



Commissioner Jane Henney
FDA Dockets Management Branch
5630 Fishers Lane, Room 1061 (HFA-305)
Rockville, MD 20852

1074 '00 APR 26 P2:27

April 21, 2000

Re: Docket No. 00P-1211/CP1 and Docket No. 99N-4282

Dear commissioner Jane Henney:

As a representative of Progressive Investment Management, Advisor to Portfolio 21 – a mutual fund that invests only in companies with a commitment to environmental sustainability – I am writing to you to urge the USDA to establish stringent pre-market safety testing regulations for genetically engineered foods.

I understand that the FDA's current policy makes no distinction between GE foods and foods bred using traditional methods, and requires neither pre-market safety testing and monitoring nor labeling of GE foods. At Progressive Investment Management we support the petition submitted by the coalition of Organic Consumers Association and the Center for Food Safety as well as fifty other groups on March 21, 2000. The FDA should use this petition as a basis for establishing the legal requirements and scientific reasoning for a new regulatory system for the review of GE foods.

There is so little known about genetic engineering and the effects this process has on human health and the environment, it is imperative the precautionary principal is used when evaluating GE foods. Following is a description of a selection of risks associated with this technology. Please consider these issues carefully and establish stringent and clear regulations on genetically engineered foods.

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Problems with Genetic Engineering

There are many documented risks connected with genetic engineering, ranging from human health risks to environmental risks to cultural/community risks. Below are examples and explanations of a selection of these risks.

Terminator Seed Technology. Some companies, such as Monsanto, have developed genetically modified crop seeds that produce only sterile plants. As a result, farmers become dependent on large corporations and must purchase new seeds every season. In addition to the clear social equity issues associated with this scheme of business, the terminator technology breaks the natural process of regeneration and thus has potentially devastating environmental implications.

Medical Risks: People are increasingly undergoing gene therapy in an attempt to deal with diseases and conditions, however, the risks of these treatments are largely unknown. In late 1999 Jesse Gelsinger was the first known victim of gene therapy. Gene therapy involves the use of a virus to carry a modified DNA segment and the virus is potentially pathogenic. Additionally, there are concerns that medical applications involving genetic engineering may produce cancer-causing genes from normal human genes. While it is still unclear in the case of Jesse Gelsinger whether his death was due to errors in the treatments he was given, or due to the gene therapy itself, this event illustrates the risks and uncertainties regarding the safety of medical applications of biotechnology.

Risks to Wildlife / Biodiversity: A study released by Cornell University has shown that a strain of genetically modified corn ("Bt corn") can be lethal to caterpillars that develop into monarch butterflies. Monarch butterflies are considered to be a flagship species for conservation, and threat to this species represents a clear threat to biodiversity. The magnitude of these risks to non-target organisms (including beneficial insects) is largely unknown, as there have been no comprehensive studies to date.

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Risks to Organic crops: Genetic manipulation that places the **Bt** gene in crop seeds poses the risk of making Bt sprays, available for pest control by organic farmers, ineffective by hastening the evolution of resistant pests. Organic farmers fear that pests will adapt quickly to the Bt gene that has been inserted into some GMO crops and that the Bt-resistant pests will then be unaffected by Bt sprays, one of the most effective natural sprays available to organic farmers.

Risks to ecosystem integrity: As the two above risks indicate, the insertion of the Bt gene into crops has potentially significant consequences for wildlife and organic farming. Beyond these risks, however, is a third one associated with the release of Bt toxins from the roots of "Bt corn." Researchers at New York University recently found that the roots of "Bt corn" exude the active form of the Bt toxin, which has a long residual in the soil. It is currently unknown what affect the Bt toxin will have on soil processes and soil microorganisms.

Genetic Pollution: In this discussion **genetic pollution** refers to the spreading of artificially modified genes (some people refer to this as genetic drift). The concern here is that GM crops could reproduce with unmodified plants thereby reducing diversity and contaminating previous unmodified crops. Additionally, genes can spread across different species and it has been shown in experiments that they can even spread from plants to animals. It is currently not clear how much genetic pollution will occur as a result of the use of GM seeds. US FDA guidelines requiring that a border of non-GM plants be in place around GM crops indicate that genetic pollution, or cross-pollination, is a real threat. If GM crops are not managed correctly there could be problems growing and certifying non-GM crops as well as problems associated with reduced genetic diversity.

Patenting and cloning of life forms: In his book "Remaking Eden: How Cloning and Beyond will Change the Human Family," Lee Silver envisions a society divided in two based on genetic makeup – the "GenRich" and the "Naturals." This theory, that people who can afford it will be able to give their children a competitive edge over other children, presents a horrifying picture of class inequities. If not properly managed, gene patents could be instrumental in promoting and institutionalizing social inequity.

Biopiracy: The process of patenting genetic material traditionally available to a community without allowing the community free use of the material, or providing any return to the community, has tremendous moral implications. Like the patenting and cloning of life forms mentioned above, **biopiracy** could be devastating to the fair and equitable distribution of resources, which is a necessity in the development of a sustainable society.

Increased chances of allergic reactions. Example: Some soybean seeds have been genetically modified to include a gene from Brazil nuts. This was done in order to improve the nutritional value of a protein supplement containing soy. As a result of this modification, however, individuals with Brazil nut allergies had reactions to the soy product. In some cases, Brazil nut allergies can trigger life-threatening reactions in susceptible people; thus, this modification presents no small risk. The "sharing" of genes from one organism to another has tremendous implications for individuals with allergies. Questions regarding the stability of genetically modified DNA segments are also relevant here and unfortunately are largely unanswered. Many people believe that the complexities and interdependencies of genes mean that removing one gene and replacing it with another will not necessarily result in the anticipated or desired trait due the fact that each gene is affected by the other genes in its DNA sequence. In short, genes do different things in different environments. This has consequences on individuals with allergies as GM crops may trigger unanticipated allergic reactions. Additionally, the modified soy product indicated no negative reactions when it was tested on animals. This study illustrates the difference between the reactions of laboratory animals and humans to GM food products, indicating a need for further study of this new technology before it is widely embraced.

The USDA has made great progress to date on its development of organic standards, I now urge you to step up to the plate and establish stringent pre-market safety testing regulations for genetically engineered foods.

Sincerely, 

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