ALLIANCE FOR BIO-INTEGRITY

Preserving the Safety of Our Food, the Health of Our Environment, and the Harmony of Our Relationship with Nature

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HOW A U.S. DISTRICT COURT REVEALED THE FLAWS IN THE FDA'S POLICY ON GENETICALLY ENGINEERED FOODS

A Report on the Results of *Alliance for Bio-Integrity, et al. v. Shalala, et al.*

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In May of 1998 the Alliance for Bio-Integrity led an unprecedented coalition of public interest groups, religious leaders, and eminent scientists in filing a lawsuit to reform U.S. Food and Drug Administration (FDA) policy on genetically engineered (GE) foods. The suit was filed in U.S. District Court in Washington, D.C., and its outcome has demonstrated the irresponsibility of FDA policy and the falsity of some of the major claims made in support of GE foods. Proponents of these foods claim that: (a) the FDA rigorously regulates them; (b) FDA policy is science-based; and (c) there is overwhelming scientific consensus that GE foods are safe. But on September 29, 2000 Judge Coleen Kollar-Kotelly issued a ruling that starkly refutes each claim. She determined that:

- *The FDA is not regulating GE foods at all.*
- *The FDA's politically appointed bureaucrats did not follow the advice and warnings of the agency's scientific staff regarding GE foods but disregarded them.*
- *There were "significant disagreements" among scientific experts about the safety of GE foods.*

Further, the judge *avoided* the issue of whether adequate safety testing has been done and *failed* to make a determination that GE foods have been demonstrated to be safe – even though such a determination is legally required in order for these foods to be on the market.

Despite the above findings, the judge upheld the FDA's policy on narrow technical grounds. As plaintiffs, our burden was to demonstrate that in May 1992, the FDA administrators had abused their discretion by acting arbitrarily and capriciously in adopting the presumption that GE foods are generally recognized as safe (GRAS). *This was the key issue: whether the administrators had acted arbitrarily in presuming that GE foods are GRAS, not whether these foods actually are.* Ultimately, the judge held that the administrators had not acted arbitrarily and that their policy could therefore stand. However, in reaching her decision, she had to disregard a considerable amount of evidence. The following paragraphs more fully explain what her opinion said and the facts it ignored, while clearing up several misunderstandings that have been generated.

A. The Suit Entailed Extensive Proceedings and Elicited a Substantial Written Opinion

In referring to the outcome of our suit, proponents of GE foods usually state merely that the court dismissed it, thereby implying that our action had no legal merit and was rejected without the need for substantial legal proceedings. In fact, extensive proceedings occurred during which both sides

submitted a series of three written arguments, after which the court issued its ruling in an elaborate written opinion. By mutual agreement, there was not a trial, because there was no need for one. That's because trials are only used to resolve disputed issues of fact, and in our case the material facts were limited to the contents of the documents in the FDA's files – and were therefore undisputed. The court's judgment was not issued until more than two years after we filed the lawsuit, and only after issuing this judgment did the court then dismiss our suit, which is the standard result in such situations.

B. Establishing That the FDA Does Not Regulate GE Foods

Plaintiffs alleged that FDA violated the National Environmental Protection Act (NEPA) by not performing an Environmental Assessment or preparing an Environmental Impact Statement. In response, the FDA argued its policy is not subject to these requirements because it does *not* regulate GE foods in any manner and is therefore not a significant federal action. The judge agreed with the FDA. She declared that its policy on GE foods is essentially one of "inaction" and does "not impose any … obligations" on the biotech industry.

C. Disregarding Evidence of Disagreement Within the Scientific Community

The FDA claims that GE foods are recognized as safe by an overwhelming consensus among scientists, and this is the sole legal basis on which it has allowed them on the market. The lawsuit refuted this claim by demonstrating there is a substantial conflict among experts. Nine well-credentialed scientific experts took the unprecedented step of joining the suit as plaintiffs to emphasize their concerns about the hazards of GE foods, and several submitted declarations detailing the scientific grounds for regarding these foods as unreasonably risky.

The judge acknowledged we had introduced many statements from experts explaining that genetic engineering is "inherently risky", and she stated: "Plaintiffs have produced several documents showing significant disagreements among scientific experts." However, she said that because she was specifically reviewing an FDA policy decision of May 1992, she was restricted to consider *only* the information the FDA had before it at that time. She then ruled that based on that information, the FDA administrators had reasonable grounds to presume there was an overwhelming consensus about safety as of May 1992.

This ruling is puzzling in light of the fact we had called the judge's attention to evidence in the FDA files demonstrating that by 1991 the agency clearly knew there was *not* a scientific consensus about the safety of GE foods. One significant piece of evidence is a letter of October 23, 1991 from FDA's biotechnology coordinator to a Canadian health official. In commenting on a document that contained proposed guidelines for assessing the safety of GE foods, the biotech coordinator stated: "As I know you are aware, there are a number of specific issues addressed in the document for which a scientific consensus does not exist currently, especially the need for specific toxicology tests." He added: "I think the question of the potential for some substances to cause allergenic reactions is particularly difficult to predict." (*As an aspect of the lawsuit, the FDA was required to give us copies of all its internal files relating to GE foods; and copies of several key documents are posted on our website* www.biointegrity.org *The letter quoted from is #8 in this set.*)

Surprisingly, the judge's opinion failed to mention this letter. It also failed to properly address the fact that by May 1992 the FDA knew that most of its own experts regarded GE foods as more risky than conventional ones – which in itself shows they are not generally recognized as safe. This point is more fully discussed in the following paragraph.

D. Permitting FDA Administrators To Ignore the Warnings of Their Own Experts – and To Misrepresent the Facts

Before the FDA issued its policy statement, it had been extensively informed by its own experts that GE foods are inherently risky and cannot be presumed safe. These records clearly show (1) that the predominant opinion of the agency's own scientific experts was that GE foods pose unique health risks and (2) that they repeatedly cautioned their superiors about these risks. The uniformity of opinion within the FDA's scientific staff is attested by the official responsible for monitoring their input, who reported: "The processes of genetic engineering and traditional breeding are different, and according to the technical experts in the agency, they lead to different risks." (*Document #1at* www.biointegrity.org) Further, during the lawsuit the FDA never cited even one document from any of its scientists supporting its claim that GE foods do not pose additional risks and do not need to be tested.

The judge acknowledged the FDA's files contained statements from its scientists "warning" about unintended harmful side effects and "criticizing" the lack of scientific basis for the FDA's policy. However, she held that the agency's politically appointed administrators were legally entitled to establish policy despite the contrary opinion of their scientific staff. Doing so, she disregarded the fact that the FDA administrators were not merely setting policy but were perpetrating a major misrepresentation of reality: they were alleging there is an overwhelming consensus that GE foods are safe when the overwhelming consensus of their own experts was that such foods entail unique risks.

Moreover, the judge failed to mention another blatant misrepresentation we had brought to her attention. The FDA administrators had not only disregarded the information from their scientists but had even denied they knew of any such thing. In their formal policy statement they claimed: "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." The law clearly does not grant federal administrators discretion to intentionally misstate basic facts, and it's remarkable that the judge allowed FDA bureaucrats to do so.

E. Overlooking the Fact That No Adequate Evidence of Safety Exists

The law explicitly requires that even if there is overwhelming expert consensus about the safety of a new food (such as GE foods), each product must still be demonstrated safe through "technical evidence." The FDA's own experts clearly informed their superiors about the kinds of tests that are necessary to yield such evidence (*e.g.* long-term toxicological feeding studies using the whole GE food). But such tests are rarely used for GE foods, and no GE food on the market has been confirmed safe through them – as our scientist-plaintiffs thoroughly explained in statements filed with the court. Moreover, we directed the judge's attention to a memo by an FDA official to the Biotechnology Coordinator admitting that the necessary evidence was lacking: " . . . [A]re we asking the scientific experts to generate the basis for this policy statement in the absence of any data?" (Document *#1 at* www.biointegrity.org)

Although in her initial summary of the law, the judge stated that technical evidence of safety is required, she then sidestepped this crucial issue and *completely* failed to address it. Consequently, she did not make any finding that GE foods have been demonstrated to be safe. Had she forthrightly addressed the issue, she would have been obliged to acknowledge that the requisite evidence was lacking in 1992 and was still lacking in 2000 – and that GE foods are on the market illegally.

F. Outcome: Continuation of FDA's 1992 Policy Despite Exposure of its Illegality

The judge ruled that the FDA administrators did not act arbitrarily in 1992 when they presumed that GE foods are generally recognized as safe – even though it is clear from the FDA's own files that (a) such general recognition has never existed within the scientific community and (b) the technical evidence of safety upon which such recognition is legally required to rest has never existed either.

The judge did not rule that GE foods actually have been shown to be safe. Nor did she determine that there ever was a general recognition of safety among the FDA scientists or within the scientific community. Moreover, she did not even say that the FDA could justifiably continue to presume that GE foods are safe. Her decision was limited to the particular exercise of discretion made by the FDA in May of 1992. She ruled that at that specific point in time, the FDA was entitled to have presumed there was a general recognition of safety among scientific experts; but she indicated we had presented evidence showing that there was not a general recognition of safety at the time we filed our suit. Further, she emphasized that the FDA's presumption is supposed to be *rebuttable* by evidence it receives to the contrary. Nonetheless, the FDA continues to pretend that there is an overwhelming consensus among experts that GE foods have been demonstrated to be safe.

Because of the major flaws in the judge's opinion, we filed an appeal in November 2000. Then in January 2001, the FDA proposed new regulations on GE foods. Although these regulations still did not require any safety testing or labeling of GE foods, had they been implemented, they would have replaced the informal policy decision of May 1992 against which our lawsuit was brought. This appeared to render it a waste of time for us to further pursue our suit, because if the proposed regulations had been enacted, our suit would have become moot and we would have needed to proceed against the new regulations by filing a new lawsuit. Therefore, the Alliance for Bio-Integrity and the other plaintiffs in our lawsuit dropped our appeal, intending to bring a new lawsuit when the regulations took effect.

However, after we dropped our appeal, and after a two-year delay in enacting the proposed regulations, the FDA announced it was withdrawing them. So the FDA continues to rely on its policy statement of 1992, and we cannot revive our appeal of the court's decision. Further, because the 1992 policy has already been upheld in a federal court, it might be difficult for anyone else to sustain a new lawsuit against it. This means that GE foods will continue to be unknowingly consumed by most Americans on a daily basis even though they are on the market in stark violation of the food safety laws.

On balance, our lawsuit accomplished a lot by exposing the FDA's fraud and revealing the unsoundness of its policy and the irresponsibility of its behavior. Even though we failed to overturn the FDA's policy, the court's ruling refutes the standard claims of the biotech industry about the rigor of FDA oversight and the proven safety of its gene-altered products. It gives the FDA nothing to be proud of nor does it give the biotech industry anything to brag about. But it does give all consumers something to be very concerned about.