Forced Feeding: Inventorying New Legal Issues in the Biotechnology Policy Debate

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I. Introduction: Looking Back to Move Ahead

In the fall of 2000 I presented a paper, Legal Issues Shaping Society's Acceptance of Biotechnology and Genetically Modified Organisms, at the American Agricultural Law Association annual meeting here in St. Louis. The paper inventoried the legal and policy issues shaping America's approach toward biotechnology and was designed to serve as a tool for understanding the ongoing debate.[1] Thirty months have passed and the pace of consideration of issues relating to society's acceptance of biotechnology has not slowed. Just as that article was being finished the nation's experience with the StarLink fiasco had begun to emerge. As will be discussed in more detail in the article, that episode alone has provided the grist for numerous lawsuits and other policy debates.[2] In the intervening thirty months several issues have become more settled. For example, except for skirmishes such as the failed ballot referendum in Oregon to mandate labels,[3] American consumers appear for the most part to accept the FDA's decision to not require labeling on the use of genetically modified food ingredients. In light of the obstacles the agency placed in the way of anyone trying to label a food as being free of GMO's it may not be surprising the issue has subsided.[4] Other issues, such as the continuing conflict between the U.S and the E.U over the European resistance to accepting unlabeled GMO foods and the legality of such action under the World Trade Organization (WTO) rules, remain topics of current public debate.[5] Predictably, several new issues have emerged which were not addressed in the original article, the most significant being the controversy over planting pharma-crops – traditional commodities genetically modified to create traits and products with pharmacological value. The opportunity this conference provided to revisit the scene to update an inventory of policy issues relating to American society's acceptance of biotechnology was too exciting to pass up. What follows is an

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[1] The article was published at 6 *Drake Journal of Agricultural Law* 81 (Spring 2001) and subsequently received the AALA's Award of Excellence for Professional Scholarship at the association's October 2002 meeting.

[2] See In re StarLink Corn Products Liability Litigation, 212 F. Supp. 2d 828 (N. D. Ill. 2002).

[3] See, e.g., Philip Brasher, "Oregon voters reject food-labeling measure," Des Moines Register, November 8, 2002, p. D1

[4] See Food and Drug Administration, "Notice, Draft Guidance for Industry: Voluntary Labeling Indicating Whether Foods Have or Have Not Been Developed Using Bioengineering; Availability," 66 Fed. Reg. 4839, Jan. 18, 2001. The guidance is available at http://www.cfsan.fda.gov/~dms/biolabgu.html (last visited March 4, 2003.)

[5] See, e.g., Philip Brasher, "Biotech ban tries patience of U.S.," Des Moines Register, March 4, 2003, p. D1, concerning Trade Representative Robert Zoellick's frustration that current geopolitical forces relating to U.S. plans to invade Iraq have for now led the U.S. to delay its plans to file a formal WTO complaint against EU policy on GMO foods.

effort both to update many of the issues discussed in the previous article and to make the analysis more timely and complete. In doing so the article will share whatever insights and observations are possible concerning the role biotechnology will play in our food and agriculture system and how policy and law will be asked to shape that future.

II. Recent Developments in Biotechnology Policy – What's Worked and What Hasn't

Before discussing recent policy developments relating to agricultural biotechnology it may be helpful to start with a brief summary of events of the last two years. On the domestic front the public acceptance of biotechnology has continued with only a few minor interruptions. From the standpoint of farms the continued and rapid adoption of GM technology – especially in the form of Roundup Ready soybeans and Bt corn is remarkable.[6] This seems especially so in light of the continuing uncertainty in the acceptance of the crops in some foreign markets. In particular the resistance of Europeans consumers to accepting gene-altered food appears to have harden, perhaps for some as a method of resisting what is seen as America's attempted political and economic hegemony.[7] Around the world the use and development of biotechnology continues to progress, with Asia being an especially active region.[8] The continued development of new crop products by the biotech sector, such as the recently approved version of Bt corn for use with corn root-worm, a major U.S. pest, promises a continued flush of new products for use by farmers.[9]

As to the actual farm-level use of biotechnology the main focus is on three issues: resistance management for Bt crops,[10] lingering concerns about how to resolve liability conflicts between biotech and non-biotech crops such as organic grain, and the potential use and regulation of pharma-crops.[11] From the legal perspective, recent litigation

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[6] See e.g., "ERS research identifies benefits, costs to farmers of using GE crops," Feedstuffs, August 26, 2002, p. 3, discussing the recent report by USDA economists documenting the rapid adoption of genetically engineered crops, including 61% of the U.S. soybean crop and 56% of the cotton crop in 2001.

[7] See Lizette Alvarez, "Consumers in Europe Resist Gene-altered Foods," New York Times, February 11, 2003, p. A3.

[8] See David Barboza, "Development of Biotech Crops Is Booming in Asia," New York Times, Feb. 21, 2003, p. A3, which report China, India, and Indonesia are already planting millions of acres of GMO crops and are investing heavily in developing locally adapted GM products.

[9] See Philip Brasher, "EPA gives final OK to new corn," Des Moines Register, February 26, 2003, p. D1 and Andrew Pollack, "U.S. Approves Type of Corn That May cut Pesticide use," New York Times, February 26, 2003, p. C8.

[10] See e.g., "Growers must follow Bt planting guidelines or be denied seed," Iowa Farm Bureau Spokesman, November 23, 2002,

[11] Just as this article was being finished the USDA announced much awaited rules for the planting of pharma-crops. See, Andrew Pollack, "U.S. Imposes Stricter Rules for Genetically Modified Crops," New York Times, March 7, 2003, p. A22, and Philip Brasher, "U.S. tightens rules for growing pharma crops," Des Moines Register, March 7,

involving the StarLink episode has begun to provide some of the legal guidance that will be needed to resolve the unavoidable conflicts between production of biotech crops and non-GMO crops.[12] From an industry perspective the resolution of intellectual property rights issues, means the real legal and policy issues will relate to how the federal government proceeds with implementation of new regulations on farmers' use of the products – such as the required refuges to manage resistance and limitations on producing pharma-crops in rotation. In summary the horizon is relative bright with only a few clouds looming too challenge the continued growth and acceptance of biotechnology in American agriculture and our food system. Farmers are planting, American consumers are eating, and most foreign customers are buying – at least for now everything is relatively peaceful. Whether the future proves to be so tranquil will depend in part on how the legal issues summarized in the following eight categories play out.

1. African Famine Provides New Opportunity to Attack Biotech Opponents – If We Don't Use it People Will Die!

The international development that provided perhaps the strongest opportunity for proponents of biotechnology to argue its benefits – and perhaps as importantly to castigate its opponents, came from an unlikely source – the need for increased food aid to relieve famines in southern Africa.[13] As America and other grain producing nations mobilized to respond to the need for grain several potential recipient nations questioned whether the food aid, in particular corn in seed form rather than ground as meal, would contain GMOs. The debate brought into focus the contrast between U.S. attitudes towards the safety of the crops and the further trade related impact of the leakage of seeds into production. Because the U.S. grain marketing system does not segregate or identify the type of corn and given the increased prevalence of the planting of GMO seeds the assumption would have to be that American food aid would contain GMOs. The issue for several African nations then became whether the risk of accepting the food aid – knowing at least some of the corn would be diverted and saved for seed and replanted – would lead to the presence of GMO corn in future crops. The concern was how this

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2002, p. D1. The rules, which include enhanced on-farm inspections requirements and limitations on the ability to rotate food crops on fields recently planted with pharma-crops may have the effect of limiting the use of the technology in Midwestern states like Iowa. The rules were published in the March 10, 2003, Federal Register, 68 Fed. Reg. 11337. This topic is discussed in more detail in the article at notes __.

[12] An excellent example of the costs and complexities involved in managing the inherent conflicts between these production systems, can be seen in the recently agreed to $110 million settlement to resolve damage clams by non-Starlink growers. For information about how the settlement is being managed see the website http://www.non-starlinkfarmerssettlement.com [last visited March 12, 2003.]

[13] See e.g., Henri Cauvin, "Between Famine and Politics, Zambians Starve," New York Times, August 30, 2002, p. A6; Henri Cauvin, "Zambian Leader Defends Ban on Genetically Altered Foods, New York Times, September 4, 2002; p. A5; and Marc Lacey, "Engineering Food for Africans," New York Times, September 8, 2002, p. A

development might affect the nation's status as "GMO free" for purposes of future sales to European countries and other countries concerned about GMOs.

The debate over these issues mushroomed into a significant international incident which helped to illuminate several ethical issues – such as could a nation, Zambia for example, refuse food aid knowing people might die as a result rather than accept GMO crops, which have no known food safety risks for consumers.[14] On closer study the food shortages appear to have subsided, with the exception of Zimbabwe.[15] But the underlying conflict provided rich fodder for American policy makers and biotechnology promoters looking for an argument to throw back at Europeans resisting use of GMOs.[16] Rather than just allege the EU resistance stems from trade preferences or anti-technology elitism, U.S. officials, most notably Trade Representative Zoellick are now able to accuse the Europeans of callous disregard and active culpability in starving poor Africans just to protect their sensitivities over eating GMOs. For example, Mr. Zoellick was quoted saying, "I find it immoral that people are not being able to be supplied food to live in Africa because people have invented dangers about biotechnology."[17] While the Europeans protested they had not pressured African nations and of course do not promote starvation, the moral issue was joined.

2. Consumer Acceptance of GMOs – So Far so Good but What About these Fish

The most significant story relating to the consumption of GMO foods in the U.S. is in many regards the lack of a story – for the most part American consumers don't seem to mind or care. When the FDA in January 2001 rejected for the latest and probably last time, requests to require mandatory labeling of GMO foods much of the remaining steam – what there was of it – went out of this effort.[18] Instead much of the attention of the opponents of GMO shifted to fighting a rear guard action to protect at least the availability of a food supply that is free, as possible, of the presence of GMO. The final approval of the national standard for organic food and the USDA organic label provided

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[14] See e.g., Danna Harman, "Some Africans prefer hunger to biotech corn," Des Moines Register, November 20, 2002, p. A1 and Rehka Basu, "Africans' logical fear of GM corn," Des Moines Register, December 8, 2002, p. Op 3.

[15] See, e.g., Rachel L. Swarns, "Southern Africa Food Shortages Show Signs of Easing Everywhere Except Zimbabwe," New York Times, Jan. 31, 2002, p. A8.

[16] See, e.g., Philip Brasher, "Activists push fear of food, U.S. says," Des Moines Register, August 31, 2002, p. 1A. The situation created great opportunity for sermonizing by US proponents of biotechnology on the theme of how could a country choose to let its citizens starve rather than accept this wonderful gift from the West. See, e.g. Tim Burrack. "Safe, GM food can save starving Africans," Des Moines Register, November 8, 2002, p. 13A.

[17] See, Elizabeth Becker, "U.S. Threatens to Act Against Europeans over Modified Food," New York Times, Jan. 10, 2003, p. A11.

[18] 66 Fed. Reg. 4706, January 18, 2001. For a general discussion of U.S. regulation of GM foods, see, Judith Beach, No "Killer Tomatoes": Easing Federal Regulation of Genetically Engineered Plants, 53 *Food and Drug Law Journal* 181 (1998).

the focus for efforts to develop and expand this 'alternative" food stream – which because the rules do not allow the use of biotechnology for organics provide an outlet for consumers seeking these foods.[19] From the perspective of American law, the FDA action rejecting labels for GMO foods flows from the agency's view of the purpose of food labels – and the legal conclusion this information is not material and labels not containing it are not misleading.[20]

The most contentious episode in the U.S. over GMO labels was a ballot initiative in Oregon, where a coalition of consumer advocates and environmentalists were placed on the fall 2002 ballot a proposal to mandate labeling for GMO foods sold in Oregon.[21] The food and biotech industry waged a multi-million dollar campaign to defeat the initiative and the U.S. government even took the unprecedented step of warning the state it believed such a law would interfere with the operation of the national food system. The combination of ads, warnings, confusion and other uncertainty no doubt helped contribute to the overwhelming defeat for the proposal.[22] Assuming the law had passed food manufacturers would have challenged it on first amendment grounds as well as claims of federal preemption. The challenge would have been similar to the successful fight waged by the food industry to defeat Vermont's 1994 attempt to require labeling of

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[19] See e.g., Elizabeth Becker, "Organic gets an additive: A U.S.D.A Seal to Certify It," New York Times, October 21, 2002, p. A10, and Editorial, "A New Organic Era," New York Times, October 21, 2002, p. A22. Unfortunately in recent weeks the integrity of the new national organic program has been placed in jeopardy because of the inclusion in the 2003 Omnibus spending bill of a rider, inserted at the request of Georgia congressman Deal, that would allow meat to be labeled as organic even if the animals were not fed organic feed, when the price of organic feed is more than double the price of conventional feed. The inclusion of this loophole has triggered a new wave of concern and support for protecting the organic food label and could produce a backlash that will re-ignite concerns about he presence of GMOs in the food supply. See, e.g. Editorial, "Staying organic," New York Times, March 5, 2003, p. A26.

[20] For a detailed analysis and criticism of the U.S. approach toward the regulation and labeling of GMO foods, see the report prepared for the Food Policy Institute by Professors Thomas McGarity and Patricia Hansen, "Breeding Distrust: An Assessment and Recommendations for Improving the Regulation of Plant Derived Genetically Modified Foods," issued on January 11, 2001 by the Consumer Federation of America. The report is available at the website: http://www.consumerfed.org/ [last visited March 12, 2003.]

[21] For a discussion of the contents of the proposed Oregon law and its potential impact on the food industry, see Patricia Callahan, "Oregon May Require Labels on Genetic Food," Wall St. Journal, Sept. 30, 2002, p. B1 and U.S.A. Today, Oct. 9, 2002, concerning a letter from the acting commissioner of the FDA to the Governor of Oregon. Information about the Oregon proposal can be found at the web site of the group Oregon Concerned Citizens for Safe Food, www.labelgefoods.org

[22] See, e.g., Philip Brasher, "Oregon voters reject food-labeling measure," Des Moines Register, November 8, 2002, p. D1.

milk produced with bovine growth hormone.[23] In that case the federal appeals court ruled the first amendment prohibited the state from compelling this type of commercial speech from dairies that didn't want to provide it. The court observed that consumers concerned about health issues could purchase BST free milk from producers who voluntarily labeled their products as not containing the additive.[24]

But the assumption that producers who choose to employ alternative production techniques are free to communicate this fact on food labels is not so clear. The best illustration is the obstacles farmers and consumers face relating to voluntary efforts to label foods as being produced without GMO ingredients. A food marketer's ability to label a food product in this manner is subject to the FDA's "voluntary guidance" relating to such labels. While the guidance appears to provide the basis for making such claims, the actual provisions make it next to impossible for food marketers to do so, short of complying with existing standards for organic food labeling, a separate, more costly and cumbersome system.[25] While the details of that guidance are beyond this paper, suffice it to say the FDA has ruled it is misleading to use the terms "GM or GMO free" in such labels and has placed the burden of proof on those who dare to label their foods as being free of the products of bioengineering. This includes a warning a "statement that a food was not bioengineered or does not contain bioengineered ingredients may be misleading if it implies that the labeled food is superior to foods that are not so labeled." [26]

The effect of the guidance and the goal of the food industry officials who requested it is not to promote voluntary labeling of GMO products, a label that while allowed is not found in the marketplace; instead, the purpose is to prevent the development of a GMO-free food sector.[27] By forcing those who want to market or purchase GMO-free foods to buy certified organic food, the food industry has been able to prevent the proliferation of foods marketed as GMO free and limit development of consumer awareness or curiosity about the presence of GMO ingredients. This approach to labeling in the U.S. demonstrates the contrast to a true "consumer right to know" approach such as used in Europe. [28] One legal uncertainty that may threaten the success

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[23] International Dairy Foods Association v. Amestoy, 92 F. 3d 67 (2nd Cir. 1996).
[24] Id at 74, where the court said, "Absent, however, some indication that this information bears on a reasonable concern for human health or safety or some other sufficiently substantial governmental concern, the manufacturers cannot be compelled to disclose it. Instead, those consumers interested in such information should exercise the power of the their purses by buying products from manufacturers who voluntarily reveal it."
[25] See, FDA Draft Guidance for Industry, "Voluntary Labeling Indicating Whether Foods Have or Have Not Been Developing Using Bioengineering," January 21, 2001, available at http://www.cfsan.fda.gov/~dms/biolabgu.html (last visited March 4, 2003.)
[26] Id. at p. 3.
[27] For the development of the guidance, see, "Food Industry Groups Petition FDA for Guides on Biotechnology-Free Claims," Food Safety Report, May 10, 2000, p. 586.
[28] For an discussion of the legal rational behind this view, which rejects the notion there is a "consumer right to know" under American food law, see Frederick Degnan, The Food Label and the Right-to-Know, 52 *Food and Drug Law Journal* 51 (1997).

of this effort is the irony that food industry initiatives to use First Amendment claims to free food marketers from the restraints of FDA regulations, claims which have found support in the federal courts, may place in doubt the government's ability to prohibit food marketers from making truthful and non-misleading claims about the lack of GMO ingredients – but that battle is yet to be fought.[29]

Before turning from the food safety and consumer acceptance issue it is important to note that at least one category of foods continue to raise legitimate consumer and even scientific concerns – namely meat and fish.[30] While most of the debate about use of GM technology has related to crops, there are policy issues relating to the adequacy of the federal rules relating to animals, in particular the possible sale of genetically engineered salmon.[31] In August 2002 a panel of the National Research Council issued a report recommending the FDA examine the use of gene-altered animals for food production.[32] The recent incident where the University of Illinois allegedly sold pigs possibly genetically engineered, an illegal act under the FDA experimental guidelines, brought the issue of GM meat and the integrity of FDA regulation of GM experimentation back into public attention.[33] In addition to the lingering concerns about the wisdom of using GM technology in meat animals, there was at least one reported incident that raised concerns about the possible food safety – or at least animal safety of GM technology. In the

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[29] See for example the recent Court of Appeals ruling in Pearson v. Shalala, 164 F.3d 650 (D.C. Cir. 1999) concerning the First Amendment limitations on the ability of FDA to regulate health claims in the marketing of dietary supplements (favoring disclaimers over prohibitions) and the U.S. Supreme Court's ruling in Thompson v. Western States Medical Center, 122 S. Ct. 1497 (2002) limiting the ability of Congress to block advertising about drug compounding. This expanded view of the First Amendment protections for commercial speech has led the FDA to initiate a process to re-evaluate the scientific standards used to approve health claims for foods. See 67 Fed. Reg. 34942, May 16, 2002; Gina Kolata, "Stung by Courts, F.D.A. Rethinks Its Rules," New York Times, October 15, 2002, p. D1; and "FDA Moves Ahead on Qualified Health Claims with Creation of Task Force," 5 Food Regulation Report 32, p. 3, Jan 22, 2003.

[30] See, e.g. Jennifer L. Brown, "Ranchers await FDA decision on cloned bulls' beef," Des Moines Register, January 18, 2003, p. D1, and Andrew Pollack, "Coned Cows Are Engineered For Quicker Cheese Making," New York Times, January 27, 2003, p. A20.

[31] See, "Concerns Raised Over Altered Fish," New York Times, January 15, 2003, p. A17, concerning a report by the Pew Initiative on Food and Biotechnology which questions the adequacy of the FDA regulations for assessing the risks related to the production of genetically modified salmon. The report "Future Fish: Issues in Science and Regulation of Transgenic Fish" is available at their web site: http://pewagbiotech.org [last visited March 13, 2003.]

[32] See Warren E. Leary, "Panel Urges Caution in Producing Gene-Altered Animals," New York Times, August 21, 2002. See also, "Ranking Risk of Gene-Altered Animals, New York Times Editorial, September 4, 2002, p. A30

[33] See Andrew Pollack, "F.D.A. Says food Supply May Contain Altered Pigs," New York Times, February 6, 2003, p. A22, and Elizabeth Weise, "Research piglets sold as food hard to find," USA Today, Feb. 7, 2003, p. 3A.

summer of 2002 an interesting story emerged out of Iowa concerning the possible relation between fertility problems in swine and feeding certain strains of Bt corn.[34] Opponents looking for the smoking gun of health problems from using GMO crops hoped the story would prove to be a major controversy.[35] For scientists the controversy raised several difficult and perhaps unanswerable questions, although the official response were the problems were caused by the farmers not the crops.[36]

3. StarLink – Biotech's Self-inflected Black Eye Illustrates Limits of Regulatory Structures

The incident that in the last two years most clearly illustrated the legal and policy dimensions of the biotechnology age was the StarLink affair. What begin as a minor incident of some GM corn appearing in taco shells blossomed into a major episode that brought into focus a range of significant issues, including, among others:

- the research and marketing decisions of biotech companies;
- the adequacy of the U.S. regulatory system for marketing GMO products;
- the cavalier attitudes some seed companies and farmers have toward use of GMOs;
- the ability of the legal system to develop and apply rules for allocating liability in cases of unintentional product contamination;
- the difficulty of developing marketing systems to segregate products not approved for use throughout America's food system;
- the role the government should play in protecting the integrity of the grain supply;

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[34] See, e.g. Tom Block, "Pseudopregnancies puzzle swine producer," and "More Iowa sow herds experiencing breeding problems," Iowa Farm Bureau Spokesman, May 18, 2002, p. 1; John Otte, "Swine pseudopregnancy mystery," Hog Producer, June 2002, p. H1. For the biotech industry the issue was a concern – but for conspiracy theorists who believe GMO foods are a serious health threat the story was heaven sent. Even in light of what appears to be growing acceptance of the safety of GMO foods some organizations continue to point out that questions remain. See e.g., Justin Gillis, "FDA Policies for Gene-Altered Foods Faulted in Report," Washington Post, Jan. 7, 2003, p. A5, discussing the recent report by the Center for Science in the Public Interest concerning gaps in the regulatory system relating to biotechnology. The report, "Holes in the Biotech Safety new: FDA Policy does Not Assure the Safety of Genetically Engineered Foods," by Dr. Doug Gurian-Sherman, is available at the website www.cspinet.org

[35] For example, Friends of the Earth, which had been responsible for exposing the StarLink contamination of corn products took a special interest in this controversy and the disposition of a supply of corn from an Iowa farm. See the website at: http://www.foe.org/camps/comm/safefood/gefood/iowa/index.html [last visited March 13, 2003.]

[36] See, "Researchers dispute claims against corn," Des Moines Register, October 11, 2002, p. 2A.

- the inherent tension between the interests of the food industry and the interests of the biotech community over the use and proliferation of products which raise regulatory and consumer acceptance risks; and
- the impact of such products on export markets for American crops.

The list of issues triggered by the StarLink affair, while not exclusive, shows how this area of American law and policy is still in a period of development. The legacy of the Starlink affair can be seen in the court rulings and litigation allocating the costs and damages from the incident, proposals for state legislation to address GMO contamination, and new regulatory proposals to restrict use of similar technologies.[37]

When boiled down to its essence the StarLink affair resulted from the combination of a foolish (and in retrospect incredibly costly) decision by Aventis to bring to the market a corn product not approved for both food and feed uses, and the unreasonable decision of the EPA to allow such split registration. These two actions were especially unfortunate in light of the inability of the grain market to provide for the segregation of the crops, and the apparently unwillingness of some of the companies marketing the technology to communicate and enforce the limitations on its use to the farmers they sold seed. Given this background it was entirely predictable that Starlink corn would find its way into the food supply, as it did. When the history of the StarLink affair is written it will reveal many lessons. One important lesson to note is that if it had not been for the brave actions of the lawyers in the Iowa attorney general's farm division who stepped in to prevent the seed companies' initial attempts to unreasonably allocate the costs and liability to the "offending" farmers, many of whom had never seen the restrictive terms of the product approval, the whole episode may have evolved quite differently. These and other lessons should make the StarLink a powerful and highly instructive educational moment for all concerned. Whether we will be wise enough to be so educated is yet to be seen.[38]

A key lesson of Starlink is whether we will take additional steps to insure that crops not approved for use in certain markets will in fact be keep from them. The current approach relied on by biotech companies is to place most of this responsibility on the producers. This is done by placing language in the technology transfer agreement to make producers responsible for this post harvest "channeling." For example, the provision used in the Grower's Copy of the "2002 Monsanto Technology/Stewardship Agreement" (probably the most widely used agricultural contract in the history of the U.S.) provides, in part:

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[37] For an article discussing many of the possible legal theories available to resolve the type of pollen drift related damages issue which can arise in a situation like the StarLink affair, see Amelia p. Nelson, Note, Legal Liability in the Wake of StarLink: Who Pays in the End?, 7 *Drake Journal of Agricultural Law* 241 (2002).

[38] See e.g, Thomas Redick and John Walsh, "Managing agricultural risks after StarLink: the role of injunctions and contracts in containing biotech crop risks," Agricultural Law Update, June 2002, p. 4.

> Channeling: Grain/commodities harvested from Roundup Ready corn, YieldGard Corn borer with Roundup Ready corn, Roundup ready canola and Roundup Ready sugar beets are approved for U.S. food and feed use, but not yet approved in certain export markets where approval is not certain to be received before the end of 2002. As a result, the grower is required to direct such grain/commodities to the following approved market options: feeding on farm, use in domestic feed lots, elevators that agree to accept the grain, or other approved uses in domestic markets only.[39]

In the "you agree" portion of the contract, the grower agrees "to channel grain produced to domestic use as necessary to prevent movement to markets where the grain has not yet received regulatory approval for import."[40]

4. Pharming – New Crops Present Practical Challenges to Protecting the Food Supply and Promise New Round of Legal Issues

No doubt the biggest story in the last year in agricultural biotechnology circles has been the attention given to the idea of pharming – the production of genetically modified crops engineered to express some form of a pharmaceutically useful product. This "new" form of biotechnology has received considerable attention in the farm press and has generated perhaps an unrealistic set of economic expectations by Midwestern farmers and politicians.[41] From a legal standpoint the development of pharming raises a whole new set of legal and policy issues, primarily because of the legitimate concerns about the food safety risks related to using food crops to produce drugs and the liability issues this will entail. Because of the nature of the risks, pharming has helped illuminate some of the fault lines that exist in the larger food system, perhaps as best illustrated by the tensions between food manufacturers – who remember well the costs and public relations impact of the StarLink in taco shells debacle – and the farming and biotech communities, both of which appear to have never met a technology they don't think should be widely available and utilized.[42] While the food sector has to date been

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[39] See "2002 Monsanto Technology/Stewardship Agreement" Grower's copy, Limited Use License, page 1.

[40] Id.

[41] The hoped for economic returns to farmers from pharma-crops may run aground on three shoals of industrialized agriculture: the number of acres actually needed for their production may be limited; the increased prices paid to farmers may be minimal since they did not contribute to the invention of the technology but instead are only providing land and services; and the additional costs and risks associated with raising the crops and meeting the regulatory requirements for production will reduce the benefits. The reality is there is little reason to expect pharma-crops to provide returns any larger than conventional crops.

[42] For example, a General Mills executive speaking on a biotech panel in Chicago, warned that food manufacturers receive no benefit from the current technology, noting, "[C]andidly, we have told the biotech industry that we are in a perilous situation until

supportive of the development and use of agricultural biotechnology, perhaps due to its own doctrinal resistance to government regulation, the pharma-crop situation has led to the somewhat remarkable development of the national food processors organization proposing a moratorium on use of the technology until such time as the possible risks of contamination of the food supply can be addressed.[43] This came after the only slightly less surprising offer by biotechnology industry to voluntarily limit the use of the technology in large pars of the country.

The public debate over the production of pharma-crops and the adequacy of their regulations began in the summer of 2002 when a collation of environmental groups, GE Food Alert, began to raise concerns about the safety of the technology and the adequacy of USDA's effort to police the field experiments underway.[44] After these concerns became public reports began to emerge of possible government actions against companies which had raised the crops under experimental field permits. The issue revolved around whether the companies had followed agency guidelines designed to insure that no pollen from the crops was allowed to drift to neighboring fields and that precautions were taken to see that volunteer crops did not emerge the next year. [45]

While these rumblings were being heard in farm country, the biotech industry stunned its supporters in the Midwest, especially in Iowa by launching what amounted to a pre-emptive strike to get ahead of public concerns about possible contamination of the food supply with drugs. In late October, the Biotechnology Industry Organization (BIO) members announced a voluntary agreement to redline much of the midwestern corn belt and not plant pharma corn in these areas to avoid possible contamination within the food supply.[46] The surprise announcement caused difficulty for Governor Vilsack in his Iowa re-election campaign and illustrated the split between the food manufacturers and the biotech industry.[47] The sudden action by the biotechnology industry led to editorials and

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consumer benefits arrive." See, Ameet Sachdev, "Biotech 'perilous' for food industry," Des Moines Register, June 20, 2002, p. 1A.

[43] See Anne Fitzgerald, "Coalition urges more attention to food safety," Des Moines Register, Feb. 8, 2003, p. D1, concerning the coalition led by the Grocery Manufacturers of America and their petition to FDA for stringent regulation of pharma-crops, using the same approach as with brick and mortar drug manufacturing facilities. Their proposal included requests the FDA prohibit use of corn and other food crops for production of plant based drugs and a request the USDA stop issuing field trial permits for the crops.

[44] See, e.g., Anne Fitzgerald, "Critics: Altered crops pose risk to health," Des Moines Register, July 12, 2002, p. A1.

[45] See, e.g., Anne Fitzgerald, "Pioneer fined for violating biotech corn permits," Des Moines Register, December 13, 2002, p. D1, concerning fines the EPA assessed to Pioneer and Dow AgroSciences for violation of requirements on growing experimental corps.

[46] See, e.g., Philip Brasher, "Debate grows from biotech ban," Des Moines Register, October 25, 2002, p. 1D.

[47] See, e.g. Philip Brasher, "Iowa denied new 'drug' corn," Des Moines Register, October 23, 2002, p. 1A

a public relations campaign to get the policy reversed.[48] The industry action brought into question the future of biotech plantings and research at places like Iowa State, which had made considerable investments in its Plant Science Institute.[49] The industry eventually agreed to lift the moratorium and instead to comply with the federal governments new enhanced rules.[50] But the adequacy of the federal rules on pharma-crops had come into focus in what would come to be known as the ProdiGene incident

In late 2002 the enforcement of the federal rules on the planting biotech crops was brought into focus in the pharming case involving the Texas company ProdiGene. Facts indicate the company had failed to adequately enforce its field cleanup requirements on two sites in Nebraska and Iowa, leading the government to assess a $3 million fine against the company, part of which was to cover the cost of the 500,000 bushels of contaminated grain the government had to purchase and incinerate.[51] The dispute, following on the heels of the BIO "redlining" proposal brought extra focus to the adequacy of the federal regulatory structure.[52] As a result of the ProdiGene incident, the FDA took a renewed interest in the adequacy of its rules and in mid-November announced plans to increase the monitoring of the companies involved in pharming research.[53]

5. Intellectual Property Rights and Agriculturally Important Genetic Material – Supreme Court Clears Last Doubt

When I wrote the article in 2000 one cloud on the horizon of the application of intellectual property protections to plant genetic material was an Iowa case involving a fight between Pioneer Hi-Bred International and an agricultural retailer over infringement of Pioneers' patent rights in its corn varieties. The case raised the issue of whether the language of the Plant Variety Protection Act (PVPA) preempted the ability of the Patent Office to grant patent protection for plant varieties such as the corn in dispute. The

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[48] See, e.g. "Lift the moratorium" Des Moines Register, November 25, 2002, p. 14A
[49] See Philip Brasher, "ISU Vows biotech research will go on," Des Moines Register, October 25, 2002, p. 1A.
[50] See, e.g., Philip Brasher, "Biotech group lifts corn ban," Des Moines Register, December 4, 2002, p. 1A, and "Bring on "biopharming," Des Moines Register Editorial, December 5, 2002, p. 12A
[51] See, Andrew Pollack, "U.S. Investigating Biotech Contamination Case," New York Times, November 13, 2002, p. C6, and Philip Brasher, "Biotech corn may have tainted soybeans," Des Moines Register, November 13, 2002, p. 1A.
[52] See, e.g. Andrew Pollack, "Spread of Gene-Altered Pharmaceutical Corn Spurs $3 Million Fine," New York Times, December 7, 2002, p. A15; Philip Brasher, "ProdiGene must pay $3 million in corn case," Des Moines Register, December 7, 2002, p. 1A; and Justin Gillis, "Tiny shoots lead to big biotech headache," Des Moines Register, December 29, 2002, p. M1.
[53] See Philip Brasher, "FDA to tighten biotech crop inspection," Des Moines Register, November 20, 2002, p. 1A and a related editorial, "Set tough rules for biofarms," Des Moines Register, November 14, 2002, p. 18A.

litigation had run a predictable course at the district court and appeals courts with the courts upholding the patents and ruling the PVPA did not prevent their issuance.[54] The courts had held there was no conflict and patents on varieties were legal. But the cloud was the U.S. Supreme Court's surprising and to many, unexplainable, decision to take certiorari in the case and hear further arguments. To make a long story short, the Court heard the case, considered the issues, and in a 6-2 decision reaffirmed what the seed and biotech community had believed all along, the PVPA does not preempt granting patents on plant varieties.[55] The case is significant because it shows the Court is not going to revisit the larger issue of the wisdom or legality of granting patents on living materials. While other policy issues of trade, pollen drift and regulatory enforcement continue to engage the public, the inside baseball aspect of biotechnology continues with IPR fights between the major players over ownership and control of significant parts of the technology.[56]

From a farmer's perspective the most immediate intellectual property rights issue is the impact of the technology transfer agreements and product labeling on the ability to save and replant biotech crops. The bottom line is that biotech crops are only marketed under arrangements that comprehensively prevent this opportunity, i.e. do not allow leakage of the technology. The legality of these agreements has been most well debated in connection with the Roundup Ready technology agreement but there is little doubt about their enforceability. In the last year some of the first court rulings illuminating the issue have been decided.[57] The bottom line is the cases present few surprises and hold the language of the planting restrictions enforceable.[58] The court case involving seed patent infringement and possible pollen drift that has received the greatest attention in the international press has been the fight between Canadian farmer Percy Schmeiser and

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[54] See 49 USPQ 2d 1813 (N.D. Iowa 19998) and 200 F. 3d 1374 (App. Ct. Fed. Cir. 2002).

[55] J.E.M. Ag Supply v. Pioneer Hi-Bred International, Inc., 534 U.S. 124 (2001), and see Anne Hazlett, "Supreme Court holds utility patents may be issued for plants," Agricultural Law Update, 19:2, Jan. 2002; Baird, Kevin M. Recent development. Patent protection of plants grows under the Supreme Court's latest decision. (J.E.M. AG Supply, Inc. v. Pioneer Hi-Bred International, Inc., 122 S. Ct. 593, 2001.) 2002 *U. Ill. J.L. Tech. & Policy* 269-280 (2002); and see Mark D. Janis and Jay P. Kesan, Intellectual property protections for plant innovation: Unresolved issues after J.E.M. v. Pioneer, 20 *Nature Biotechnology* 1161, November 2002.

[56] See e.g., Andrew Pollack, "Dispute Ends for Monsanto and DuPont," New York Times, April 3, 2002, and David Elbert, "Pioneer sues rival over patent," Des Moines Register, October 18, 2002, p. 1D

[57] See e.g., Monsanto Co. v. McFarling, 302 F.3d 1291 (Fed. Cir. 2002).

[58] See e.g., David Moeller, "Monsanto Gets Injunction Against Seed-Saving Farmer," Farmers Legal Action Group (FLAG) newsletter, Fall 2002, Vol. 17, Issue 4, p. 9 and Donald Uchtmann, "Can farmers save Roundup Ready beans for Seed? McFarling and Trantham cases say "no", Agricultural Law Update, October 2002, p. 4.

Monsanto of Canada concerning his alleged infringement on Roundup ready canola.[59] The Canadian district court ruled he had infringed Monsanto's rights, rejecting his theory the canola came onto this property through drift or other unintentional sources.[60] The decision was upheld in September 2002 by the Canadian appeals court although the case may still go up for further appeal.[61]

6. State Initiatives to Allocate Responsibility and Liability for Pollen Drift – Who Pays for "Adventitious" Presence

In my 2000 article, I commented that "[G]enetic pollution or "pollen drift' is perhaps the most intellectually interesting legal issue relating to biotechnology."[62] I still believe this is true although the development of the legal precedent addressing these issues has been limited.[63] The StarLink litigation and settlement is perhaps the most significant developments because it establishes responsibility for the damages resulting from use of the technology. However because the case involved a violation of the regulatory approval of the product it may not serve as controlling precedent in the more difficult case where the lawful use of an approved product still results in measurable commercial damages to a non-compatible crop. As a result, court room battles to resolve the predictable conflicts over pollen drift from the production of GMO crops and potential liability for contaminating neighboring non GMO crops, such as organic, still loom on the legal horizon.[64]

State attempts to regulate the actual planting and use of biotech crops is another legal front on which several developments have occurred. For example in March 2001 the North Dakota legislature considered but rejected a proposal prohibiting planting GMO wheat for two years.[65] In 2002 the Indiana legislature passed legislation designed to inject state law into the questions of liability and responsibility for use of biotech crops.[66] A new legislative approach to addressing pollen drift damages, creating a "Grain Integrity Indemnity Fund" was introduced in the 2003 Iowa General Assembly.[67] This idea, based on the state's grain indemnity fund which protects farmers who store or

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[59] Information about this dispute can be found at website: http://www.percyschmeiser.com [last visited March 13, 2003.]
[60] See Monsanto Canada Inc. v. Schmeiser, 2001 FCT 256, 202 F.T.R 78
[61] See Schmeiser v. Monsanto Canada, inc., 2002 FCA 309
[62] Hamilton, supra note 1 at p. 103.
[63] For an excellent discussion of many of the dimensions of this issue, as influenced by the StarLink affair, see Thomas P. Redick and Christina G. Bernstein, Nuisance Law and Prevention of "Genetic Pollution": Declining a Dinner Date with Damocles, 30 *ELR* 10328, May 2000.
[64] See, e.g., Anne Fitzgerald, "Specialty pollen concern blowin' in wind," Des Moines Register, March 7, 2002, p. 1D.
[65] See, Andrew Pollack, "Proposal to Bar Altered Wheat Seems Doomed," New York Times, March 31, 2001, p. A9.
[66] See House Enrolled Act, No. 1119, Second Regular Session 112th General Assembly.
[67] House File 108 by Rayhons, Lukan and Dolecheck, 2003 Iowa General Assembly.

sell grain from financial losses, would assess a small fee or excise tax on each bushel of grain sold in the states to fund a $25 million indemnity fund to sued to cover validated claims of damages from pollen contamination. While the idea can be criticized for failing to allocate the financial liability to either the developers of the technology or the actual users, the approach has the major benefit of providing a accessible pool of funds for compensating injured growers. Instead of requiring each dispute to become a courtroom battle over proof of causation and measuring damages, assuming the court can identify a theory of liability, the indemnity fund approach would give farmers what they need most, a way to be covered for their damages.

7. International Trade Restraints on Marketing GMO Crops – When Will We Be Heard?

The most contentious area of the biotechnology debate continues to be the relation of the U.S. with the E.U. and the issue of E.U. regulations on the importation and labeling of U.S. raised GM crops. While the E.U. has made progress on developing its new standards perhaps the best way to describe the situation, at least in the winter of 2003, was continuing tensions moving inexorably to a WTO trade war.[68] The only problem from the U.S. perspective is that another more important war moved onto center stage making it politically and diplomatically difficult to bash the Europeans over GMO policy while at the same time trying to motivate them to support our efforts to wage war on Iraq.[69] As a result, the drumbeat for a trade war with the E.U. over GMO policy, which many see as a much needed test of the resolve and efficacy of WTO rules and process and the defense of sound science, has for the time being had to take a back seat to more pressing geopolitical concerns.[70] Even among those nations embracing biotechnology there exist issues relating to both free trade in the technology and efforts to protect domestic economic opportunities. The situation in China is perhaps the best example of this schizophrenic situation, with the nation embracing use of biotechnology but using an uncertain regulatory environment to chill the ability of Western companies to export crops to the country.[71] While Chinese regulations on biotechnology continue to evolve and raise concerns for U.S. exports, some American companies have been able to develop plans for moving forward with China.[72]

8. Resistance and GMOs – Refuges, RoundUp and Resistant Weeds

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[68] See e.g,, Philip Brasher, "Fear threatens U.S. crop sales in Europe," Des Moines Register, November 11, 2002, p. 1A.
[69] See Elizabeth Becker, "U.S. Delays Suing Europe Over Ban on Modified Food," New York Times, Feb. 5, 2003.
[70] See Philip Brasher, "Biotech ban Tries patience of U.S." Des Moines Register, March 4, 2003, p. 1D.
[71] See, Joseph Kahn, "The Science and Politics of Super Rice," New York Times, October 22, 2002, p. C1.
[72] See e.g. Anne Fitzgerald, "Joint-venture to produce, sell seed corn to Chinese farmers," Des Moines Register, Dec. 12, 2002, p. 1D, concerning a recent agreement between Pioneer Hi-bred International and a major Chinese seed corn company.

From a technological standpoint one significant issue related to the widespread adoption of GMO technology is how its use will eventually lead to the development of resistance in whatever the target pest. From a regulatory perspective this concern is most directly an issue in the regulation of bio-pesticides such as Bt corn. The regulatory focus is on the need for farmers to follow resistance management plans which include planting non-Bt refuges. The counter-intuitive nature of requiring farmers to not use an effective technology and the unwelcome task of actually enforcing regulations relating to refuges have helped complicate this topic. The EPA in late November 2002, announced a "two-strikes" policy concerning farmer compliance with the field refuge requirements for planting Bt corn, with role for companies in the enforcement.[73] The issue of resistance management took another turn early in 2003 when new research was reported indicating the increased appearance of weeds resistant to the use of Roundup.[74] The significance of the story was illustrated when the issue became the subject of a somewhat surprising editorial "Too much Roundup."[75]

III. Conclusion: The Future of Law and Biotechnology

The paper has tried to present a concise update of many of the significant legal and policy issues shaping American law as relates to agricultural biotechnology. Some issues such as the international bio-safety protocol and the recent completed international agreements on plant genetic resources were beyond the scope of the discussion. Other areas of ongoing litigation, such as the StarLink settlement could be the basis for their own lengthy treatment. What is clear from the discussion is that a series of significant legal and policy questions will continue to shape how agricultural biotechnology will be accepted in America. As the article makes clear on the issue of food safety and consumer acceptance, unless some new incident happens to raise evidence of safety concerns, the market place will continue to welcome GMO foods. In the near term one of the most significant issues is whether the genetically altered salmon will be marketed and if so, what type of environmental restrictions will be placed on its production. From the perspective of farmers and state legislators the future of pharma-crops will offer promise and problems. It will be interesting to see whether the market reality for the crops can match the expectations they appear to be generating. On the international front the tension between the U.S. and E.U over GMOs will remain as a source of conflict, which may or may not be addressed when the E.U. approves its long promised policy on the production of GMO crops. Biotechnology is a powerful and elegant technology that will undoubtedly play a role in the future of world agriculture. The complex social issues relating to biotechnology will test the ability of the legal system to develop rules and mechanisms to guide its use.

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[73] See Philip Brasher, "Rules govern biotech planting," Des Moines Register, Nov. 27, 2002, p. D1.

[74] Philip Brasher, "Round-up resistance weeds are cropping up all over," Des Moines Register, Jan. 10, 2003, p. A1.

[75] Editorial "Too much Roundup," International Herald Tribune, Feb. 20, 2003, p. 8.