The Three Mile Island of Biotech?

by John Nichols

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The Nation

Hamilton County, Nebraska, is where food comes from. You can visit the Plainsman Museum on Highway 14 to learn about "farm life from the 1880s to the 1950s," or you can just drive on up the highway and learn about farm life in 2002 at any of the dozens of family farms that still grow corn and soybeans on fields that some families have worked since their ancestors homesteaded here just after the Civil War. For more than a century, farmers in this fertile stretch of a state where folks still refer to themselves as "cornhuskers" have planted food crops each spring and trucked the harvest in the fall to towering grain elevators on the edge of the bustling Great Plains town of Aurora. Those grains become the cereals, the breads, the cake mixes and the soy patties that feed America and the world.

This fall, however, the predictable patterns of Hamilton County and American food production took on the characteristics of a dystopian science-fiction story. An area farmer, who a year earlier had supplemented his income by quietly planting a test plot with seed corn genetically modified to produce proteins containing powerful drugs for treatment of diarrhea in pigs, this year harvested soybeans for human consumption from the same field. He trucked them off to the Aurora Co-op, where they were mixed with soybeans from other fields throughout the county in preparation for production as food. Just as the soybeans were about to begin their journey to the nation’s dinner plates, a routine inspection of the test field by US Department of Agriculture inspectors revealed that corn plants that should have been completely removed were still growing in the field from which the soybeans had been harvested--raising the prospect that the pharmaceutical crop had mingled with the food crop.

Suddenly, as they say in Aurora, all kinds of hell broke loose. In November, USDA investigators swooped into town to order the lockdown of a warehouse filled with 500,000 bushels of food-grade soybeans that had been contaminated by contact with the beans containing remnants of the pharmaceutical corn. Aurora Co-op managers quietly secured the soybeans. But when word of the incident leaked out, Greenpeace campaigners climbed a tall white elevator to unfurl a banner that read: "This Is Your Food on Drugs!" Agitated officials of the Grocery Manufacturers of America expressed "concerns about the possible adulteration of the US food supply." Consumer groups made unfavorable comparisons between the incident in Hamilton County and the last great genetically engineered food debacle, which occurred two years ago when GE StarLink corn that had been approved solely for animal feed turned up in taco shells, chips and other food products.

Biotech industry groups and the government agencies with which they have worked closely to promote the increased use of genetically modified organisms in food crops rushed to assure consumers that all was well. Anthony Laos, CEO of ProdiGene, the Texas biotech company that has made Aurora ground zero for experiments in putting drugs into food, and that faced a possible $500,000 fine and the loss of its testing permit, promised to cover the $2.8 million cost of the contaminated crops. Jim Rogers, a spokesman for USDA’s Animal

and Plant Health Inspection Service--which has been criticized for lax oversight of pharmaceutical crop experiments, commonly known as "biopharming"--said, "It's isolated, it's in one location, it's not being moved." That same week it was revealed that ProdiGene had been ordered, just two months earlier, to burn 155 acres of corn from an Iowa field where stray biotech plants had "jumped the fence" and contaminated conventional corn crops.

But there is no two-strikes-and-you're-out rule at the USDA. ProdiGene got off with a $250,000 fine and a promise to follow regulations better. The company kept its permit to plant experimental crops, and biotech promoters continue to push for policies that could allow as much as 10 percent of US corn production to be devoted to pharmaceutical crops by 2010. "The future of biopharmaceuticals has simply never been brighter," said Laos. Farm and food activists worry that the events of fall 2002 will be little more than a bump in the road to the brave new world of biopharming.

"This is the Three Mile Island of biotech," says Mark Ritchie, president of the Institute for Agriculture and Trade Policy, comparing this fall's incidents to the near-meltdown of the Pennsylvania nuclear power plant, which led to a dramatic shift in public attitudes about expansion of that industry. "The biotech industry says that because some soybeans were quarantined at the last minute, no one should worry. Well, at Three Mile Island, they contained things. But that didn't mean it wasn't a crisis, and it certainly didn't mean that people should have said, 'Oh, everything's fine now. Let's just let these guys get back to business as usual.'"

Richie says it's crucial to seize the moment--this is possibly the last chance to prevent the disasters that are all but certain to occur if biotech corporations are allowed to continue on their current course. "This is not the point to back off; this is the point to move very aggressively to get a handle on what is happening, and to control it," he says. "We're at the earliest stage of the attempt to genetically engineer corn plants to make them factories for producing powerful and potentially dangerous drugs, and already we have examples of contamination of food crops. This is scary stuff." [See Mark Schapiro, "Sowing Disaster?" October 28.]

How scary? Britain's Royal Society has expressed concerns about allergic reactions that could result from ingesting, inhaling or even touching biotech crops, while a new study by GE Food Alert, a coalition of health, consumer and environmental groups, details scientists' concerns about the prospect that eating crops containing biopharmaceuticals could weaken the immune system.

No one, not even the top scientists with the USDA, the Food and Drug Administration or the Environmental Protection Agency, can say with absolute certainty that the Iowa and Nebraska incidents are the only cases in which experimental pharmaceutical crops have jumped the fence from test plots and mixed with food crops. An expert committee of the National Academy of Sciences this year came to the conclusion that just as residue from more traditional GE cornfields has contaminated neighboring organic fields, so "it is possible that crops transformed to produce pharmaceutical or other industrial compounds might mate with plantations grown for human consumption, with the unanticipated result of novel chemicals in the human food supply."

The potential public health threat creates another threat -- the health of American agriculture.

Says Iowa State University agriculture professor Neil Harl, "If consumers take on the belief that corn products are being contaminated with products designed for vastly different uses -- like HIV vaccines or hepatitis B vaccines or any of a variety of other things that are being discussed -- and if they think this contamination poses a threat to them, that's going to create the risk of a negative reaction to corn grown in the United States. And consumers are kings. If consumers start to have doubts about US corn, farm-state economies are going to be in very serious trouble."

That prospect frightens Keith Dittrich, a corn farmer from north of Aurora who has shied away from offers to plant biopharm test plots. "This is being sold to farmers as a new specialty crop that could make them a lot of money," says Dittrich, the president of the American Corn Growers Association. "But if these experiments end up costing farmers markets in Europe or the United States, we could be looking at a short-term profit that turns into a long-term disaster." According to research by the ACGA, US corn farmers have already lost more than $814 million in foreign sales over the past five years as a result of restrictions on genetically modified food imports imposed by Europe, Japan and other countries.

"When it comes to what is being proposed, and what is actually happening with regard to genetic modification of food crops, we're absolutely navigating uncharted waters at a high rate of speed. And we're being pushed to speed up by people with dollar signs in their eyes and no concern whatsoever for farmers or consumers," says Nebraska Farmers Union president John Hansen. "There may be a television program here or an article there about what's happening, but I don't think most Americans have any idea of the extent to which things have been pushed forward without the kind of research and precautions that ordinary common sense would demand."

Biopharming represents the new frontier of biotechnology, where agribusiness meets the pharmaceutical industry to explore a once unimaginable prospect: manipulating the genetic code of plants to induce them to generate AIDS vaccines, blood-clotting agents, digestive enzymes and industrial adhesives. If their initiative works, the corporate promoters of biopharming predict, expensive laboratories and factories will by the end of this decade be replaced by hundreds of thousands of acres growing pharmaceutical corn and soybeans that will allow consumers to realize ProdiGene's promise that you can "Have Your Vaccine and Eat It, Too!" And those corporations will yield huge returns -- ProdiGene predicts billion-dollar markets for products it has patented.

The dream of a biopharmed future is still presented as the noble cousin of GE cash-crop schemes. To the extent that Americans discuss genetic engineering, they usually refer to the process by which genes and segments of DNA that do not naturally occur in a particular food crop are added to it in order to make it easier, cheaper and more profitable to raise -- such as the splicing of an antifreeze gene from flounder to produce a cold-resistant tomato. Biopharming pushes the limits of genetic engineering to a new plateau, where scientists re-engineer crops to produce drugs that can be extracted from kernels and beans far more cheaply than they can be produced in factories.

In their race to patent and market pharmaceutical crops, ProdiGene, Monsanto, Dow Chemical and various universities have quietly obtained permission from the USDA to have

farmers plant open-air test plots across the United States; on these plots, the corporations are attempting -- with some success -- to turn corn, soybeans, rice and even tobacco into "plant pharmacies" that can provide edible vaccines for everything from hepatitis B to diabetes. Though biopharming is still in the experimental stage, the experiment has already seen twenty corporations and universities conduct more than 315 open-air field trials in undisclosed locations. These plots have brought thousands of acres -- virtually all of them in the vicinity of fields growing traditional food crops -- into biopharm production.

The race to the fields has sped up in recent years, in part because the biotech industry has many allies in the Bush Administration and a Republican Congress that prefers "voluntary regulation" by industry to real regulation by the government. And these firms are actively recruited by state officials and university chancellors who believe that a biotech boom could turn Wisconsin or Iowa into a version of Silicon Valley. (ProdiGene was recruited to Texas during George W. Bush's governorship.) As a result, calls for limits on biopharming are often met with cries of "no way" from farm-state politicians.

"Nature is not a pharmaceutical factory. It was never meant to be. But we have reached the point where it may be possible to make it that, and that prospect excites politicians and corporate executives who see this as a new way to make money," says Bill Freese, a policy analyst with Friends of the Earth who wrote GE Food Alert's groundbreaking report on the dangers of manufacturing drugs and chemicals in traditional food crops. "They talk a great deal about the benefits for society. But it's really the economics that attract them. They think they can grow drugs more cheaply and have lower production costs than if they were produced in factories. Also, if a drug goes well, they can just scale up the acres involved in production. If the drug is a bust, they can just fire the farmers."

ProdiGene press releases describe the firm as being "well positioned to capitalize on the opportunities in the large and expanding recombinant protein markets." ProdiGene promotes itself as "the first...company to produce and market a recombinant protein product from transgenic plants," and it maintains a portfolio of ninety current and pending patents -- including one to use plants to develop vaccines that can be eaten rather than injected. As a seed company and pharmaceutical industry executive, ProdiGene CEO Laos has for decades preached the bio-utopian "future of farming" gospel. To a greater extent than other biopharmers, he is determined to continue using corn as his company's preferred pharmaceutical plant. "We have looked at many different alternatives, and the best system available today for this technology is corn," he says.

And ProdiGene is getting lots of help. Its research on an edible AIDS drug is funded by the National Institutes of Health, and it recently developed a partnership with Eli Lilly. ProdiGene has collected more permits to initiate biopharm field trials than any other corporation in the United States -- eighty-five, while the next most active experimenter, Monsanto, has just forty-four. Half of ProdiGene's permits are for fields in Iowa and Nebraska -- the state that, according to the USDA, has been the site of the largest number of open-air field trials. And many of those fields are in Hamilton County, where Laos lived before taking charge of ProdiGene.

Laos has allies in the Corn Belt. In December, after the Nebraska and Iowa incidents, the Biotechnology Industry Organization (BIO) backed off a proposal to temporarily stop

growing GE drug- and chemical-producing crops in major corn-growing states after the plan encountered noisy opposition from Iowa's Democratic Governor, Tom Vilsack, and other farm-state politicians, who still see biopharming as a boon. Many farmers in Hamilton County have planted test fields at the behest of seed salesmen associated with Laos and ProdiGene. The salesmen offer small premiums -- $600 for planting an acre of experimental corn and another $300 for managing it in the year after the experiment is done -- along with the promise of bigger bonuses when the biotech train leaves the station. "They tell you: 'Once this gets going, the farmers who are in on it are going to make a lot of money growing these crops,'" says Mike Alberts, an Aurora-area farmer who this year turned down an opportunity to grow a ProdiGene test plot. "Farmers around here have had it hard for a long time, and a lot of them don't want to miss out on something they're calling the future of farming."

Critics of the biotech industry say that the federal agencies that should be strictly regulating burgeoning biopharm experimentation -- the USDA, the Food and Drug Administration and the Environmental Protection Agency -- are still too busy promoting GE crops as the cure for what ails American agriculture to recognize that they could turn into a curse. The USDA continues to hail GE crops as a boon for farmers, gleefully promoting biopharming with a website that features such headers as: "Animal Urine -- A New Source of 'Pharmed' Medicine?" Even now, the agency allows agribusiness firms to withhold details about the nature of their experimental crops and the locations of test plots from the public -- including neighboring food farmers -- by declaring the data "Confidential Business Information."

The regulatory system isn't working. It looks like we've got pharmaceutical chaos in the fields," says former North Dakota Agriculture Commissioner Sarah Vogel. "I'm not sure that some of these people in Washington or the corporate boardrooms quite understand the threat these incidents tell us are being created for food safety and the future of American agriculture." Part of the problem, according to Jean Halloran, who directs Consumers Union's Consumer Policy Institute, is that technological advances have outpaced not just regulations but basic questions of whether biopharming should be allowed at all. "What's infuriating is that there has been no public debate on whether we should be proceeding to this technology. They just went ahead and did it," Halloran says of an industry that, for the most part, is policed only with vague guidelines and threats of action if, as in the case of ProdiGene's plots, something goes really wrong. "We're in the middle of an official comment period on a set of guidelines -- not regulations, just guidelines -- at the same time that we are learning that we've got these problems with the testing. Doesn't that sound like we've missed a step?"

After the near-disaster in Hamilton County, there may be some scaling back of the explosive growth in the number of biopharm test plots in corn-growing states. ProdiGene and USDA officials talk of "isolating" the firm's open-air test fields, just beyond the edge of the cornbelt in Nebraska's Sand Hills or perhaps in the Southwest. But independent observers who know about farming and food safety are skeptical about this kind of self-regulation. They note that roughly 20 percent of the nation's corn production -- including that of much of Nebraska -- occurs outside the "drug-free zone" that BIO advanced and then abandoned. More significant, they argue that open-air test plots are not necessarily "isolated" by distance from traditional food crops.

Iowa State's Harl explains that even an isolated field can be hit with a tornado or heavy winds that will drop a kernel of corn far from the test plot. "Birds, deer, runoff from fields into rivers -- it's hard to list all the ways that seeds and kernels can be carried substantial distances," says Harl, who adds that because of consumer confidence and liability concerns, "ultimately, I think we are going to conclude that we have to produce a zero-contamination rule. That requires us to control the total environment -- and that means in a greenhouse."

Federal regulators have begun to feel pressure to tighten regulation of biopharm experiments and production, and not just from environmental, consumer and grocery industry groups, which have long been troubled by the prospect of drug crops contaminating food crops. In November Senate majority leader Tom Daschle and Agriculture Committee chair Tom Harkin wrote Agriculture Secretary Ann Veneman to ask "whether existing procedures and safeguards are sufficient to ensure that similar incidents do not occur in the future." A more energetic push came from the National Food Processors Association, whose president, John Cady, said the USDA and the FDA "should impose a stringent and mandatory regulatory framework to ensure protection of the US food supply and US food exports from any inadvertent or even intentional contamination by plant-made materials that have not been approved for human food and animal feed purposes." At the same time, however, farm groups allied with agribusiness -- chief among them the American Farm Bureau Federation -- issued a statement reaffirming their faith in biotech crops and essentially asking federal officials to continue encouraging biopharming.

Harl, who has served on the USDA's Advisory Committee on Agricultural Biotechnology, says federal agencies are going to have to fundamentally alter their approach to biopharming. "This is part of a broader regulatory phenomenon that has not been faced yet. If we are going to allow this type of production, then we have to ramp up the regulatory regimen," he says. The USDA, the FDA and the EPA must resolve turf wars over which agency is in charge of regulating not just test plots but, potentially, wide-scale production of pharmaceutical crops. That will require development of a regulatory regimen that makes public the details about where biopharm fields are planted and where biopharm products are being processed, and that insures regular testing through all the steps of food processing to assure that pharmaceutical crops are not being mixed with food crops. "We won't have discipline until we have testing at every point of commingling," Harl says. "We have some tests, but they are not what they must be: fast, easy and cheap."

Before any of these steps occur, however, Jean Halloran of Consumers Union suggests a more fundamental move. "We should ask whether pharmaceutical products should be engineered into food plants in the first place," she says. "Our view is that the answer to the question should be no." She notes that the drugs that biopharming promises to deliver can be gotten through other means. "The practical aspects of trying to keep these pharmaceutical plants separate from the regular food plants is an insurmountable problem," she says. "It just can't be done. It can't be done because of the fallibility of human beings. It can't be done because you can't control pollen flow. It can't be done because you can't control mother nature that way. And if you can't control mother nature and fallible human beings, we've come to the conclusion that you shouldn't try."