Biopharming Ad Hoc Committee
January 23, 2006
Meeting Minutes

Present

Members: Katy Coba, Thayne Dutson, Bernie Faber, Keith Harcourt, Candace Mueller, Jim Rue, Gail Shibley, Bob Shoemaker, Steve Strauss, and Lisa Weasel.
Staff: Paul Cieslak, Chuck Craig, Don Hansen, Jim Kanoff, Joel Sherman, and Dave Stone.
Guests: Kirstin Carroll, PhD, Oregon State Outreach in Biotechnology Program; Joseph Cortright, Impressa Consulting; Rick North, Oregon Physicians for Social Responsibility; and Alex Pulaski, The Oregonian.

Handouts: January 23, 2006 Meeting Agenda; Final November 28, 2005 Meeting Minutes; DRAFT December 19, 2005 Meeting Minutes; Proposed Biopharm Taskforce Road Map; Article – The Myth of the Biotech Revolution; Bio-Pharming in Colorado: A Guide to Issues for Making Informed Choices; Evaluating Experimental Biotechnology Permits for Plant Made Industrial and Pharmaceutical Products in Colorado; U.S. Department of Agriculture, Office of Inspector General, Southwest Region, Audit Report, Animal and Plant Health Inspection Service Controls Over Issuance of Genetically Engineered Organism Release Permits, Executive Summary, Animal and Plant Health Inspection Service Controls Over Issuance of Genetically Engineered Organism Release Permits (Audit Report 50601-8-Te); Article – Federal Preemption and State Anti-"GM" Food Laws; Article – Revving up the Green Express; ORS 244.120; and example permit review.

Introduction and Opening Remarks

Jim Rue welcomed the members and invited introductions. Sean Neilson has resigned his position and has been replaced by Bob Shoemaker.

The December 19, 2005 meeting minutes were approved as written.

Conflict of Interest

Committee members discussed how conflicts of interest would be disclosed. Before deliberation or vote, the Chair will ask members to disclose whether they have a potential or actual conflict of interest and will then proceed on that basis as per statute. If there is an actual conflict of interest, the Committee member will refrain from voting.

Roadmap Review and Taskforce Discussion

The proposed Biopharm Taskforce Roadmap was distributed and discussed. Members discussed the direction that the Committee is taking and acknowledged

that while they need to consider all perspectives involved (science, social, ethical and legal), the focus of their policy recommendations needs to primarily be on the public health and agricultural aspects.

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

Members to review proposed roadmap and provide additional comments to Dan Hilburn, Dave Stone or Christina Hartman.

Permit Review Example – Don Hansen
An example of the request form that the Oregon Department of Agriculture (ODA) receives from the U.S. Department of Agriculture (USDA) was distributed to Committee members. Requests are reviewed by the ODA to see if any Oregon specific quarantines apply and to make sure that the request does not violate any of Oregon's existing rules.

Action: A copy of the amylase/alfalfa permit will be provided to the Committee.

Review Technical Materials – Dave Stone, Joel Sherman
The technical workgroup provided an overview of the materials provided to the Committee members.

- *USDA, Audit Report, Animal and Plant Health Inspection Service (APHIS) Controls Over Issuance of Genetically Engineered (GE) Organism Release Permits, Executive Summary*. The USDA conducted an internal audit of 91 sites in 22 different states and found:
    - APHIS needs to strengthen its accountability for field test of GE crops.
    - APHIS lacks the basic information about the field test sites they approve and are responsible for monitoring. To correct this, APHIS will begin using global position system (GPS) coordinates to identify the test sites.
    - APHIS doesn't review notification applicants' containment protocols.
    - At the conclusion of the field test, APHIS doesn't require permit holders to report on the final disposition of the GE pharmaceutical and industrial harvest, which were modified for nonfood purposes and may pose a threat to the food supply if unintentionally released.
    - APHIS, Biotechnology Regulatory Services (BRS) is responsible for providing oversight to another program of APHIS called the Plant Protection and Quarantine (PPQ) Program. Because of the lack of

coordination between the two, a memorandum of understanding was implemented to clarify responsibility for conducting inspections.
    - Violations were not followed up on or tracked.

  APHIS officials generally agreed with the recommendations stemming from the audit and have completed or began implementing 23 of the 28 recommendations.

- *Biopharming in Colorado: A Guide to Issues for Making Informed Choices, October 2004, Summary Report and Evaluating Experimental Biotechnology Permits for Plant Made Industrial and Pharmaceutical Products in Colorado*. Colorado developed a process for evaluating experimental biotechnology permits with input provided by four stakeholder groups, one in each quadrant of the state. Included in the process are the steps the Colorado Department of Agriculture (CDA) will go through to provide information to the public, the timeline for the evaluation and the steps taken to see if there are any Colorado specific issues that would apply and need to be regulated. Rather than making general rules surrounding biopharming, Colorado evaluates each permit on a case-by-case basis, looking at the individual circumstances surrounding each permit. In conversations with Colorado, their input was that the decisions should rely neither on fear nor on hope but rather on a rational approach. In relation to the economic aspect, biopharming could be economically beneficial if it were part of an integrated system, not only attracting crop production, but research and development activity and processing facilities.

Joseph Cortright, President, Impressa Consulting

Impressa consulting studies regional and metropolitan economics and in particular focuses on industries that seem to be primarily driven by fundamental advances in knowledge. Most recently they completed a study for the Brookings Institution of the biotechnology industry in the United States.

The study looked at the distribution of the biotechnology industry, focusing on the top 51 metropolitan areas in the United States. Most biotechnology products tend to be human diagnostic and therapeutic products. The biotechnology industry is comprised of two very big distinct segments; large global firms that manufacture and distribute pharmaceuticals throughout the world and small single establishment firms. Most big pharmaceutical companies outsource their research and development functions to small biotechnology companies. Because the chance of success is very remote, investment strategies are planned around the notion of failure.

The biotechnology industry is a pyramid of a lot of research activity with only a few things being distributed on the marketplace. For example, at any one time there are about 25,000 National Institutes of Health (NIH) funded research products with approximately 5,000 biomedical related patents issued in the United States each year. While approximately 100 drugs are in the final stages of the Food and Drug Administration approval process, actually only about ten products account for nearly all the sales in the industry.

The biotechnology industry is concentrated in Boston, San Francisco, Philadelphia, New York, San Diego, Seattle, Raleigh-Durham, Washington/Baltimore and Los Angeles. Using six measures of research and commercialization as a focus, it was found that these nine biotech regions are leaders because they have strong research capacity and the ability to convert research into successful commercial activity.

Signs of Life: The Growth of Biotechnology Centers in the US can be found at http://www.brookings.edu/es/urban/publications/biotech.pdf.

Dr. Neil Hoffman, Animal and Plant Inspection Services (APHIS), Biotechnology Regulatory Services (BRS)

If commercialization of a plant product will require approval from the FDA's Center for Drug Evaluation and Research or the FDA's Center for Veterinary Medicine or the USDA's Center for Veterinary Biologics, then the engineered plant is considered to be a pharmaceutical crop. The first pharmaceutical permit was issued in 1991 and since then about 90 permits have been issued.

According to APHIS:

- Confinement measures must prevent inadvertent human exposure and minimize occupational and environmental exposure.
- The permittee must ensure rigorous compliance, develop methods for detecting the products and cooperate fully with regulators.

Confined field trials are reviewed by BRS for: the reproductive biology of the organism; engineered traits; environmental conditions; site security; monitoring; inspection; plans for termination; and post-harvest monitoring and land use. There are also a series of standard operating procedures that the applicant provides to APHIS that must be approved prior to the field trials being approved.

Key components to confined field trials include: training, crop selection, site, contracting, product considerations, documentation, disposal, compliance, monitoring, remediation and security.

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

Monday, February 27, 2006, 1-3 p.m.
Human Services Building, Rms. 137AB
500 Summer Street, NE, Salem

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