ARIZONA STATE UNIVERSITY
COLLEGE OF LIBERAL ARTS AND SCIENCES
DEPARTMENT OF PLANT BIOLOGY
MAIN CAMPUS
PO BOX 871601
TEMPE, AZ 85287-1601
(480) 965-3414
FACSIMILE
(480) 965-6899

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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 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 that are usually grown for food and feed.

I recognize that PMP technology represents a major opportunity for a new biomanufacturing technology for protein pharmaceuticals that will have broad benefit to human health and agriculture. I have personally been involved for the past 12 years in academic research focused upon plant production of subunit vaccines for human and animal disease prevention. We have conducted three human clinical trials that have validated the concept of transgenic crops for delivery of orally active subunit vaccines. I am confident that we will be able to produce commercially acceptable oral vaccines in genetically modified crops; these will have unique advantages for safer and less expensive vaccines for human public health, and vaccines for production animals that 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.

While confident about the technical potential of PMPs, I also recognize the potential risks to agriculture and the food industry if PMP product development should result in public distrust of biomanufacturing using agricultural crops. The commercial success of PMP technology depends upon strong, transparent regulations. Any company that wishes to produce PMP products must adhere to strict stewardship principles and procedures, for which strong regulatory guidelines are needed. I commend USDA and FDA for their efforts to establish guidelines that allow 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 lead research on high quality biotechnology products that provide broad societal benefit, including new PMP-based products.

Sincerely,

Hugh S. Mason, Ph.D.
Associate Professor, Dept. of Plant Biology
Phone 480-727-8228
Email: hugh.mason@asu.edu

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