ARTHRITIS FOUNDATION®
Take Control. We Can Help.™

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January 10, 2003

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

Re: Guidance for Industry: Drugs, Biologics, and Medical Devices Derived From Bioengineered Plants for Use in Humans and Animals," Docket No. 02D-0324

Dear Sir or Madam:

On behalf of the Arthritis Foundation, I would like to express my support for the Food and Drug Administration (FDA) and U.S. Department of Agriculture's (USDA) proposed guidelines on the production of pharmaceutical products from commodity grains intended for food and feed. We believe these guidelines will provide an appropriate balance between important scientific innovation that holds the promise of safe and more cost-effective therapies for patients and the necessary safeguards to ensure the safety of our food supply for consumers.

The Arthritis Foundation is the nation's leading voluntary health agency that represents the interests of more than 70 million Americans with arthritis. There are over 100 different forms of arthritis, and it remains the nation's leading cause of disability. Individuals with arthritis require access to comprehensive health care that can include preventive care, self-management programs, surgical interventions, rehabilitation services, and prescription drug, biological and medical device therapies. In recent years, a number of new therapies for arthritis and related diseases have been introduced to the public, which have dramatically improved the quality of life for many individuals living with the disease.

Plant-made pharmaceutical technology represents an important opportunity to produce safe and lower-cost therapies. However, the Foundation also recognizes the potential risks to consumers and the nation's food supply if adequate safeguards are not in place. To realize the potential of this technology, we believe there must be strong, transparent regulations coupled with an industry-wide commitment to stewardship. All stakeholders in this issue, government, the scientific community, industry, and consumers must work together to develop flexible, science-based, performance standards in order to protect our nation's food supply, and realize the potential benefits of this innovative technology.

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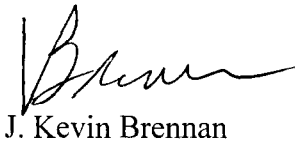
The Foundation supports the pursuit of all new reasonable opportunities for advancements in medicine, especially those with the potential to develop safer, more effective, and less costly treatments that can reach patients more quickly. The primary benefit of plant-made pharmaceuticals for patients may be the opportunity plants afford to produce a greater variety of novel life-saving drugs at more affordable prices.

Even if only a small portion of the biologics currently in development become approved therapies, crop plants could provide a viable alternative to traditional protein production methods. Based on this opportunity, our nation must establish appropriate guidelines that allow us to move forward. Crop plants that produce protein pharmaceuticals could provide manufacturers with an alternative source of proteins free of potential animal contaminants; they could boost manufacturing capacity while they lower capital investments; and they would offer an environmentally sustainable and renewable resource for the production of drugs in large volume.

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. From cancer, HIV, heart disease and diabetes to Alzheimer's, cystic fibrosis, multiple sclerosis and arthritis, medical science is developing new approaches to the treatment of human disease that potentially could save hundreds of thousands of lives.

We strongly support this technology, and we 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,



J. Kevin Brennan
Senior Vice President
Health Policy