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2. Confidential Information (Not for Publication)

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Please indicate whether or not your brief contains any confidential information

No

Please provide an explanation for any sections of the brief that you wish to remain confidential to the Commission

Response

These sections should be removed from the body of the brief and provided as a separate document marked CONFIDENTIAL

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3. Signed (Not for Publication)

Signed

Signature of the witness

Steven Druker

Signed

Date 28 October 2000

(For Publication)

4. Name of Witness

Steven M. Druker

5. Name of "Interested Person" (on behalf of whom the Witness will appear)

Nelson GE Awareness Group

6. Witness Brief Executive Summary

Executive Summary

Provide an overarching summary of the evidence and recommendations made [in respect of items (1) and (2) of the Warrant]. The Executive Summary should be no more than **3** pages in length

Please note that individual section summaries will be required and therefore the Executive Summary should focus on summarising the issues addressed in the brief and provide cross references to the sections in which the issues are covered rather than summarising the substantive content

1. Section B (j) (i) addresses the issue of food safety in terms of both scientific and legal parameters. It explains the differences between genetically modified (GM) foods and conventional ones, why these differences entail unique health hazards, and the growing extent to which experts are warning about these hazards. It also details how the United States Food and Drug Administration (FDA) has (a) covered up the warnings of its own scientific experts about the hazards and (b) systematically misrepresented key facts. It explains how the marketing of GM foods is contrary to the food safety laws of the United States and any national laws that embrace the precautionary principle.

2. In light of the problems addressed in the above section, Section A (2) recommends a complete moratorium on the commercial planting and sale of every GM food unless and until it can be confirmed safe through reliable testing.

3. I am qualified to discuss these issues because I am a public interest attorney representing nine scientists in a lawsuit against the FDA who assert that its policy on GM foods is scientifically unsound. I have worked closely with them and understand their objections to the assumptions upon which the approval of GM foods has been based; and I have extensively studied the scientific issues in general. Further, because the FDA was compelled to divulge its internal records during the lawsuit, I know what its own scientific staff actually said about the differences between GM foods and their conventionally produced counterparts. My expertise in the scientific and legal issues has been recognized by the National Research Council, which invited me to appear on its Food Safety Panel at a conference in Washington, D.C. in May, 1999, and by the FDA, which invited me to appear on the Scientific, Safety and Regulatory Issues Panel at its public meeting in Washington, D.C. in November, 1999.

See Appendix One at the end of this document for Plaintiff List in Lawsuit referred to above.

This witness brief contains additional documents. Please see attached.

Evidence by Section (as specified in the matters set out in the Warrant)

Evidence by Section

Witness briefs are to be structured in line with the matters specified in the Warrant and the sections numbered accordingly

Each section should stand alone, and include a section summary, identifying the issues addressed in the section

Witness briefs may address **all** or only **some** of the sections (as specified in the Warrant). However section numbers should be retained, for example, if a brief addresses matters (a), (c) and (e), the sections shall be numbered (a), (c), and (e), rather than a, b, and c

Witness briefs may, within each section, adopt a sub-section approach using different headings; however, each paragraph should be consecutively numbered

Section A Recommendations

The Warrant has set the Commission the task of receiving representations upon, inquiring into, investigating, and reporting on the items set out in Section A (1) and (2) below

Section A (2)

A (2) any changes considered desirable to the current legislative, regulatory, policy, or institutional arrangements for addressing, in New Zealand, genetic modification, genetically modified organisms, and products

Section A (2) Summary

Considering the food safety concerns and U.S. government misbehaviors explained in Section B(j) (i), it is appropriate for New Zealand to institute a complete moratorium on GM food-yielding organisms

A (2)

1. Considering the food safety concerns and the U.S. government misbehaviors explained in Section B (j) (i), New Zealand would do well to discriminate fact from fiction and stand firmly for sound science and a precautionary approach based upon it. Such a course entails at minimum a moratorium on the commercial planting and sale of every GM food-yielding organism unless and until its safety has been confirmed through rigorous tests that can screen for the full range of known hazards.

2. Otherwise, as the information about the FDA's misbehavior and the inadequacy of the testing in the EU becomes more fully known, there will be a far more massive consumer backlash than at present, greatly restricting the marketing of GM foods even in the U.S. In such a situation, New Zealand would suffer economically if it had already permitted a large portion of its land to be filled with GM crops. More important, if some of these foods are in fact dangerous, the health of the populace could be significantly damaged.

Section B Relevant Matters

The Warrant has set the Commission the task of receiving representations upon, inquiring into, and investigating, the matters set out in Section B (a) – (n) below

Section B (j)

B (j) the main areas of public interest in genetic modification, genetically modified organisms, and products, including those related to:

- (i) human health (including biomedical, food safety, and consumer choice)
- (ii) environmental matters (including biodiversity, biosecurity issues, and the health of ecosystems)
- (iii) economic matters (including research and innovation, business development, primary production, and exports)
- (iv) cultural and ethical concerns

Section B (j) Summary

This section examines the issue of food safety in terms of both scientific and legal parameters. It discusses the substantial differences between genetically modified (GM) foods and their conventional counterparts and explains why hundreds of experts are concerned about the unique human health hazards they entail. This reveals that the biotechnology industry and many promoters of GM foods in the scientific community consistently misrepresent basic facts. The section also provides evidence of the extent to which the United States Food and Drug Administration (FDA) has (a) covered up the warnings of its own scientific experts about the unique hazards and (b) systematically misrepresented key facts. It then discuss how the evidence currently at hand indicates that the marketing of GM foods (even if fully labelled) is contrary to the food safety laws of the United States and the laws of any nation that embrace the precautionary principle.

The evidence about FDA misbehavior and the flaws in its policy is highly relevant, since arguments for the approval of GM foods in countries such as New Zealand to a large extent rely on the claim that they have been carefully examined and approved by the FDA. The precautionary principle is relevant since it is supposed to govern the actions of the EU and many other nations.

B (j)(i)

I. Why Concerns About the Safety of GM Foods Are Scientifically Justified

A. Numerous Distinguished Scientists Have Issued Warnings

1. We have repeatedly heard claims from the biotech industry, and from scientists receiving its financial support, that producing new varieties of food-yielding organisms through recombinant DNA technology (referred to as genetic engineering or bioengineering) is a minor extension of traditional breeding, that it is more precise, and that its products are just as safe if not safer than those of traditional breeding. However, hundreds of well-credentialed life scientists who do not rely upon industry funding strongly disagree with these claims. I am the legal representative of

nine such experts, scientists so concerned about the hazards of genetically engineered foods that they have taken the unprecedented step of joining as plaintiffs in the lawsuit my organization has brought against the FDA to challenge its presumption that these new foods are as safe as their conventionally produced counterparts. These scientist-plaintiffs include a professor of molecular and cell biology at the University of California at Berkeley; an internationally renowned plant biologist at the University of Minnesota; 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. (A list of the plaintiffs is attached.)

2. In addition to the nine experts who have expressed their concern through litigation, scores of others have expressed theirs by signing open letters to the world's governments stating that genetically engineered foods entail unacceptable risks to human and environmental health and calling for a moratorium on their commercial planting and marketing. Signatories include a professor of biology from Harvard University, a professor of molecular biology from M.I.T., and the director of the prestigious Woods Hole Research Center. (See www.i-sis.org)

B. Human Health Hazards That Are Not Disclosed by the Proponents of Bioengineered Foods

3. These experts are concerned because they are well aware that despite the claims of the of the biotech industry and its proponents that genetic engineering is substantially the same as traditional breeding, it is in fact deeply different.

The Fallacy of Equating Gene-Splicing With Traditional Breeding

4. Traditional breeding is based on sexual reproduction between like organisms. The transferred genes are similar to genes in the cell they join. They are conveyed in complete groups and in a fixed sequence that harmonizes with the sequence of genes in the partner cell. In contrast, bioengineers isolate a gene from one type of organism and splice it haphazardly into the DNA of a dissimilar species, disrupting its natural sequence. Further, because the transplanted gene is foreign to its new surroundings, it cannot function without a big artificial boost. In most cases, biotechnicians achieve this unnatural boosting by taking the section of DNA that promotes gene expression in a pathogenic virus and fusing it to the gene prior to insertion. This causes the transplanted gene to act independently of the host organism's intricate control system, unlike any of the native genes. Consequently, not only does the foreign gene produce substances that have never been in that species before -- it produces them in an essentially unregulated manner.

5. Accordingly, molecular biologist Liebe Cavalieri says it is "simplistic, if not downright simple-minded" to claim that genetic engineering is substantially the same as traditional breeding -- and that to do so is a "disgraceful sham." (*The Congressional Quarterly Researcher*, September 4, 1998; Press Conference, Washington, D.C. May, 1998) Considering that most people have not been informed about the reliance on viral boosters and have no idea that the transplanted genes are acting independently of the host organism's regulatory system and are, in an important respect, behaving more like an invading virus than a native gene, it is clear Professor Cavalieri's use of the word "sham" is not an exaggeration.

Unprecedented Risks to Our Food

6. Due to its deep differences with traditional breeding, genetic engineering entails unprecedented risks to the consumer. (a) Because the foreign genes enter the host DNA haphazardly and disrupt the region into which they wedge, they can broadly and adversely alter cellular function. (b) The viral boosters (called "promoters") artificially attached to the foreign genes are powerful and can induce erratic expression of surrounding native genes. They can also activate biochemical pathways that are ordinarily inactive. (c) The transplanted genes' continual and unregulated production of foreign substances drains energy from the organism's vital functions, which can induce metabolic imbalances. It can also upset complex biochemical feedback loops.

7. Each of these types of disruption can cause the generation of toxins and carcinogens -- or other harmful effects -- in unpredictable ways, and the minimal testing currently performed cannot adequately screen for the numerous potential problems. In addition, the foreign proteins can cause serious allergic reactions.

8. For the above reasons, and for several others, independent experts state that GM foods pose abnormal risk. Professor Philip Regal of the University of Minnesota, a renowned plant biologist, says it is "scientifically justified" to be concerned about their safety -- and he warns that some could be "quite dangerous." (Declaration submitted to the U.S. District Court, May 28, 1999 -- attached, along with the declaration of another eminent expert, Dr. Richard Lacey.)

II. FDA Policy Is Irresponsible and Immoral

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

9. The unique hazards of genetically engineered foods are apparent to any scientist who objectively analyzes biological reality. That is why when the experts at the U.S. Food and Drug Administration (FDA) undertook an extensive examination, they readily recognized them and clearly reported them to their superiors. This came to light when the FDA was compelled to give us copies of its files during the course of the lawsuit. Photocopies of key documents are in a numbered list on the Alliance for Bio-Integrity website <www.biointegrity.org> The numbers after the following quotations refer to the document's number on our website list. Copies of the documents are attached, with the document's list number placed at the top.

10. Numerous memoranda from FDA experts contain 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 . . ." (4) 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." (2) Citing the potential for such unintended dangers, the Director of FDA's Center for Veterinary Medicine (CVM) called for bioengineered products to be demonstrated safe prior to marketing. He stated: "... CVM believes that animal feeds derived from genetically modified plants present unique animal and food safety concerns." (10) He explained that residues of unexpected substances could make meat and milk products harmful to humans. And the head of the Biological and Organic Chemistry Section chided agency bureaucrats for turning prior policy "on its head" in attempting to equate bioengineered foods with their conventional counterparts. He also pointed out that lack of definitive evidence that a bioengineered food is dangerous is not an assurance of safety, noting that "in this instance ignorance is not bliss." (7)

11. The many 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." (1)

12. In light of these unique risks, FDA scientists advised that GM 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." (6) 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, FDA Biotechnology Coordinator, Dr. James Maryanski, acknowledged in a letter to a Canadian official on Oct. 23, 1991 that there was not a scientific consensus about safety. He also admitted, "I think the question of the potential for some substances to cause allergenic reactions is particularly difficult to predict." (8)

B. The FDA Has an Admitted Agenda to Promote the Biotechnology Industry

13. Although the FDA's technical experts were functioning as objective scientists, its political appointees were attuned to a White House directive to promote the U.S. biotech industry. This promotional policy was initiated by the Reagan/Bush administration and has continued through Clinton/Gore. The FDA openly admits it has been operating under a policy "to foster" the biotech industry. ("Genetically Engineered Foods," *FDA Consumer*, Jan.-Feb. 1993, p.14)

14. In 1991, the FDA created a new position of Deputy Commissioner for Policy to supervise the formulation of its policy on genetically engineered foods. The individual appointed was Michael Taylor, a Washington, D.C. lawyer who had been representing Monsanto and other members of the biotech industry on food regulatory issues. During Mr. Taylor's tenure as Deputy Commissioner, references to the unintended negative effects of bioengineering were progressively deleted from drafts of the policy statement (over the protests of agency scientists); and a final statement was issued which (a) ignored the warnings and recommendations of the agency's staff scientists, (b) claimed there was an overwhelming consensus among scientists that GM foods are as safe as others, and (c) permitted industry to market GM foods without any safety testing. Subsequently, Mr. Taylor was hired by Monsanto as Vice-President for Public Policy. Moreover, when Vice-President Dan Quayle introduced the FDA's policy in 1992, he referred to it as "regulatory relief" for the industry.

C. The FDA Persistently Misrepresents the Facts about Bioengineered Foods

15. Not only did the political appointees and other decision-makers at the FDA disregard the warnings of their own scientists about the unique risks of gene-spliced foods, they covered them up and took a public position that is quite opposite. On May, 29 1992 they issued an official policy statement asserting there is an overwhelming consensus among scientists that GM foods do not entail different risks than conventional foods. This statement even goes on to declare: "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.)

I invite the members of this commission to consider the statements from FDA experts about the unique differences -- and risks -- of genetically engineered foods and then to consider if they can accept the agency's claim about having no information of differences as a good faith effort to represent reality or whether it instead appears to be a shameful ploy intended to deceive the public and evade the law.

16. The FDA continues to misrepresent the facts. For example, on February 28, 2000, Dr. James Maryanski, the primary FDA spokesperson on GM foods, responded to a press conference I held earlier that day presenting the facts about the FDA's scientific review. Addressing the OECD Conference on the Safety of Bioengineered Food in Edinburgh, Scotland, Dr. Maryanski stated that the agency's scientists had merely been asking questions about the various issues involved in bioengineered food – although the record clearly shows they were making declarative statements (many quite emphatic) about the unique hazards. Further, on May 3, 2000, the FDA Commissioner declared: “FDA's scientific review continues to show that all bioengineered foods sold here in the United States today are as safe as their non-bioengineered counterparts.” But the FDA had made it clear in January, 1999 that it had not conducted substantial reviews, stating: “FDA has not found it necessary to conduct comprehensive scientific reviews of foods derived from bioengineered plants ... consistent with its 1992 policy.” (Reported in *The Lancet*, May 29, 1999) To my knowledge, the only action taken by the FDA between the dates of these statements that comes close to a scientific review was holding three public meetings, at which its officials were repeatedly reminded about the warnings of its own experts and informed of similar warnings by numerous others. Further, the FDA's own records reveal that, to the extent the agency has conducted a scientific review, it showed that bioengineered foods pose unique health hazards; and no subsequent data has demonstrated otherwise.

D. FDA Policy Is Scientifically Unsound

A Flawed Foundational Assumption

17. FDA's policy presumes every GM food is as safe as its conventional counterpart unless demonstrated otherwise. (The only exception is for foods from one of the few species involved in the most common food allergies.) The FDA does not require any testing, and testing is done on a purely voluntary basis by the manufacturer, with all critical decisions left to its discretion. In May, 2000, the FDA proposed revisions to its policy that still do not require *any* substantial testing, let alone the kinds of testing recommended by its own experts.

18. The FDA's official approach ignores its own scientists' warnings about the potential for genetic engineering to cause the production of harmful substances that have never before been seen in any of the involved species and are therefore unpredictable. Rather, the agency focuses almost exclusively on those factors that are known and predictable: 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. It is this kind of narrow approach that Professor Cavalieri has termed "simplistic if not simple minded," and it is because FDA's approach is so unsound that he and eight other experts have joined my organization in bringing a lawsuit against it.

Brazen Disregard of Expert Warnings

19. The tendency of FDA officials to disregard even the most emphatic warnings of their own experts about risks of GM foods is clearly demonstrated by how they decided the issue of anti-biotic resistant marker genes. Because most cells subjected to gene implantation techniques fail to incorporate the foreign gene, a large number must be used, and a marker must be attached to the foreign gene in order to identify the cells that have taken it up. The manufacturers decided that genes coding for resistance to anti-biotic chemicals would be the most economical markers. They especially desired to use a gene that confers resistance to kanamycin, which has an important medical use. On September 30, 1992, FDA's Biotechnology Coordinator requested the Division of Anti-Infective Drug Products to evaluate the proposed use of the kanamycin resistance marker gene. (11) On December 3, 1992, the Division's experts submitted their written opinion. To emphasize their concern, they capitalized all the letters in the key sentence of their conclusion: "IT WOULD BE A SERIOUS HEALTH HAZARD TO INTRODUCE A GENE THAT CODES FOR ANTI-BIOTIC RESISTANCE INTO THE NORMAL FLORA OF THE GENERAL POPULATION." (emphasis in original) (12) In sending the document to another FDA official, the Division's director included a cover letter titled, "The tomatoes that will eat Akron." (The first commercial use of the marker was planned for the Flavr Savr tomato.) He said: "You really need to read this consult. The Division comes down fairly squarely against the kan gene marker in the genetically engineered tomatoes. I know this could have serious ramifications." (12) On March 30, 1993 the Division's Supervisory Microbiologist sent a follow-up memo to the Biotechnology Coordinator in which he strongly criticized the proposed use of the marker. He noted that although other markers are available, industry prefers the anti-biotic resistant ones because they are more economical. He stated that to make the choice on this basis was wrong, considering the risks involved: "In my opinion, the benefit to be gained by the use of the kanamycin resistance marker in transgenic plants is out weighed by the risk imposed in using this marker and aiding its dissemination nation wide. If we allow this proposal, we will be adding a tremendous quantitative load of genetic material to the environment which will probably assure dissemination of kanamycin resistance." (13)

20. Nonetheless, the FDA approved the use of the kanamycin resistance gene not only in tomatoes but in other vegetables as well. Currently, most bioengineered foods contain anti-biotic resistance genes.

Fraudulent Misrepresentation of Test Results

21. FDA officials have even fraudulently misrepresented the results of a key safety test – the test performed on the first GM whole food that came to market. That food was Calgene's "Flavr Savr" tomato. Although not required to test the tomato, Calgene voluntarily subjected it to toxicological feeding studies and asked the FDA to review the data. The FDA scientists found this data failed to demonstrate safety and instead called the tomato's safety into question. For instance, Dr. Robert J. Scheuplein, director of the FDA's Office of Special Research Skills, stated: "... 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." (15) Dr. Carl B. Johnson of the Additives Evaluation Branch concurred that "... unresolved questions still remain." (16)

22. Yet, the FDA approved that product anyway and claimed that all safety issues had been satisfactorily resolved. Further, it said that because the tomato had performed so well, it would be unnecessary for any other GM food to be subjected to the same rigorous standard of testing.

E. The FDA Obscures the Fact that a GM Food Has Caused Death and Disability

23. Moreover, it is important to note that although government officials repeatedly boast that no GM food has ever caused harm, one such food did kill dozens of Americans and permanently disabled over 1,500 others. That food was a genetically engineered supplement of the amino acid L-tryptophan marketed in the U.S. in 1989 by the Japanese manufacturer, Showa Denko K.K. In producing it, biotechnicians spliced a gene to increase the yield of L-Tryptophan into the DNA of bacteria, from which the substance was then extracted. Within a few months of entering the market, this bioengineered supplement caused an epidemic of an unusual malady (called EMS) that resulted in the death of 37 people and the permanent disability of at least 1,500 others. (*FDA's Regulation of the Dietary Supplement L-Tryptophan*. Human Resources and Intergovernmental Subcommittee of the Committee on Government Operations, U.S. House of Representatives, Washington, D.C., 1991)

24. For many preceding years, other manufacturers had marketed L-tryptophan supplements produced from bacteria without use of gene-splicing. Epidemiological evidence from the Center for Disease Control does not link any tryptophan from these other manufacturers with outbreaks of EMS. (Kilbourne, E. *Journal of Rheumatology Supplement*, vol. 46, Oct. 1996) Further, Showa Denko's genetically engineered tryptophan was found to contain at least one unusual toxic contaminant never before seen in any of those conventionally produced batches. Although there is no conclusive proof that EMS resulted from genetic engineering, the link has not been ruled out; and many experts think it likely that whatever toxins caused the disease were unexpected side effects of the gene-splicing procedure, since it is well-recognized that this procedure can alter cellular activity and generate novel toxins. (*For a specific discussion of bioengineered L-Tryptophan, see T.J. Simat, et. al. "Synthesis, Formation and Occurrence of Contaminants in Biotechnologically Manufactured L-Tryptophan," Proceedings of the 9th International Meeting on Tryptophan Research, Hamburg, Germany, 10-14th Oct., 1998*). The main reason a definitive answer has not been reached is that the relevant evidence in Showa Denko's laboratory was destroyed before it could be examined.

25. FDA scientists confirm that the bioengineering process might have caused the EMS. On September 27, 1991, Dr. James Maryanski, Coordinator of FDA's Biotechnology Working Group, discussed the matter with officials from the Government Accounting Office. According to his record 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) During a private conversation I had with Dr. Maryanski on November 30, 1999, he acknowledged bioengineering still cannot be ruled out.

26. However, in its public pronouncements, the FDA is far less forthright and even obscures the fact that the fatal batch of Tryptophan had been bioengineered. On July 18, 1991, Dr. Douglas L. Archer, Deputy Director of FDA's Center for Food Safety and Applied Nutrition (CFSAN), testified before the House of Representatives Subcommittee on Human Resources and Intergovernmental Relations about the L-Tryptophan tragedy. He said the incident confirmed the FDA's warnings about the hazards of many health food supplements and declared that the deaths and injuries "demonstrate the dangers inherent in the various health fraud schemes that are being perpetrated on segments of the American Public."

27. Dr. Archer's prepared remarks never indicated that the toxic batches of L-Tryptophan had been produced through genetic engineering, nor did he once raise the possibility it was this

process rather than any presumed problems with L-Tryptophan supplements in general that was the cause of the illnesses.

28. Consistent with its claim that all L-Tryptophan supplements are suspect, the FDA removed all of them from the market. Thus, even though no conventionally produced L-Tryptophan has been linked with an EMS outbreak, all such supplements have been banned, while all genetically engineered foods have been cleared for sale without testing, even though there are scientifically justified grounds to suspect the bioengineering process itself was the cause of the EMS epidemic. To date, the executive branch of the U.S. government continues to blur the fact that the fatal L-Tryptophan was genetically engineered and persists in claiming 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 (genetically engineered foods), and that's because we have been extremely careful in our process of approving them." (Reported by *Reuters*, Sept. 16, 1999)

III. FDA Policy is Contrary to the Clear Intent of U.S. Law

29. Not only does FDA policy violate sound science, it is contrary to the clear intent of the U.S. Food, Drug and Cosmetic Act. In the food additive amendment to this statute, Congress instituted the precautionary principle and definitively decreed that no new substance shall be added to food unless that substance has been demonstrated safe through standard scientific procedures. 21 U.S.C. Sec. 321.

A. Claiming General Recognition of Safety When It Does Not Exist

30. While the FDA agrees that the foreign genes that get inserted into a plant, along with the substances they produce, 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). However, as already noted, FDA records indicate that because such manipulations can induce unpredictable side effects, they are not even recognized as safe among the agency's own scientists let alone by a consensus in the scientific community. Further, it is important to emphasize that the extent of the disagreement clearly precludes GRAS status. As both the FDA's regulations and the federal courts make clear, general recognition of safety can only be imputed if there is an overwhelming consensus in the community of qualified experts. While unanimity is not required, a significant disagreement prevents a determination that consensus exists. United States v. 4680 Pails, 725 F. 2d 976, 990 (5th Cir. 1984); United States v. Seven Cartons ... Ferro-Lac, 293 F. Supp. 660, 664 (N.D. Il. 1968), modified on other grounds, 424 F. 2d 136 (7th Cir. 1970).

B. Absence of Required Test-Based Evidence

31. Moreover, 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. 21 CFR Sec. 170.3(h). 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." 21 CFR Sec. 170.30(b). 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." 21 CFR Sec. 170.3(i). Yet, the FDA's records do not indicate that any such tests exist; and three experts have submitted declarations to the court in support of

our lawsuit stating that the scientific literature is devoid of evidence demonstrating that even one genetically engineered food is safe. Further, as explained in II. 21, 22 above, the main study that attempted to demonstrate the safety of a GM food through standard toxicological testing raised an unresolved safety question.

32. 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 now 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 many of its own as well as numerous other experts.

C. The U.S. District Court Acknowledged There is Significant Conflict Among Experts

33. On September 29, 2000, the U.S. District Court for the District of Columbia delivered a ruling in our lawsuit. The court acknowledged the existence of a significant conflict among experts about the safety of GM foods, stating: "Plaintiffs have produced several documents showing significant disagreements among scientific experts." However, it said that because it was specifically reviewing FDA's policy decision of 1992, it was restricted to consider only the information the FDA had before it at that time. The court also acknowledged there was substantial evidence of expert concern about the safety of GM foods in the FDA's own files prior to its 1992 decision. However, it held that as a matter of administrative law, the higher level decision-makers were entitled to disregard the opinions of their scientific staff. Accordingly, the court ruled that the FDA's 1992 presumption that GM foods are generally recognized as safe by experts can continue to stand, even though such recognition did not exist in 1992 and does not exist today. Doing so, the court explicitly confirmed that FDA policy does not regulate GM foods and does not impose any obligations on the biotech industry.

34. The court's ruling is based on technical aspects of U.S. administrative law and does not determine that GM foods are safe. Instead, it shows there are reasonable grounds to doubt their safety. It also makes it obvious that even if the FDA's behavior is technically permissible due to the substantial discretion granted it by the Administrative Procedure Act, the behavior thwarts the intent of the Food, Drug and Cosmetic Act, which aims to protect the public from alterations to food that have not been confirmed safe through standard testing.

35. Moreover, the court's arguments are flawed, and it appears to have repeatedly misinterpreted the law. Further, it failed to address key issues of fact that were clearly brought to its attention. First, shortly before the FDA issued its policy statement claiming that GM foods are generally recognized as safe, its biotechnology coordinator wrote to a Canadian health official that there was no scientific consensus about safety. (See II. 12) Second, the political appointees did not just ignore their experts' input; they lied about it. They claimed they were "not aware of any information showing that foods derived by these new methods differ from other foods in any meaningful or uniform way." (See III. 15, 16) Third, as the court recognized, the law requires that each GM food be demonstrated safe through "technical evidence"; but there is no such evidence for any of the GE foods on the market. (See II. 21, 22; III. 31, 32) Therefore, the Alliance for Bio-Integrity intends to appeal the decision, and, as the more detailed summary and critique of the opinion which is attached demonstrates, there are sound reasons to believe it will be reversed. (Also included is a copy of the opinion.)

IV. The Marketing of GM Foods Violates the Precautionary Principle

36. In light of the substantial conflict among experts and the lack of solid evidence that any GM food is safe, the marketing of GM foods today, even if fully labeled, violates the precautionary principle. That principle holds that if there are reasonable grounds to doubt the safety of a new food, it must be demonstrated safe before it can be marketed.

37. Accordingly, the marketing of GM foods violates the European Union's food laws, since they are based on a preventive, precautionary approach. The European Parliament describes its food laws as "based on the preventive protection of consumer health ...founded on a scientifically-based risk analysis supplemented, where necessary, by appropriate risk management based on the precautionary principle...." *Resolution of 10 March 1998 on the Green Paper: General Principles of Food Law in the EU*. In this Green Paper of 30 April 1997, the European Commission states it "...will be guided in its risk analysis by the precautionary principle, in cases where the scientific basis is insufficient or some uncertainty exists."

38. It is important to note that the tests currently relied on in the EU are inadequate to screen for the presence of unpredictable new toxins and other harmful substances. Numerous experts concur in this and recognize that no GM food has yet been established safe by the kinds of tests competent to screen for the full range of potential negative side effects.

APPENDIX ONE

LIST OF SCIENTIST PLAINTIFFS

Following are the nine scientists who are plaintiffs in the law suit challenging FDA policy on genetically engineered foods:

Dr. Richard Strohman, Emeritus Professor of Molecular and Cell Biology at the University of California, Berkeley. He has written extensively on biotechnology issues.

Dr. Philip J. Regal, Professor of Ecology, Behavior and Evolution at the University of Minnesota. He is one of the nation's most distinguished plant biologists and has written extensively on the genetic engineering of plants and the ecological and human health risks associated with it.

Dr. John Fagan, Professor of Molecular Biology at Maharishi University of Management. Recipient of Research Career Development Award from the National Cancer Institute. He has written extensively on the hazards of genetic engineering and gained world-wide attention in 1994 when he returned a \$613,000 grant to the NIH as an ethical stand against genetic engineering.

Dr. Liebe Cavalieri, Molecular Biologist, Professor, Division of Natural Sciences, State University of New York at Purchase. He has written extensively on biotechnology issues.

Dr. David Ehrenfeld, Professor of Biology, Rutgers University. He has written on the dangers of genetically engineered foods.

Dr. David Fankhauser, Professor of Biology and Chemistry, University of Cincinnati.

Hanif Khalak, Computational Biologist, The Institute for Genomic Research, Rockville, MD. Though he does research that facilitates applications of biotechnology for curing human disease, he thinks that the current applications of biotech in food production are based in scientifically flawed assumptions.

Dr. Gary Kaplan, MD, PhD, Director of Clinical Neurophysiology, North Shore University Hospital; Assoc. Professor of Clinical Neurology, NYU School of Medicine.

Dr. Rama Dwivedi, Associate Director, Targeted Mutagenics, Department of Pediatrics, Northwestern University Medical School. Although he performs biotechnology for medical purposes, he believes that the program to genetically reconfigure food organisms, as currently conducted, is scientifically unsound.