Biopharming Ad Hoc Committee
February 27, 2006
Meeting Minutes

Present
Members: Katy Coba, Bernie Faber, Keith Harcourt, Candace Mueller, Jim Rue, Gail Shibley, Steve Strauss and Lisa Weasel. Thayne Dutson and Bob Shoemaker were unable to attend.
Staff: Paul Cieslak, Chuck Craig, Dan Hilburn, Joel Sherman and Dave Stone.
Guests: Dr. Kirstin Carroll, Oregon State Outreach in Biotechnology Program; Rick North, Oregon Physicians for Social Responsibility; Dr. Carol Mallory-Smith, Oregon State University; Dr. Paul Jepson, Oregon State University; and Terry Witt, Oregonians for Food and Shelter.

Handouts: February 27, 2006 Meeting Agenda; DRAFT January 23, 2006 Meeting Minutes: Final December 19, 2005 Meeting Minutes: Revised Ad Hoc Committee Charge; Revised List of Members; Proposed Biopharm Taskforce Road Map; Article – Risk Analysis for Plant-Made Vaccines; Article – Transgenic Expression of Bean a-Amylase Inhibitor in Peas Results in Altered Structured and Immunogenicity; Article – Social Acceptance of Plant-Made Vaccines: Indications from a Public Survey; Report – Executive Summary, Blueprint for the Development of Plant-Derived Vaccines for the Poor in Developing Countries; and State Legislation Related to Biopharmaceutical or Industrial Crops.

Meeting called to order at 1:11 p.m.

Introduction and Opening Remarks
Jim Rue welcomed the members and invited introductions.

The January 23, 2006 meeting minutes were approved as written.

Speaker Update and Roadmap
Committee members approved of the proposed Biopharm Taskforce Road Map.

Administrative Issues
The need to develop an outline of the Committee's recommendations was discussed.

Action:
Members to use e-mail as a tool for discussion, specifically if they have a technical question or need clarification.

Dave Stone and Dan Hilburn will develop a draft outline by April 17 that identifies a range of potential outcomes. The outline will be discussed at the April 24

Biopharming Ad Hoc Committee meeting.

Permit Review Revisited – Dan Hilburn

An example of a permit was circulated for the Committee's review. The information provided on a permit and the information provide on a request is very similar. Confidential business information (CBI) is not included in the information received and reviewed by the Oregon Department of Agriculture (ODA). Requests are reviewed by the ODA for compliance with Oregon specific laws, quarantines and control issues. While Oregon does have statutory authority to establish control areas, they do not currently have specific statutory authority over genetically modified organisms (GMO).

State Matrix – Joel Sherman

A state matrix of proposed or enacted state legislation related to biopharmaceutical and industrial crops was distributed to the Committee in response to an action item approved by the Committee in January.

From the information provided, the theme of the action taken by most legislative bodies to address biopharmaceutical crops tends to focus on outright or limited prohibition although a few states have tried to establish tracking systems. Bills proposing to regulate crops failed more than the bills that proposed creating a study or task force.

Additional information can be found at:
http://pewagbiotech.org/resources/factsheets/legislation/.

Technical Materials – Dave Stone

An overview of the materials provided to the Committee members was provided.

- *Risk Analysis for Plant-Made Vaccines*. The article outlines the human health and environmental risks associated with plant-made vaccines. Some of the risks include: gene transfer; exposure to antigens in non-target organisms; oral tolerance; allergenicity; inconsistent dosage; worker exposure; and unintended exposure to antigens in the food chain. The United States Department of Agriculture (USDA) and the United States Food and Drug Administration (FDA) regulate many of the associated risks. The article also outlines potential benefits to human health.

- *Blueprint for the Development of Plant-Derived Vaccines for the Poor in Developing Countries*. The Blueprint is based on a series of four international consultations and outlines why plant-made vaccines may have potential economic and technical feasibility in developing countries.

- *Social Acceptance of Plant-Made Vaccines: Indications from a Public Survey*. The article highlights that public acceptance of plant-made vaccines is highly variable

depending upon global location and that through a survey of 706 respondents, there was strong potential support for plant-made vaccines. This may also indicate that there may be more support for medical biotechnology than with agricultural biotechnology.

- *Transgenic Expression of Bean Alpha-Amylase Inhibitor in Peas Resulted in Altered Structure and Immunogenicity*. The paper examined changes in structure in transgenic plants and reactions in mice that were fed these plants.

In recent news, Dow has received from the USDA Center for Veterinary Biologics, the world's first regulatory approval for a plant-made vaccine.

Dr. Paul Jepson, Professor and Director Integrated Plant Protection Center, Department of Entomology, Oregon State University

Dr. Jepson discussed ecological assessment and biotechnology.

The forms of ecological and economic risk tend to relate to: changes in the intensification state; gene flow to wild relative, seed crops and to sensitive neighboring crops; management of invasiveness; and impacts related to the gene crop.

With biotechnology, gene flow issues are the main concern. The reason for this concern is that:

- Practices can disrupt the normal disturbance dynamics of the system, exceeding its intrinsic resilience and potentially driving the system to a new adverse state;
- Practices can clearly cause an unacceptable effect on productivity on the environment within or beyond agriculture; and
- Practices can inhibit trade or other commercial activity.

To minimize the risk it is important to think about the complex system that we have and understand how all the pieces work together; and to define local conditions and sensitivities precisely. Dr. Jepson noted that Oregon has numerous distinct ecosystems that have varying climate, topography, biodiversity and other factors.

Action: Presentation by Dr. Jepson will be electronically distributed to the Committee members.

Dr. Carol Mallory-Smith, Professor, Crop and Soil Science, Oregon State University

Dr. Mallory discussed gene flow using the gene flow of rice, corn and safflower as an example.

Gene flow is the moving of a gene from one plant or population to another leading to the

presence of the gene in another plant. Gene flow is one of the major issues surrounding the introduction of biopharm crops and occurs through pollen and seed movement and vegetative propagation.

Pollen gene flow can be reduced by separation of the compatible species, biological barriers and other technologies that are being developed.

Gene flow through seed movement is easier than through pollen movement because there are many more avenues of escape and there isn't any need for compatible and receptive relatives.

Seed gene flow can be reduced by: adding safeguards to the system; monitoring; providing dedicated equipment; cleaning the equipment; producing the crops in areas where volunteers can be easily controlled; producing crops where there is no chance for admixture to occur; and using seeds of different colors so that they're easily recognizable.

Before layers of management can be placed, it's important to understand the biology of specific crops.

In terms of biopharm crops, 100% containment can't be guaranteed with the technology that currently exists as all systems are leaky to some degree.

Meeting adjourned: 3:00 p.m.

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

Monday, March 27, 2006, 1-3 p.m.
Portland State Office Building, Suite 913
800 NE Oregon Street, Portland

If you would like this these minutes in an alternate format,
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