfaces in other polls as well, such as a 1999 poll of 1,000 households conducted by the International Food Information Council that found only 34 percent of respondents knew that supermarkets already sell genetically engineered foods.<sup>56</sup>

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<sup>51</sup> *Id.* at 717.

<sup>52</sup> See Daniel J. Fiorino, *Table 1. U.S. Statutory Framework (1969-1993)*, Making Env'tl. Policy 26 (Univ. of Cal. Press, 1995).

<sup>53</sup> *Fact Sheets*, (Greenpeace) <<http://www.greenpeaceusa.org/media/factsheets/californiatext.htm>> Visited Nov. 7, 2001.

<sup>54</sup> *Id.*

<sup>55</sup> *Agricultural Biotechnology: Myths & Facts* (International Food Information Council Foundation, Oct. 2001) <<http://www.ific.org/proactive/newsroom/release.vtml?id=18024>> Visited Dec. 12, 2001.

<sup>56</sup> International Food Information Council - March, 1997 & February, 1999 <<http://www.foe.org/safefood/gefoodscnsmeropin.htm>> Visited Dec. 13, 2001.

Denying the public's "right" to know about biotechnology activities, the government refuses to require industry to expend the resources to meet the public demand for what the government regards as abstract and superfluous information. Companies readily admit a fear that the labels will stigmatize their products. Emphasizing product over process, the government rejects the notion that biotechnology products are particularly threatening. In practice, this policy permits the release of genetically modified organisms into the environment without informing the public. Contrary to global trends, no labeling requirements exist for the sale of bio-engineered foods. In its campaigns, Greenpeace, along with other organizations, characterizes the government's refusal to require labeling as a "gross malfeasance" that disregards the public's interest in staying informed.<sup>57</sup> In addition, eight State Attorneys General, and the American Association of Retired Persons, have asked the FDA to require mandatory labeling of all genetically-engineered foods, as has the American Association of Retired Persons.<sup>58</sup> Similarly, some premier restaurants and grocery store chains, such as the Frontera Grill and Fresh Fields, are also boycotting the use or stocking of bio-engineered foods.

## *2. Industry Standards Regarding Adequate Safety Measures Should Not Develop Independent of Government Regulation.*

The U.S. is undeniably at a competitive advantage in the biotechnology industry. While Europe and Asia impose strict constraints on experiments, the U.S. approves hundreds of new biotechnology products, promotes investment and, for now, gains financially. Considering biotechnology a strategic industry, in a recent report on *Bacillus thuringiensis* (commonly referred to as "Bt") plant-pesticides, the EPA praised "the efforts of all stakeholders to promote pesticide resistance management" and expressed a desire to "not overly burden the regulated community [or] jeopardize the registration of reduced risk pesticides."<sup>59</sup> Many environmental groups, however, challenge what constitutes a burden versus a necessary safeguard in asking for stricter regulations and more extensive notification regarding biotechnology projects and products.

While biotechnology has the potential for great accomplishments, profit, rather than a desire to serve the public interest, largely motivates the industry. Most biotechnology companies target their research to create products that 1) are herbicide resistant, 2) are pesticide resistant, or 3) display specific, marketable traits, such as increases in nutritional value and improved shelf-life.<sup>60</sup> Honing in on the perfect complement to its Round-up herbicide, Monsanto's Round-up Ready, herbicide-resistant soybeans account for 50 percent of all genetically engineered crops sold worldwide.<sup>61</sup> Ecologically, the amount of chemicals sprayed on crops is increasing, not decreasing, as farmers turn to biotechnology products. For example, one recent study exposes that farmers who plant Round-up Ready seeds inundate their crops with two to five times more herbicide than farmers who rely on standard weed control methods.<sup>62</sup> Right now, 70 million acres of genetically engineered crops in the U.S. are grown to withstand or produce pesticides.<sup>63</sup>

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<sup>57</sup> Greenpeace Interview, *supra* note 26.

<sup>58</sup> *Other Evidence of U.S. Support for Labeling of Genetically Engineered Foods* <<http://www.foe.org/safefood/gefoodscnsmeropin.htm>> Visited Dec. 13, 2001.

<sup>59</sup> *The Environmental Protection Agency's White Paper on Bt Plant-pesticide Resistance Management*, 1 (Office of Pesticide Programs, Environmental Protection Agency, 1998).

<sup>60</sup> Kolehmainen, *supra* note 7 at 273.

<sup>61</sup> *Roundup Ready Soybeans Contain Unidentified DNA* (Environmental News Service) <<http://ens-news.com/ens/aug2001/200111%2D08%2D16%2D06.html>> Visited Dec. 12, 2001.

<sup>62</sup> *Facts Sheets*, *supra* note 53.

<sup>63</sup> *Id.*

Adverse effects from biotechnology could impact the economy, the environment, and public health, as well as erode public confidence in government. Plants could display increased allergenicity and toxicity or confer resistance to antibiotics. For example, in 1996, unexpectedly, consumers suffered serious allergic reactions after chomping down on soy with inserted Brazilian nut genes.<sup>64</sup> Meanwhile, the constant release, rather than intermittent spraying, of pesticides could desensitize predators, who are infamous for their ability to adapt. New crops may display special vulnerabilities to bacteria and develop new diseases that spread to native populations. Loss of biodiversity could result from plants out-crossing with other varieties of plants, bio-engineered plants possessing novel resistance traits that make them hardier than their wild relatives, or simply through the genetic erosion of unique traits. Moreover, the possibility exists that recombinant DNA could cause bacteria to mutate.

Sometimes the biotechnology experiments of companies are seriously and blatantly flawed. For example, carp engineered with human growth hormones developed deformities that interfered with their ability to feed or swim.<sup>65</sup> Bacteria genetically engineered to produce lactose were found to kill wheat planted within the same soil.<sup>66</sup> Cotton crops designed to withstand the cold displayed not only increased frost tolerance, but also lower yields. Scientists mistakenly inserted a gene into a Petunia to produce red petals and were surprised to discover that the experiment produced flowers exhibiting the color red, decreased fertility, and altered growth patterns.<sup>67</sup>

Evidencing gaps in Monsanto's awareness of the genetic structure of one of its popular, commercial, EPA-approved crops, Belgian scientists, and not Monsanto's field testing, detected a mystery strain of DNA in Round-up Ready soybeans.<sup>68</sup> The Belgian team explained to the world press: "Our results establish that during integration of the insert DNA, several rearrangements occurred. The genomic plant DNA at the pre-integration site may have been rearranged."<sup>69</sup> In addition, the scientists reported finding "a DNA segment of 534 bp DNA for which no sequence homology could be detected." The scientists concluded that "during integration of the insert DNA rearrangements or a large deletion may have occurred."<sup>70</sup> In response, Greenpeace published the DNA sequence prominently on its website.<sup>71</sup>

The government does not verify the DNA sequence information that biotechnology companies provide. Yet, instead of withdrawing approval for the soybean or turning to an outside source for scientific review, the government asked for assurances from Monsanto that the DNA was "silent" and did not create a novel protein. Particularly alarming, the Belgian scientist's finding marked the second occasion on which the team observed inaccuracies in Monsanto's description of its best selling genetically engineered soybeans.

The risks from bio-engineering are difficult to quantify or qualify in a short time period. The government acts like defects in the biotechnology process will express themselves on cue

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<sup>64</sup> Teel, *supra* note 9 at 658.

<sup>65</sup> See *Genetically Engineered Fish Under Development*, (Greenpeace) <[http://www.greenpeaceusa.org/ge/fish\\_varieties\\_text.htm](http://www.greenpeaceusa.org/ge/fish_varieties_text.htm)> Visited Nov. 7, 2001.

<sup>66</sup> M.T. Holmes, et. al., *Effects of Klebsiella Planticola on Soil Biota and Wheat Growth in Sandy Soil*, 326 *Applied Soil Ecology* 1-12 (1998) <<http://www.sierraclub.org/biotech/references.asp>> Visited Dec. 12, 2001.

<sup>67</sup> Kolehmainen, *supra* note 7 at 276.

<sup>68</sup> *Roundup Ready Soybeans Contain Unidentified DNA*, (Environmental News Service) <<http://ens-news.com/ens/aug2001/20011%2D08%2D16%2D06.html>> Visited Dec. 12, 2001.

<sup>69</sup> *Id.*

<sup>70</sup> *Id.*

<sup>71</sup> See <[http://www.greenpeace.org/~geneng/highlights/gmo/Monsanto\\_DNA\\_MP.htm](http://www.greenpeace.org/~geneng/highlights/gmo/Monsanto_DNA_MP.htm)> Visited Dec. 10, 2001.

during field testing. Yet, arriving at conclusive proof as to the safety of a product is difficult when scientists cannot be sure that even the particular ecosystem chosen for field testing is sufficiently representative. Unanticipated problems may escape the attention of scientists who are looking for specific signs of trouble. Metabolic changes can influence the way a genetically engineered organism reacts upon exposure to various chemicals. Sometimes defects are latent. Additionally, the process may result in an unstable product, with the regeneration, recombination, or mutation of loosed cells or organisms.

Concerned with the risks of biotechnology, some private groups are mobilizing consumer-interest campaigns to protest against current applications. Greenpeace and the Sierra Club both offer pre-written letters for consumers to sign and send to food manufacturers and retailers, such as Kellogg's and Kraft, requesting an end to the use of bio-genetically engineered ingredients. Fashioning slogans for protests, Greenpeace has heckled the biotechnology industry about the ills of "Frankenflakes" and "fishberries." Groups are also actively disseminating information to increase public awareness. In this regard, Sierra Club displayed particular initiative by forming a Genetic Engineering Committee in 1999 to explore ways to encourage regulatory reform through grass roots efforts.<sup>72</sup> Ultimately, however, feeling vulnerable and disaffected, some groups within the U.S. are resorting to "eco-terrorism." For example, in 1999, environmental groups, such as Reclaim the Seeds, gathered from Maine to California on a weekly basis to destroy genetically engineered crops.<sup>73</sup>

#### **IV. The Court System is not the Proper Vehicle to Redress Legislative Shortcomings.**

The law within our country is meant to balance the equities of a situation, to consider how applying a principle on a large scale will affect the community at large, and to extend legal rights to individuals in a just and consistent fashion. Legislatures possess the duty of making social policy judgments. The court then bears the responsibility of resuscitating justice when legal rights are denied.

If biotechnology generates a harm, the public deserves recourse, but, for now, the law does not foresee a specific remedy. Additionally, while no crime should go unpunished, ensuring equity also means providing for fair penalties, and right now, the degree and scope of accountability of biotechnology companies if their products result in a harm is legally undefined. The law is even ambiguous as to which players are liable – the developer, the farmer, and the retail store or just the developer?

Tort law involves common sense rights that should be readily apparent even when unwritten. In essence, tort law is a residuary category of civil liability, in which harms remain legally cognizable even though they are not directly included in a contract or statutory scheme. Yet, problems arise for the judicial system when a new harm arises and the law fails to identify what type of injury is necessary for an individual to have standing and the standard by which to impose liability.

Tort law contains four basic elements: 1) a duty to comply with a particular standard of care, 2) a breach of that duty, 3) proof that the breach of that duty caused damages, and 4) damages. Determining the appropriate standard of care is pivotal to imposing liability.

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<sup>72</sup> *The Genetic Engineering Committee* (The Sierra Club) <<http://www.sierraclub.org/biotech/report.asp>> Visited Dec. 12, 2001.

<sup>73</sup> Kunich, *supra* note 2 at 815.

In tort law, there are two alternative standards of care that may result in liability. Under a strict liability regime, a biotechnology company would be liable for any damage that its products cause regardless of whether the harm was foreseeable or whether it took reasonable precautions in conducting its experiments. The inquiry stops with identifying the actor and linking its activity to the harm. Typically, strict liability applies to abnormally dangerous activities and defects in products. For example, a plaintiff could claim that a design flaw in a genetically engineered peach produced a horrible, unexpected allergic reaction. If the product caused the allergic reaction, then the company that designed the peach would assume responsibility for paying damages. In Foundation on Economic Trends v. Thomas, the plaintiff argued that the EPA should require all biotechnology companies to maintain liability insurance to ensure the financial ability to compensate the public for adverse effects on the environment.<sup>74</sup> Underlying the plaintiff's petition was the concept that biotechnology raises special concerns that merit special regulatory controls.

Under a negligence regime, proof of carelessness or disregard for the law is necessary – a show of intentional wrongdoing, meaning not that the individual knew that he or she could cause harm, but that he or she intentionally performed the activity nonetheless. For biotechnology, a claim of negligence could result from conflict over property rights. For instance, returning to the case regarding the peach, labeling, depending on the wording of the label, could actually aid a biotechnology company in defending such a suit if a negligence standard applies. Warning the consumer of a potential danger should alter consumer expectations, so that even though the product caused an allergic reaction, the product performed as safely as the ordinary consumer would expect given the warning.<sup>75</sup> For the biotechnology industry, though, negligence suits would predominantly involve property rights. For example, conversion is a cause of action if one farmer's bio-engineered crops cross-pollinate with another farmer's organic crops, transferring the recombinant DNA. For now, the courts can waiver between applying strict liability or negligence in determining liability for biotechnology products on a case-by-case basis. The ambiguity regarding what standard could apply confronts both the public and the biotechnology companies with a fear of the outcome. In terms of regulatory effect, such uncertainty is exacerbated by the knowledge that a jury may take into account different harms than would an agency, which could deter a company from conducting certain types of research.

In determining whether to hear a case, a judge will first need to determine whether a person has a right to adjudicate a private claim arising from the harm or risk of harm created by the biotechnology product. What harms are actionable? Although no binding precedent exists, courts in the past have applied a standard in "risk of illness" cases that the harm be more probable than not, which loosely means at least a 50.1 percent chance of occurring.<sup>76</sup> Given the complexity of biotechnology, proving the odds of contracting an illness to a jury may be impossible. Even linking the disease to a biotechnology product could be problematic. The public is sidelined while the courts wade through how the tort concepts of foreseeability and reasonableness apply to biotechnology. Such uncertainty, again, is not a good way to provide for public security. Additionally, the courts are only implicated once a damage is palpable, which means that they insufficiently guard against future damages.

Struggling through the complex chemistry involved in a patent case, the revered Judge Learned Hand mused: "I cannot stop without calling attention to the extraordinary condition of

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<sup>74</sup> *Foundation on Economic Trends v. Thomas*, 661 F. Supp. 713 (D.D.C. 1986).

<sup>75</sup> See Restatement (Second) of Torts 402A cmt. K (1965).

<sup>76</sup> Ferretti, *supra* note 50 at 731.

the law which makes it possible for a man without any knowledge of even the rudiments of chemistry to pass upon questions such as these... How long we shall continue to blunder along without the aid of unpartisan and authoritative scientific assistance in the administration of justice, no one knows....<sup>77</sup> Juries and judges are usually not scientists. Yet, in court, they are expected to assess conflicting scientific evidence and ascribe fault for the impact or potential impact of what they can only describe as a mysterious process. Another kink in assessing the company's conduct is acknowledging a difference between what the jury knows as it is hearing the case versus what the company knew when it was making its investment. In dealing with tort cases involving biotechnology, the courts also must decide whether state law applies and what weight to give to scientific evidence and prior governmental findings of safety.

## V. Conclusion

In regulating biotechnology, the government must recognize that the Coordinated Framework is sufficient only as a temporary measure. The public and biotechnology industry deserve a more coherent, transparent statutory scheme that better assigns liability, better safeguards the public and the environment, and better recognizes the unique features of the processes of biotechnology. The U.S. government should first acknowledge public concerns by instituting mandatory labeling. Right now, the opportunity still exists for industry to grow with regulation, anticipating costs and determining the necessity of insurance. Potentially, regulators could establish different standards of care based on the intended use of a product, such as, for example, placing greater burdens on those who are developing new food products than on those who are developing new medicines to cure diseases.

The tort system, with its high transaction costs and inconsistencies, is unrealistically being forced to assume part of the regulatory responsibility as a result of the many gaps and ambiguities in the Coordinated Framework. Without legislative input, the judiciary's decisions could influence the financial success or failure of the biotechnology industry. Fundamentally, the judiciary is not the proper forum for determining U.S. policy toward the biotechnology industry or for providing suitable regulation. Instead, the court system should develop its jurisprudence based on legal guidance from legislative bodies.

Legislation is supposed not only to represent collective values, but also to provide for individual legal rights. The government should not wait until harm is apparent to intervene in the interest of public health and environmental integrity. New laws must attain greater precision. Exploring this new frontier in technology may demand bravely entering into new frontiers in the law as well.

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<sup>77</sup> *Parke-Davis & Co. v. H.K. Mulford Co.*, 189 F. 95, 115 (S.D.N.Y. 1911) cited in Dan L. Burk and Barbara A. Boczar, *Symposium: Biotechnology and Tort Liability: A Strategic Industry at Risk*, 55 U. Pitt. L. Rev. 791, 864 (1994).