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ALLIANCE FOR BIO-INTEGRITY
Dedicated to Preserving the Safety of Our Food, the Health of Our Environment, and the Harmony of Our Relationship with Nature

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"Why Food & Drug Administration Policy on Genetically Engineered Food Violates Sound Science & U.S. Law"

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AT THE FDA PUBLIC MEETING ON GENETICALLY ENGINEERED FOODS,
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Panel on Scientific, Safety, and Regulatory Issues

A. Introduction

I am very pleased to be here, and I commend you, Commissioner Henney, for holding these meetings. I am also somewhat surprised to be here, since I am one of the strongest critics of your agency's policy on bioengineered foods and have coordinated a major lawsuit against it--a suit which is pending in U.S. District Court. The fact you have invited me indicates not only that you are interested in hearing from all sides, but suggests that you are also open to making meaningful changes.

B. FDA Policy is Scientifically Unsound

This is encouraging, since current FDA policy is sorely in need of change. While it claims to be science-based, it is seriously out of line with the standards of science -- and with the requirements of federal law.

1. Eminent Scientists Fault the Policy for Ignoring Biological Reality

Numerous experts both here and abroad have criticized FDA policy as scientifically flawed, and nine of these experts are so concerned about the extent to which they view it as unsound and irresponsible that they have taken the unprecedented step of becoming plaintiffs in the lawsuit my organization is leading to amend the policy and institute mandatory, rigorous safety testing of all genetically engineered foods. These scientist-plaintiffs are eminent, and their concerns deserve attention. They include a professor of molecular and cell biology at the University of California at Berkeley, a respected molecular biologist at the State University of New York, and the associate director of targeted mutagenics at Northwestern University Medical School. This latter scientist routinely employs bioengineering in the medical field, but is troubled it is being used in food production without adequate safeguards. Also included is Professor Philip Regal, an internationally renowned plant biologist at the University of Minnesota, who has stated in a sworn declaration to the court "... there are scientifically justified concerns about the safety of genetically engineered foods and some of them could be quite dangerous."

Why are our nine plaintiffs and so many other scientists so concerned about FDA policy? They think the agency is disregarding the well-recognized potential for recombinant DNA techniques to produce unexpected toxins and carcinogens in a different manner and to a different degree than do conventional methods. For one thing, the foreign genetic material invariably disrupts the region of host DNA into which it wedges, and this can adversely alter cellular function. Another source of potential problems is the routine practice of fusing powerful promoters from viruses or pathogenic bacteria to the transferred genes. This is necessary because genes ordinarily do not express well when implanted within a foreign cellular environment. However, besides boosting the foreign genes, these promoters can cause overexpression (or even suppression) of surrounding native genes. Further, these foreign promoters cause the transgenes to act independently of the host organism's intricate control mechanisms and to express their products in an essentially unregulated manner. This unregulated flow of foreign substances can upset complex biochemical feedback loops. Moreover, these powerful agents can activate metabolic pathways that are ordinarily inactive.

Each of the above types of disruption can induce unexpected toxins, carcinogens or allergens -- or degrade nutritional value in an unpredictable manner.

Unfortunately, the FDA's official position ignores this heightened potential for unpredictable negative side effects. Rather, the agency focuses almost exclusively on the factors that are known: the transferred genetic material and the substances it is known to produce. In effect, it is evaluating each transgenic substance as if it were an ingredient mixed into a pre-existing food rather than as a factor that can cause unpredictable deleterious changes in the developmental process of a food organism. As one of our plaintiffs, the respected molecular biologist Dr. Liebe Cavalieri has stated, such an approach is "simplistic if not simple minded."

2. Numerous FDA Scientists Have Warned About the Risks of Bioengineered Food

What is especially troubling is that the risks the FDA is systematically ignoring are not only recognized by eminent experts outside the agency but by numerous scientists on its own staff. This came to light when the FDA had to give us copies of its files during the course of the lawsuit. Memorandum after memorandum contains warnings about the unique hazards of genetically engineered food. As FDA microbiologist Dr. Louis Pribyl stated: "There is a profound difference between the types of unexpected effects from traditional breeding and genetic engineering ...." He added that several aspects of gene splicing ". . . may be more hazardous . . ." Similarly, Dr. E.J. Matthews of the FDA's Toxicology Group warned that " . . . genetically modified plants could ... contain unexpected high concentrations of plant toxicants...," and he cautioned that some of these toxicants could be unexpected and could " . . . be uniquely different chemicals that are usually expressed in unrelated plants." The numerous in-house critiques of the agency's proposed policy are best summed up by Dr. Linda Kahl, a compliance officer, who protested that the agency was "... trying to fit a square peg into a round hole . . . [by] trying to force an ultimate conclusion that there is no difference between foods modified by genetic engineering and foods modified by traditional breeding practices." She declared: "The processes of genetic engineering and traditional breeding are different, and according to the technical experts in the agency, they lead to different risks."

In light of these unique risks, FDA scientists advised that genetically engineered foods should undergo special testing. The Division of Food Chemistry and Technology cautioned, "... some undesirable effects such as ... appearance of new, not previously identified toxicants ... may escape breeders' attention unless

genetically engineered plants are evaluated specifically for these changes. Such evaluations should be performed on a case-by-case basis, i.e., every transformant should be evaluated before it enters the marketplace." These experts advised the evaluation should include toxicological tests.

Not only was the agency aware of uncertainties within its own ranks, it also knew there was considerable disagreement about the safety of genetically engineered foods in the scientific community at large. For instance, the FDA Biotechnology Coordinator, Dr. Jim Maryanski, acknowledged in a letter to a Canadian official on Oct. 23, 1991 that there was not a scientific consensus concerning the need for toxicology tests. He also admitted, "I think the question of the potential for some substances to cause allergenic reactions is particularly difficult to predict."

Nonetheless, the FDA not only disregarded the warnings of many of its own scientists about the unique risks of gene-spliced foods, it covered them up and has taken a public position that is quite opposite. It's official policy statement declares: "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 ...." (Statement of Policy: *Foods Derived From New Plant Varieties*, May 29, 1992, Federal Register vol. 57, No. 104 at 22991.) In light of the numerous statements from its own scientific experts about the unique differences -- and risks -- of genetically engineered foods, it's difficult to view this claim as a good faith effort to represent reality. Rather, it appears to be a ploy intended to deceive the public and evade the law. It is unconscionable for the FDA to stoop to such behavior when the safety of our food is at stake.

C. FDA Policy is Illegal

It should be obvious that, besides violating sound science, the FDA policy violates the U.S. Food, Drug and Cosmetic Act. In the food additive amendment to this statute, Congress instituted the precautionary principle as the law of the land when it comes to new substances being added to our food. Congress definitively decreed that no new substance shall be added to our food unless that substance has been demonstrated to be safe through standard scientific testing.

While the FDA agrees that the foreign genetic material, and the substances it produces, that get inserted into an edible plant are in principle food additives, it maintains they are exempt from regulation because they fall under the exception for substances that are "generally recognized as safe" (GRAS). It argues they are sufficiently similar to substances that are GRAS to support an inference that they are likewise safe. However, as already noted, FDA records indicate that implanting transgenic material into the DNA of a food-producing plant is not even generally recognized as safe among the agency's own scientists let alone by a consensus in the scientific community.

Second, the law is explicit that any recognition of safety must be based on "scientific procedures," and both the FDA and the courts have heretofore consistently interpreted "scientific procedures" as referring to studies published in peer-reviewed literature. Further, the FDA's own regulations emphasize that the tests supporting a general recognition of safety "...require the same quantity and quality of scientific evidence as is required to obtain approval of the substance as a food additive." This means, in the FDA's words, that the tests must demonstrate "a reasonable certainty ... that the substance is not harmful under its intended conditions of use." Yet, neither the FDA's records nor the scientific literature indicate that such a test exists for even one genetically engineered food.

In fact, the main test referenced in FDA files that attempted to demonstrate the safety of a bioengineered food through standard toxicology tests failed to do so. In his comments on this study, Dr. Robert J. Scheuplein, director of the FDA's Office of Special Research Skills, wrote: "... the data fall short of 'a

demonstration of safety' or of a 'demonstration of reasonable certainty of no harm' which is the standard we typically apply to food additives. To do that we would need, in my opinion, a study that resolves the safety question raised by the current data." Yet, the agency approved that product anyway on the grounds it was generally recognized as safe -- even though the law requires such recognition be based on precisely the kind of test that had failed to demonstrate safety. That food was Calgene's "Flavr Savr" tomato, the first genetically engineered organism the FDA reviewed. Interestingly, FDA officials claim that the Flavr Savr passed muster so well that the rigor of its testing will not have to be repeated for other bioengineered foods.

So, although the "generally recognized as safe" exemption was intended to permit marketing of substances whose safety has already been demonstrated through sound testing, the FDA is using it to circumvent testing and to approve substances based on inferences drawn from less rigorous forms of analysis -- inferences that are dubious in the eyes of several of its own as well as many other experts.

D. Genetically Engineered Food Has Caused Death and Disability

In 1988, a Japanese manufacturer, Showa Denko K.K., began marketing a genetically engineered food supplement of the amino acid L-tryptophan in the U.S. In this process, a gene coding for L-Tryptophan was spliced into the DNA of bacteria, and the substance was then extracted. Prior to that time, Showa Denko and other manufacturers had been marketing conventionally produced tryptophan supplements for many years with no ill effects. However, within a few months of entering the market, the genetically engineered supplement caused the deaths of 37 people and the permanent disability of at least 1500 others. (Source: House of Representatives 1991. *FDA's Regulation of the Dietary Supplement L-Tryptophan*. Human Resources and Intergovernmental Subcommittee of the Committee on Government Operations, United States House of Representatives, Washington, D.C.)

It was later shown that the genetically engineered tryptophan contained unusual and highly toxic contaminants. None of the conventionally produced tryptophan previously sold by Showa Denko or concurrently sold by other companies were toxic. Although it was never definitively established that the toxicity resulted from the genetic engineering process, neither has the link been ruled out; and many experts think it is likely that the toxin was an unexpected side effect of the bioengineering procedure. (*Id*.) It is well-recognized that this procedure can alter cellular activity and generate novel toxins, and the FDA's files contain numerous statements from its own scientists acknowledging this hazard. In the case of the L-Tryptophan, it is probable that the bacterial metabolism was disrupted in such a way that toxins were synthesized. The main reason a definitive answer has not been reached is that all the relevant evidence in Showa Denko's laboratory was destroyed before it could be examined.

Further, it is important to note that the toxins in the supplements were at such a low concentration that standard chemical analysis did not detect them and gave the false impression that the bioengineered batches were pure and safe to consume. Toxicological testing via animal feeding studies could have detected the problem.

On July 18, 1991, Douglas L. Archer, the Deputy Director of FDA's Center for Food Safety and Applied Nutrition (CFSAN), was invited to testify before the House of Representatives Subcommittee on Human Resources and Intergovernmental Relations regarding the agency's actions in response to the L-Tryptophan tragedy. Dr. Archer stated that the deaths and cripplings "demonstrate the dangers inherent in the various health fraud schemes that are being perpetrated on segments of the American Public." He indicated that the problem is that the medical and health claims being made for supplements such as L-Tryptophan are unsubstantiated and that the risks from their use as drugs can be significant.

Dr. Archer's prepared remarks did not once indicate that the toxic batches of L-Tryptophan had been produced through genetic engineering, nor did he once raise the possibility that it was this process rather than the inherent unsafety of L-Tryptophan supplements that was the cause of the illnesses. In fact, in his prepared remarks, he made no mention of genetic engineering. (*Id*.)

On September 27, 1991, Dr. James Maryanski, Coordinator of FDA's CFSAN Biotechnology Working Group, met with representatives of the Government Accounting Office and was questioned about L-Tryptophan and the potential that genetic engineering was the cause of the recent illness (termed EMS). According to Dr. Maryanski's memo of the meeting: "I said that we have no new information, that we do not yet know the cause of EMS nor can we rule out the engineering of the organism." (emphasis added). (*FDA Administrative Record at 22,923*.)

On May, 29 1992, the FDA published its policy statement on genetically engineered foods, which presumes there is a reasonable certainty that these foods will not be harmful and therefore does not require they be safety tested. However, as of the date of this summary (October 28, 1999) no one has produced any evidence that rules out the genetic engineering process as the cause of the EMS, and many experts continue to think it is the most probable cause.

To date, the executive branch of the U.S. government continues to ignore the fact that the fatal L-Tryptophan was bioengineered and persists in pretending that no genetically engineered food has been linked with a human health problem. For instance, in September, 1999, David Aaron, U.S. deputy secretary of commerce, declared, "Not a rash, not a sneeze, not a cough, not a watery eye has been developed from this (GM foods), and that's because we have been extremely careful in our process of approving them." (*Reported by Reuters*, 9-16-99)

The only concrete action the FDA took in response to the spate of bioengineered L-Tryptophan poisonings was to remove *all* L-Tryptophan supplements from the market. This action is consistent with the agency's claim that genetic engineering is an innocuous process similar to traditional breeding and that the problem stemmed from the risks of health supplements in general.

Thus, even though no conventionally produced L-Tryptophan has been known to cause the illness in question, all such supplements have been banned, while all genetically engineered foods have been cleared for marketing without safety testing, even though there are scientifically justified grounds to suspect the bioengineering process itself was the cause of the L-Tryptophan poisonings.

E. It Is Time For the FDA to Act Responsibly

The FDA says it is now in a listening mode. If it's ears have truly been open, then it's conscience should have been touched. The safety of the world's food supply is at stake. There is more than enough evidence to convince a reasonable man or woman that current FDA policy is unscientific, unwise, irresponsible, and illegal.

Commissioner Henney, I implore you to reconsider the agency's policy and to act as the responsible public servant I am sure that you are.

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