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U.S. News & World Report

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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:

In response to the recent draft entitled, "Guidance for Industry: Drugs, Biologics, and Medical Devices Derived From Bioengineered Plants for Use in Humans and Animals," Docket No. 02D-0324, I support the FDA and USDA's guidelines to ensure the safe production of plant-made pharmaceutical crops from commodity grains intended for food and feed. I agree that any company wishing to participate in producing bioengineered plants must adhere to strict, self-imposed stewardship principles and procedures.

While plant-made pharmaceutical technology represents a great opportunity with tremendous potential, I also recognize the potential risks to agriculture and the food industry. The success of this technology is predicated upon strong, transparent regulations coupled with an industry-wide commitment to stewardship. Government, the scientific community, and industry must continue to cooperate to develop flexible, science-based, performance standards in order to protect U.S. agriculture, instill confidence across the food chain, and to ultimately realize the potential benefits of this innovative technology.

I 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.

Using plants to produce pharmaceuticals presents several clear advantages: overcoming many of the cost, capacity and safety challenges associated with mammalian and microbial systems.

- 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.
- This new application of biotechnology will provide increased access to innovative pharmaceuticals, which is not possible or practical using current production methods. New drugs may be developed using plants as biological factories to fight diseases such as cancer, HIV, heart disease, arthritis and diabetes, among many others.
- Most pharmaceutical proteins today are produced using animal cell culture or microbial fermentation, which have limited production capacity. In addition,

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PMP production eliminates 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.

Even if only a small portion of the biologics currently in development turns out to be blockbuster drugs, crop plants could provide a viable alternative to traditional protein production methods. Because of this, we cannot afford to neglect this innovative technology. Crop plants that produce protein pharmaceuticals can provide drug manufacturers with an alternative source of proteins free of potential animal contaminants; they can boost manufacturing capacity while they lower capital investments; and they 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 hepatitis, 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,

Henry Milgrom, MD
Senior Faculty Member
Professor of Pediatrics