Biopharming Ad Hoc Committee
March 27, 2006
Meeting Minutes

Present

Members: Dr. Thayne Dutson, Bernie Faber, Dr. Keith Harcourt, Candace Mueller, Jim Rue, Gail Shibley, Bob Shoemaker, Dr. Steve Strauss, and Dr. Lisa Weasel. Katy Coba was unable to attend.
Staff: Shannon Brubaker, Dr. Paul Cieslak, Dr. Don Hansen, Christina Hartman, and Dr. Dave Stone.
Guests: Bruce Anderson, NW Food Processors Association; Dr. Daniel Goldstein, The Monsanto Company; Dr. Doug Gurian-Sherman, Center for Food Safety; Dan Floyd, Oregon Grocery Association; Rick North, Oregon Physicians for Social Responsibility; David Rosenfeld, Oregon Health Forum; and Terry Witt, Oregonians for Food and Shelter.

Handouts: March 27, 2006 Meeting Agenda; Final January 23, 2006 Meeting Minutes; DRAFT February 27, 2006 Meeting Minutes; Speaker Biosketches; Proposed Biopharm Taskforce Road Map, March 27, 2006; Department of Human Services and Oregon Department of Agriculture Statutes of Authority; Article – Biopharmaceuticals Derived from Genetically Modified Plants; Article – Responding to the Challenge of Novel Technology: An Industrial Hygiene and Safety Program for Antibody Production in Maize; and Presentation by Dr. Goldstein.

Meeting called to order at 1:08 p.m.

Introduction and Opening Remarks

Jim Rue welcomed the members and invited introductions.

The February 27, 2006 meeting minutes were approved as written.

Speaker Update and Roadmap

An updated Biopharm Taskforce Road Map including key placeholder dates for policymaking was distributed to the Committee members and discussed.

Dr. Daniel Goldstein, Senior Science Fellow, Director, Medical Toxicology, The Monsanto Company

Dr. Daniel Goldstein discussed the production of Plant-Made-Pharmaceutical (PMP) in food crops.

The advantages of using food crops for PMPs are:

- Natural selection favors plants with minimal resource investment in small, spontaneously dispersed seed;
- Agricultural crops are bred for large seed, high protein production, and reduced dispersal of seed;
- Food crops are easy to scale up or down;
- Seeds provide a great source of stability;
- Seeds are biologically designed to survive adverse conditions for a long period of time; and
- Using seeds provides greater storage stability and the ability to respond to demand in an emergency.

The production of PMPs in food crops shouldn't be rejected because of potential hazard but instead evaluated on a case-by-case basis defining the appropriate circumstances and conditions of use so that risks are managed. Risk is the function of two things, hazard and likelihood (Risk = Hazard x Likelihood). The risk is what happens if significant exposure occurs (hazard) and containment fails (likelihood).

PMP production is designed to be a closed loop management system from planting through harvesting using dedicated materials. While containment is the appropriate system for handling materials with low to moderate hazard potential, it isn't necessarily perfect. Limited exposure through pollen or dust and the remote possibility of subsistence consumption exists. One concern of containment failure is diversion to the food supply. Because PMPs are a largely diluted factor in the commodity chain and are something that would affect a small number of people, the potential risk of diversion to the food supply is low.

Dr. Goldstein provided some examples of the hazards associated with PMPs through dust, pollen, food, and nature of the PMP. While the hazard to humans is found to be negligible, systematically evaluating the hazard is still an important part of managing risk.

Businesses face risk to their status and public image as well as consequences of public wrath and increased government scrutiny. The ramifications businesses may face in the case of contamination resulting in an injury is that the product would be discontinued; and public debate and increased scrutiny would then be placed on the technology itself. The goal is to minimize if not eliminate the risk to the public and

from a regulatory standpoint, ensure that while businesses may fail to do their job, the public doesn't face any consequences.

Because minimal acreage is needed (approximately 10-20,000 acres) to produce a high drug yield and meet almost any imaginable pharmaceutical need, the impact on farmers is minimal.

Monsanto did have permits issued by the U.S. Department of Agriculture's (USDA), Animal and Plant Inspection Service (APHIS), but is not currently working in the PMP area and doesn't have any active permits.

Dr. Doug Gurian-Sherman, Center for Food Safety

Dr. Doug Gurian-Sherman discussed the potential health risk of pharmaceutical producing crops.

The technology surrounding PMPs is controversial. Because it's difficult for anyone to be completely objective, it's important to look at the data and note the certainties and uncertainties, risk and potential benefits and to then come to a conclusion.

Focus should be on regulating the industry instead of regulating field trials or commercialized biopharm crops. Currently, there are very few field trials and no commercialized products except for research purposes and while it's easy to regulate the extremes, the gray areas are still inevitable. The challenge that would arise if the technology took off is dealing with more trials and more opportunity for escape that in turn increases the uncertainties involved with the technology. Given the uncertainties and the difficulty of establishing case-by-case risk assessment, it's important to assess the cumulative risk and impact of the technology as well as the potential for human error.

In terms of the APHIS review, there is no formal environmental assessment required prior to planting and when environmental assessments are prepared, typically, a risk assessment is not required for field trials. For this reason the USDA relies heavily on confinement to prevent or limit risk which in turn increases the fitness potential for that gene to survive. Confinement requirements were strengthened several years ago to increase the isolation distances, stagger or alternate planting times and use dedicated equipment. Despite the new requirements, confinement can't be assured. A study done by the National Research Counsel (NRC) in 2004 found that methods for biological confinement of crop genes are imperfect, often not completely understood and can't be relied upon

to prevent contamination. A study done by the Union of Concerned Scientists found that there are multiple routes of contamination possible through gene flow, processing and equipment.

An important piece is to not underestimate but to acknowledge the uncertainties of exposure. Many crops with different characteristics provide various opportunities for escape and a lot of different levels of exposure.

The human health risks associated with PMPs are immunological risks and are difficult to assess because many factors such as age, health, does, etc. determines immune response. Immunological disease occurs when tolerance to normally harmless proteins breaks down and the lack of tolerance to inhaled or food proteins causes allergy and the loss of tolerance to self-proteins causes autoimmune diseases.

The uncertainties surrounding PMPs are that:

- Little risk assessment is done prior to commercialization;
- There are many opportunities for contamination or gene flow;
- Human health risks could occur at low-level exposure;
- Immunological risks are difficult to predict or test; and
- Until the product nears commercialization, many of the risks are unknown and even after testing, many risks will remain.

Dr. Gurian-Sherman agrees with the NRC that production of proteins in food crops are ill advised because of the many uncertainties of human health and environmental impacts and contamination.

Action: Dr. Gurian-Sherman to provide specific references for the 2004 studies done by the National Research Counsel and the Union of Concerned Scientists.

State Authorities and Legislative Placeholder – Chuck Craig

The Oregon Department of Agriculture (ODA) has submitted a legislative placeholder for biopharmaceutical crop regulation if that is something that the Committee decides is necessary or desirable. The last day ODA has to submit substantive information to the Office of the Legislative Counsel is June 14. If the language of the legislative placeholder is kept general, the bill can be amended once the legislative session begins.

Action: Updates of the legislative placeholder will be provided at the April meeting and will be addressed before the June deadline.

Administrative Issues

Proposed Biopharm Taskforce Road Map
Speakers that would provide legal and social/ethical perspectives were recommended as well as the views of an immunologist and allergist. Members expressed concern about the time line the Committee is faced with and the need to consider the goals of the task force before involving additional speakers.

Action: Dr. Gary Marchant from Arizona State University and Dr. Eric Flamm from the FDA will be invited to the April meeting and the Committee will continue discussing the direction that needs to be taken.

Committee members to provide topics of interest and recommendations of speakers to Dan Hilburn and Dave Stone.

Public Comments

Mr. North commented that while he agrees with Dr. Goldstein that there isn't a huge economic impact on farming, he disagrees with the impact to other species. Studies have shown harmful affects to over 20 species of insects. The vast majority of biopharm crop testing isn't testing for the affects on animals.

Meeting adjourned: 3:31 p.m.

The next Biopharm Ad Hoc Committee meeting will be held on:

Monday, April 24, 2006, 1-3 p.m.
Human Services Building, Rms. 137CD
500 Summer Street, NE, Salem

If you would like this these minutes in an alternate format,
please contact Christina Hartman at (971) 673-1291.