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Clinical Research Division

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Dockets Management Branch (HFA-305)
Food and Drug Administration
5630 Fishers Lane, Rm. 1061
Rockville, MD 20852

Dear Sir or Madam:

I am sending this letter concerning your document entitled, "Guidance for Industry: Drugs, Biologics, and Medical Devices Derived From Bioengineered Plants for Use in Humans and Animals," Docket No. 02D-0324, I agree with the FDA and USDA's guidelines to ensure the safe production of plant-made pharmaceutical crops from commodity grains. I also concur that the production of bioengineered plants must adhere to strict, self-imposed stewardship principles and procedures.

As a medical oncologist, I believe that plant-made pharmaceutical technology represents a tremendous opportunity to produce monoclonal antibodies and other protein-based reagents to treat cancer. The feasibility of this approach was demonstrated in a scientific presentation from Dr. Ron Levy's group from Stanford at the American Society of Hematology meeting on December 9 , 2002 in Philadelphia. In this presentation, an anti-lymphoma vaccine was produced in plants and shown to be effective at inducing an immune response against malignant lymphomas. A second application in the field of oncology is the production of fusion proteins of antibodies and streptavidin for use in pretargeted radioimmunotherapy of cancer. The success of this approach has already been demonstrated by Dr. Axworthy and colleagues at NeoRx Corporation using protein products made in corn plants under contract with Monsanto. Despite the tremendous potential success of this and similar approaches, however, the potential risks to agriculture and the food industry are also evident and mandate strong regulations and an industry-wide commitment to stewardship.

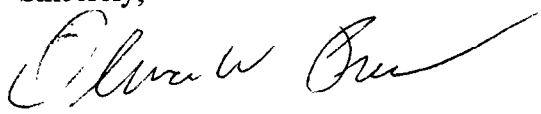
I strongly believe that it is important to pursue all new reasonable opportunities for advancements in medicine, especially those with the potential to develop cost effective treatments that can reach patients more quickly. From the standpoint of economics, efficiency and safety, this new technology possesses significant potential including the provision of a greater variety of novel life-saving drugs at more affordable prices, the ability to expand production unfettered by currently limited bioreactor availability, and elimination of the risks of human and animal viruses and prions that can be associated with current production methods. Finally, plants are a renewable and sustainable resource for the production of pharmaceuticals.

This innovative technology appears to offer great promise for the economical and efficient production of novel proteins to diagnose, treat or prevent a wide variety of human diseases, especially cancer, AIDS, heart disease and diabetes and could potentially many lives in the United States and around the world.

020-0324 C170

I strongly support this technology, and applaud FDA and USDA's efforts to regulate this industry in a way that both allows for its advancement and protects the food supply.

Sincerely,



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