ASU AzBio

January 3, 2003

1126 [illegible]

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 am writing to support the FDA and USDA's development of guidelines to ensure the safe production of plant-made pharmaceutical (PMP) crops using commodity crops which are usually grown for food and feed.

I recognize that PMP technology represents a major opportunity for a new biomanufacturing means to obtain protein pharmaceuticals that will have broad benefit to human health. For the last twelve years I have personally been involved in academic research directed at the creation of new subunit vaccines for human and animal disease prevention. We have conducted three human clinical trials that have validated the concept of creating transgenic crops which contain orally active subunit vaccines. The basis of the immunogenic activity of these plants is that they contain transgenes that encode proteins that mimics an analogous protein from a pathogen. From a technical standpoint, I can state with great confidence that it will be possible to produce new, commercially acceptable oral vaccines in genetically modified crops; these will have unique advantages for safer and less expensive vaccines for human public health, and effective vaccines for production animals that will improve the safety of the food chain. I am, therefore, very supportive of developing a Federal Regulatory framework which will be necessary to have commercial development and introduction of these new products.

02D-0324

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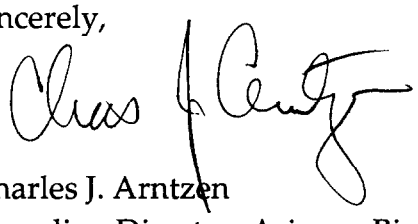
While I am very confident in the technical potential of PMPs, I also recognize the potential risks to agriculture and the food industry if PMP product development would result in public distrust of biomanufacturing using agricultural crops. The commercial success of PMP technology is predicated upon strong, transparent regulations. I personally feel strongly that any company or public sector research group wishing to participate in producing PMP products must adhere to strict stewardship principles and procedures. For this, strong regulatory guidelines are needed. I commend USDA and FDA for their efforts to call for comments on guidelines that allows for PMP technology advancement while also protecting the food supply. I strongly urge them to move rapidly to create the full regulatory framework so that the US can continue to be in a leadership position for high quality biotechnology products that have broad societal benefit, including new PMP-based products.

Sincerely,



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