Biopharming Ad Hoc Committee
December 19, 2005
Meeting Minutes

Present

Members: Katy Coba, Thayne Dutson, Bernie Faber, Keith Harcourt, Candace Mueller, Jim Rue, Gail Shibley, Steve Strauss, and Lisa Weasel. Sean Neilson was unable to attend.
Staff: Paul Cieslak, Chuck Craig, Don Hansen, Christina Hartman, Dan Hilburn, Joel Sherman, and Dave Stone.
Guests: Kirstin Carroll, PhD, Oregon State Outreach in Biotechnology Program; Shawn Miller, Oregon Grocery Association; Rick North, Oregon Physicians for Social Responsibility; and Terry Witt, Oregonians for Food and Shelter.

Handouts: December 19, 2005 Meeting Agenda; Meeting Schedule; Contact List of Members; Possible Stakeholder/Interested Parties List; DRAFT Charge; DRAFT November 28, 2005 Meeting Minutes; B-Engrossed SB 570; Oregon Department of Agriculture Written Testimony on SB 570; Oregon Department of Human Services Written Testimony on SB 570; APHIS Field Test Permits for Bio-Pharm Crops; Biopharm Related Experience in Other States and Countries; Letter from Food Products Association, Jeffrey T. Barach, PhD, to APHIS, Regulatory Analysis and Development dated March 25, 2005; Article: What's so Scary About Rice?; Article: The Side Effects of Drugged Crops; Article: On Risk and Plan-Based Bipharmaceuticals; Proposed Biopharm Taskforce Road Map; and Biosketch of Potential Speakers.

Meeting called to order by Jim Rue at 1:10 p.m.

<u>Administrative Issues</u>

Jim Rue welcomed the members and invited introductions. The Biopharming Ad Hoc Committee Charge was approved as written. The November 28, 2005 meeting minutes were approved as corrected.

Members discussed how to incorporate the positions and input of interested parties. *Decision*: Communication to interested parties will include clear directions on the options available for providing comments and input to the Committee. Information solicited from interested parties will be given to the technical workgroup. The technical workgroup will distribute information to the Committee and structure presentations of the interested parties at the Committee meetings or at a public meeting specifically scheduled for this purpose. Time at each meeting will be allotted for public comments.

Action:

- ***Include individual commodity groups on the list of interested parties. Members to submit individuals to include on the list of interested parties to Christina Hartman.***
- ***Research the possibility of developing a website for the Biopharming Ad Hoc Committee.***

Technical Workgroup Presentation

The technical workgroup provided an overview of the materials provided to the Committee members.

- *Article on risk and plant-based biopharmaceuticals by Robert K.D. Peterson and Charles J. Arntzen.* Examines the applicability of the risk assessment paradigm for assessing human and ecological risks from biopharmaceuticals.

  Comments: Problem formulation is a key aspect to addressing the risk assessment paradigm for biopharmaceuticals.

- *Two articles from Business Week and a letter from the Food Products Association (FPA) to the U.S. Department of Agriculture's (USDA), Animal and Plant Inspection Service (APHIS).* Provides background and reactions to rice plants genetically engineered to express the proteins human lysozyme or human lactoferrin (proteins normally found in breast milk, tears, and saliva) to be used to treat stomach disorders.

- *Biopharm Related Experience in Other States and Countries.* Summarizes three case studies done in California, Colorado, and Hawaii; and state and international regulations and proposed bills related to biotech crops.

  Comments: Shows that Oregon is not alone in their thinking as multiple states are proposing or have existing legislation regulating biotech crops.

  The case study of Hawaii, where a lawsuit was filed against the state to release confidential business information, highlights the policy and legal arguments involved with withholding confidential business information from public disclosure. In Oregon, records are mainly available to the public. If the Committee decided that as part of the review process the state would receive confidential business information, consideration of Oregon's ability to keep the information confidential would need to be discussed.

Action: Technical workgroup to put together a matrix to compare common tendencies and strengths of proposed or enacted legislation specifically showing whether: indoor, outdoor, bioindustrial, biopharmaceutical, non-food only, common pieces, and other unique experiences. This matrix will help Committee members determine what should or should not be considered.

- *Proposed Biopharm Taskforce Road Map and Biosketch of Potential Speakers.* Draft proposal of future agenda items and speakers for the Committee meetings.

  Comments: Since the deadline for draft legislation is April 15, both the Department of Agriculture and Department of Human Services will be submitting a legislative placeholder so that the Committee may have the opportunity to submit legislation at a later date if they wish to do so.

  Action: Members to provide comments on the proposed road map to Dan Hilburn and Dave Stone.

Speaker Presentation: California's Experience with Biopharming – David Nunenkamp, Deputy Secretary, California Department of Food and Agriculture.

David Nunenkamp provided a telephone presentation on California's experience with biotechnology.

California's focus has been on their agriculture policy as it relates to biotechnology and statutory structure not regulated by California but by the federal government. Because of the significant national and international ramifications, the USDA, APHIS, Biotechnology Regulatory Services (BRS) program, issues permits to those interested in field-testing a pharmaceutical or industrial crop after an extensive review process. BRS will not issue a permit over the state's objections. Once field tests are in place and permits are granted, they may be inspected by APHIS.

Through their experience with biotechnology, California has realized that: the government has done a dismal job communicating; people want to know the health effects; science provides conflicting answers; and the Food and Drug Administration (FDA) is unavailable much of the time when issues arise. These issues are clearly a driver for all states to look at ways to be involved directly in the verification and regulatory process.

In California, a field test of a rice product with lysozyme and lactoferrin was conducted and was moving towards commercialization. The developer lost the support of the people because they felt that the benefits to mankind offset any sort of risk. This arrogance combined with the action taken by the California Rice Commission, that has the benefit of statute to review applications and make recommendations to the Secretary of the California Department of Food and Agriculture, encouraged the developer to move on.

Discussion
The Committee discussed the role of the California Food Biotechnology Task Force and their report to the legislature.

If California were to remount their efforts, they would create a concrete contract outlining the authorities and responsibilities of the state and federal government that would then be used as a framework to assess various risks and how the risks can be minimized. The state would rely upon the federal government for enforcement and the state would do the audit and monitoring.

The federal government is working on creating a pilot program that would give some states the ability and funding to act as the monitor and inspector of the federal process for permits and notification. Conditions would require that the state inspectors be trained by BRS so they would have the background to determine if there's been a violation. The problem that some states may face is their ability to protect confidential business information. To protect confidential business information, changes would need to be made to the federal regulatory structure. This agreement would be welcomed by the states that wish to be actively involved with the federal government and to act as the service organization for them.

Mr. Nunenkamp suggested the Committee contact Cindy Smith, Deputy Administrator with BRS; and Rebecca Beck, Associate Deputy, Emerging and International Programs with BRS.

Public Comments

Conflict of interest – Following statute (ORS 244.120), Committee members will declare their potential conflict of interest if a vote could potentially benefit them or a family member. If there is an actual conflict of interest, the conflict of interest will be declared and the Committee member will refrain from voting.

Speakers – The Committee should seek out speakers that have conflicting opinions and then schedule their presentations for the same meeting. Speakers presenting to the Committee should also disclose if they have any financial arrangement with a

biopharm company.

The next Committee meeting will be used to discuss the economics of biopharming and to scope out the structure of the technical presentation and public comment.

Action: Steve Strauss and Lisa Weasel will work with the technical workgroup to identify potential speakers for the Committee meetings.

Meeting adjourned 3:14 p.m.

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

Monday, January 23, 2006, 1-3 p.m.
Portland State Office Building, Rm. 918
800 NE Oregon Street, Portland

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