An FDA-Created Health Crisis Circles the Globe

How corporations engineered the non-regulation of dangerous genetically modified foods

Government officials around the globe have been coerced, infiltrated, and paid off by the agricultural biotech giants. In Indonesia, Monsanto gave bribes and questionable payments to at least 140 officials, attempting to get their genetically modified (GM) cotton approved.[1] In India, one official tampered with the report on Bt cotton to increase the yield figures to favor Monsanto.[2] In Mexico, a senior government official allegedly threatened a University of California professor, implying "We know where your children go to school," trying to get him not to publish incriminating evidence that would delay GM approvals.[3] While most industry manipulation and political collusion is more subtle, none was more significant than that found at the US Food and Drug Administration (FDA).

The FDA's "non-regulation" of GM foods

Genetically modified crops are the result of a technology developed in the 1970s that allow genes from one species to be forced into the DNA of unrelated species. The inserted genes produce proteins that confer traits in the new plant, such as herbicide tolerance or pesticide production. The process of creating the GM crop can produce all sorts of side effects, and the plants contain proteins that have never before been in the food supply. In the US, new types of food substances are normally classified as food additives, which must undergo extensive testing, including long-term animal feeding studies.[4] If approved, the label of food products containing the additive must list it as an ingredient.

There is an exception, however, for substances that are deemed "generally recognized as safe" (GRAS). GRAS status allows a product to be commercialized without any additional testing. According to US law, to be considered GRAS the substance must be the subject of a substantial amount of peer-reviewed published studies (or equivalent) and there must be overwhelming consensus among the scientific community that the product is safe. GM foods had neither. Nonetheless, in a precedent-setting move that some experts contend was illegal, in 1992 the FDA declared that GM crops are GRAS as long as their producers say they are. Thus, the FDA does not require *any* safety evaluations or labels whatsoever. A company can even introduce a GM food to the market without telling the agency.

Such a lenient approach to GM crops was largely the result of Monsanto's legendary influence over the US government. According to the *New York Times*, "What Monsanto wished for from Washington, Monsanto and, by extension, the biotechnology industry got. . . . When the company abruptly decided that it needed to throw off the regulations and speed its foods to market, the White House quickly ushered through an unusually generous policy of self-policing." According to Dr. Henry Miller, who had a leading role in biotechnology issues at the FDA from 1979 to 1994, "In this area, the U.S. government agencies have done exactly what big agribusiness has asked them to do and told them to do."

Following Monsanto's lead, in 1992 the Council on Competitiveness chaired by Vice President Dan Quayle identified GM crops as an industry that could increase US exports. On May 26, Quayle announced "reforms" to "speed up and simplify the process of bringing" GM products to market without "being hampered by unnecessary regulation."[5] Three days later, the FDA policy on non-regulation was unveiled.

The person who oversaw its development was the FDA's Deputy Commissioner for Policy, Michael Taylor, whose position had been created especially for him in 1991. Prior to that, Taylor was an outside attorney for both Monsanto and the Food Biotechnology Council. After working at the FDA, he became Monsanto's vice president. In the summer of 2009, the Obama administration put Taylor back in the FDA, as the US Food Safety Czar.

Covering up health dangers

The policy he oversaw in 1992 needed to create the impression that unintended effects from

GM crops were not an issue. Otherwise their GRAS status would be undermined. But internal memos made public from a lawsuit showed that the overwhelming consensus among the agency scientists was that GM crops can have unpredictable, hard-to-detect side effects. Various departments and experts spelled these out in detail, listing allergies, toxins, nutritional effects, and new diseases as potential problems. They had urged superiors to require long-term safety studies.[6] In spite of the warnings, according to public interest attorney Steven Druker who studied the FDA's internal files, "References to the unintended negative effects of bioengineering were progressively deleted from drafts of the policy statement (over the protests of agency scientists)."[7]

FDA microbiologist Louis Pribyl wrote about the policy, "What has happened to the scientific elements of this document? Without a sound scientific base to rest on, this becomes a broad, general, 'What do I have to do to avoid trouble'-type document. . . . It will look like and probably be just a political document. . . . It reads very pro-industry, especially in the area of unintended effects."[8]

The FDA scientists' concerns were not only ignored, their very existence was denied. Consider the private memo summarizing opinions at the FDA, which stated, "The processes of genetic engineering and traditional breeding are different and according to the technical experts in the agency, they lead to different risks."[9] Contrast that with the official policy statement: "The agency is not aware of any information showing that foods derived by these new methods differ from other foods in any meaningful or uniform way."[10] On the basis of this manufactured and false notion of no meaningful differences, the FDA does not require GM food safety testing.

To further justify their lack of oversight, they claimed that GM crops were "substantially equivalent" to their natural counterparts. But this concept does not hold up to scrutiny. The Royal Society of Canada described substantial equivalence as "scientifically unjustifiable and inconsistent with precautionary regulation of the technology." In sharp contrast to the FDA's position, the Royal Society of Canada said that "the default prediction" for GM crops would include "a range of collateral changes in expression of other genes, changes in the pattern of proteins produced and/or changes in metabolic activities."[11]

Fake safety assessments

Biotech companies do participate in a *voluntary* consultation process with the FDA, but it is derided by critics as a meaningless exercise. Companies can submit whatever information they choose, and the FDA does not conduct or commission any studies of their own. Former EPA scientist Doug Gurian-Sherman, who analyzed FDA review records obtained through the Freedom of Information Act, states flatly, "It is clear that FDA's current voluntary notification process (even if made mandatory) is not up to the task of ensuring the safety of future GE [genetically engineered] crops." He says, "The FDA consultation process does not allow the agency to require submission of data, misses obvious errors in company-submitted data summaries, provides insufficient testing guidance, and does not require sufficiently detailed data to enable the FDA to assure that GE crops are safe to eat."[12] Similarly, a Friends of the Earth review of company and FDA documents concluded:

"If industry chooses to submit faulty, unpublishable studies, it does so without consequence. If it should respond to an agency request with deficient data, it does so without reprimand or follow-up. . . . If a company finds it disadvantageous to characterize its product, then its properties remain uncertain or unknown. If a corporation chooses to ignore scientifically sound testing standards . . . then faulty tests are conducted instead, and the results are considered legitimate. In the area of genetically engineered food regulation, the 'competent' agencies rarely if ever (know how to) conduct independent research to verify or supplement industry findings."[13]

At the end of the consultation, the FDA doesn't actually approve the crops. Rather, they issue a letter including a statement such as the following:

"Based on the safety and nutritional assessment you have conducted, it is our understanding that Monsanto has concluded that corn products derived from this new variety are not materially different in composition, safety, and other relevant parameters from corn currently on the market,

and that the genetically modified corn does not raise issues that would require premarket review or approval by FDA. . . . As you are aware, it is Monsanto's responsibility to ensure that foods marketed by the firm are safe, wholesome and in compliance with all applicable legal and regulatory requirements."[14]

The National Academy of Sciences and even the pro-GM Royal Society of London[15] describe the US system as inadequate and flawed. The editor of the prestigious journal *Lancet* said**,** "It is astounding that the US Food and Drug Administration has not changed their stance on genetically modified food adopted in 1992. . . . The policy is that genetically modified crops will receive the same consideration for potential health risks as any other new crop plant. This stance is taken despite good reasons to believe that specific risks may exist. . . . Governments should never have allowed these products into the food chain without insisting on rigorous testing for effects on health."[16]

Promoting and regulating don't mix

The FDA and other regulatory agencies are officially charged with both regulating biotech products and promoting them—a clear conflict. Suzanne Wuerthele, a US EPA toxicologist, says, "This technology is being promoted, in the face of concerns by respectable scientists and in the face of data to the contrary, by the very agencies which are supposed to be protecting human health and the environment. The bottom line in my view is that we are confronted with the most powerful technology the world has ever known, and it is being rapidly deployed with almost no thought whatsoever to its consequences."

Canadian regulators are similarly conflicted. The Royal Society of Canada reported that, "In meetings with senior managers from the various Canadian regulatory departments . . . their responses uniformly stressed the importance of maintaining a favorable climate for the biotechnology industry to develop new products and submit them for approval on the Canadian market. . . . The conflict of interest involved in both promoting and regulating an industry or technology . . . is also a factor in the issue of maintaining the transparency, and therefore the scientific integrity, of the regulatory process. In effect, the public interest in a regulatory system that is 'science based'—that meets scientific standards of objectivity, a major aspect of which is full openness to scientific peer review—is significantly compromised when that openness is negotiated away by regulators in exchange for cordial and supportive relationships with the industries being regulated."[17]

The conflict of interest among scientists at the European Food Safety Authority (EFSA) GMO Panel is quite explicit. According to Friends of the Earth, "One member has direct financial links with the biotech industry and others have indirect links, such as close involvement with major conferences organized by the biotech industry. Two members have even appeared in promotional videos produced by the biotech industry. . . . Several members of the Panel, including the chair Professor Kuiper, have been involved with the EU-funded ENTRANSFOOD project. The aim of this project was to agree [to] safety assessment, risk management and risk communication procedures that would 'facilitate market introduction of GMOs in Europe, and therefore bring the European industry in a competitive position.' Professor Kuiper, who coordinated the ENTRANSFOOD project, sat on a working group that also included staff from Monsanto, Bayer CropScience and Syngenta." The report concludes that EFSA is "being used to create a false impression of scientific agreement when the real situation is one of intense and continuing debate and uncertainty."[18] This parallels the deceptive façade at the FDA.

The pro-GM European Commission repeats the same ruse. According to leaked documents obtained by Friends of the Earth, while they privately appreciate "the uncertainties and gaps in knowledge that exist in relation to the safety of GM crops . . . the Commission normally keeps this uncertainty concealed from the public whilst presenting its decisions about the safety of GM crops and foods as being certain and scientifically based." Further, in private "they frequently criticize the European Food Safety Authority (EFSA) and its assessments of the safety of GM foods and crops, even though the Commission relies on these evaluations to make recommendations to member states. . . [and] to justify its decisions to approve new GM foods."[19] For example, the Commission privately condemned the submission information for one crop as "mixed, scarce,

delivered consecutively all over years, and not convincing." They said there is "No sufficient experimental evidence to assess the safety."[20]

Evaluations miss most health problems

Although the body of safety studies on GM foods is quite small, it has verified the concerns expressed by FDA scientists and others.

- The gene inserted into plant DNA may produce a protein that is inherently unhealthy.
- The inserted gene has been found to transfer into human gut bacteria and may even end up in human cellular DNA, where it might produce its protein over the long-term.
- Toxic substances in GM animal feed might bioaccumulate into milk and meat products.
- Farmer and medical reports link GM feed to thousands of sick, sterile, and dead animals.

But there is not a single government safety assessment program in the world that is competent to even *identify* most of these potential health problems, let alone protect its citizens from the effects.[21]

A review of approved GM crops in Canada by professor E. Ann Clark, for example, reveals that 70% (28 of 40) "of the currently available GM crops . . . have not been subjected to any actual lab or animal toxicity testing, either as refined oils for direct human consumption or indirectly as feedstuffs for livestock. The same finding pertains to all three GM tomato Decisions, the only GM flax, and to five GM corn crops." In the remaining 30% (12) of the other crops tested, animals were *not* fed the whole GM feed. They were given just the isolated GM protein that the plant was engineered to produce. But even this protein was not extracted from the actual GM plant. Rather, it was manufactured in genetically engineered bacteria. This method of testing would never identify problems associated with collateral damage to GM plant DNA, unpredicted changes in the GM protein, transfer of genes to bacteria or human cells, excessive herbicide residues, or accumulation of toxins in the food chain, among others. Clark asks, "Where are the trials showing lack of harm to fed livestock, or that meat and milk from livestock fed on GM feedstuffs are safe?"[22]

Epidemiologist and GM safety expert Judy Carman shows that assessments by Food Safety Australia New Zealand (FSANZ) similarly overlook serious potential problems, including cancer, birth defects, or long-term effects of nutritional deficiencies. [23]

"A review of twelve reports covering twenty-eight GM crops - four soy, three corn, ten potatoes, eight canola, one sugar beet and two cotton - revealed no feeding trials on people. In addition, one of the GM corn varieties had gone untested on animals. Some seventeen foods involved testing with only a single oral gavage (a type of forced-feeding), with observation for seven to fourteen days, and only of the substance that had been genetically engineered to appear [the GM protein], not the whole food. Such testing assumes that the only new substance that will appear in the food is the one genetically engineered to appear, that the GM plant-produced substance will act in the same manner as the tested substance that was obtained from another source [GM bacteria], and that the substance will create disease within a few days. All are untested hypotheses and make a mockery of GM proponents' claims that the risk assessment of GM foods is based on sound science. Furthermore, where the whole food was given to animals to eat, sample sizes were often very low - for example, five to six cows per group for Roundup Ready soy - and they were fed for only four weeks."[24]

Hidden information, lack of standards, and breaking laws

Companies claim that their submissions to government regulators are "confidential business information" so they are kept secret. Some industry studies that have been forced into the public domain through Freedom of Information requests or lawsuits have been appalling in design and execution. This is due in part to the lack of meaningful and consistent standards required for assessments. Gurian-Sherman says of the FDA's voluntary consultation, "Some submissions are hundreds of pages long while others are only 10 or 20."[25] A Friends of the Earth report on US regulation and corporate testing practices states, "Without standardization, companies can and do design test procedures to get the results they want." [26] Regulators also reference

international standards as it suits them. According to the Centre for Integrated Research in Biosafety, for example, FSANZ "relaxed adherence to international standards for safety testing when that better suited the Applicant's submitted work, and imposed international standards whenever that was a lower standard than we recommended."[27]

Regulators also break laws. The declaration of GRAS status by the FDA deviated from the Food and Cosmetic Act and years of legal precedent. In Europe, the law requires that when EFSA and member states have different opinions, they "are obliged to co-operate with a view to either resolving the divergence or preparing a joint document clarifying the contentious scientific issues and identifying the relevant uncertainties in the data."[28] According to FOE, in the case of *all* GM crop reviews, none of these legal obligations were followed.[29]

Humans as guinea pigs

Since GM foods are not properly tested before they enter the market, consumers are the guinea pigs. But this doesn't even qualify as an experiment. There are no controls and no monitoring. Without post-marketing surveillance, the chances of tracing health problems to GM food are low. The incidence of a disease would have to increase dramatically before it was noticed, meaning that millions may have to get sick before a change is investigated. Tracking the impact of GM foods is even more difficult in North America, where the foods are not labeled. Regulators at Health Canada announced in 2002 that they would monitor Canadians for health problems from eating GM foods. A spokesperson said, "I think it's just prudent and what the public expects, that we will keep a careful eye on the health of Canadians." But according to CBC TV news, Health Canada "abandoned that research less than a year later saying it was 'too difficult to put an effective surveillance system in place.'" The news anchor added, "So at this point, there is little research into the health effects of genetically modified food. So will we ever know for sure if it's safe?"[30]

Not with the biotech companies in charge. Consider the following statement in a report submitted to county officials in California by pro-GM members of a task force. "[It is] generally agreed that long-term monitoring of the human health risks of GM food through epidemiological studies is not necessary because there is no scientific evidence suggesting any long-term harm from these foods."[31] Note the circular logic: Because no long-term epidemiological studies are in place, we have no evidence showing long-term harm. And since we don't have any evidence of long-term harm, we don't need studies to look for it.

What are these people thinking? Insight into the pro-GM mindset was provided by Dan Glickman, the US Secretary of Agriculture under President Clinton.

"What I saw generically on the pro-biotech side was the attitude that the technology was good, and that it was almost immoral to say that it wasn't good, because it was going to solve the problems of the human race and feed the hungry and clothe the naked. . . . And there was a lot of money that had been invested in this, and if you're against it, you're Luddites, you're stupid. That, frankly, was the side our government was on. Without thinking, we had basically taken this issue as a trade issue and they, whoever 'they' were, wanted to keep our product out of their market. And they were foolish, or stupid, and didn't have an effective regulatory system. There was rhetoric like that even here in this department. You felt like you were almost an alien, disloyal, by trying to present an open-minded view on some of the issues being raised. So I pretty much spouted the rhetoric that everybody else around here spouted; it was written into my speeches."[32]

Fortunately, not everyone feels that questioning GM foods is disloyal. On the contrary, millions of people around the world are unwilling to participate in this uncontrolled experiment. They refuse to eat GM foods. Manufacturers in Europe and Japan have committed to avoid using GM ingredients. And the US natural foods industry, not waiting for the government to test or label GMOs, is now engaged in removing all remaining GM ingredients from their sector using a third party verification system. The Campaign for Healthier Eating in America will circulate non-GMO shopping guides in stores nationwide so that consumers have clear, healthy non-GMO choices. With no governmental regulation of biotech corporations, it is left to consumers to protect

themselves.

To learn more about the health dangers of GMOs, and what you can do to help end the genetic engineering of our food supply, visit www.ResponsibleTechnology.org.

To learn how to choose healthier non-GMO brands, visit www.NonGMOShoppingGuide.com.

International bestselling author and filmmaker Jeffrey Smith is the leading spokesperson on the health dangers of genetically modified (GM) foods. His first book, *Seeds of Deception*, is the world's bestselling and #1 rated book on the topic. His second, *Genetic Roulette: The Documented Health Risks of Genetically Engineered Foods*, provides overwhelming evidence that GMOs are unsafe and should never have been introduced. Mr. Smith is the executive director of the Institute for Responsible Technology, whose Campaign for Healthier Eating in America is designed to create the tipping point of consumer rejection of GMOs, forcing them out of our food supply.

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