Final
Biopharming Ad Hoc Committee
July 24, 2006
Meeting Minutes

Present
Members: Katy Coba, Dr. Thayne Dutson, Bernie Faber, Dr. Keith Harcourt, Candace Mueller, Jim Rue, Bob Shoemaker, Gail Shibley, Dr. Steve Strauss, and Dr. Lisa Weasel.
Staff: Shannon Brubaker, Dr. Don Hansen, Dr. Dan Hilburn, and Dr. Dave Stone.
Guests: Rick North, Oregon Physicians for Social Responsibility, David Rosenfeld, Oregon Health News, and Terry Witt, Oregonians for Food and Shelter.

Handouts: July 24, 2006 Meeting Agenda and Meeting Schedule, Final May 22, 2006 Meeting Minutes, Draft June 19, 2006 Meeting Minutes, Draft – Oregon Biopharmaceutical Committee Policy Statement & Recommendations Document, Draft – Consensus views of Oregon Biopharm Committee, Example – USDA, APHIS Memorandum of Understanding.

Meeting called to order at 1:06 p.m.

Introduction and Opening Remarks

Jim Rue welcomed the members and invited introductions.

The June 19, 2006 meeting minutes were approved with no changes.

Roadmap

Jim Rue, gave an overview of the upcoming meetings, he explained to the committee the process for public comment on the policy recommendations, explaining that the document will be posted for 30 days on the Internet and that public will be able to submit comments to the committee for consideration. He explained that the committee will need to come to a consensus by October 1, in order for state agency drafting.

The committee decided that the August meeting should be canceled and that all public comment will be reviewed at the September 25th meeting.

Policy Discussion

Below is a copy of the first draft of the Policy Statement and Recommendations. After each paragraph there are discussion notes brought up at the Committee meeting.

The Oregon Department of Agriculture (ODA) and Department of Human Services (DHS), charged by the Governor and the Senate, convened a Biopharmaceutical Ad Hoc Committee, in November 2005. The Committee's goal was to develop a consensus policy recommendation to the Governor for the possibility of future biopharmaceuticals produced in Oregon. Biopharmaceuticals or biopharm refers to the use of plants that have been modified via recombinant DNA processes (i.e. "genetic engineering") to produce medicinal compounds such as vaccines and enzymes. The Committee co-chaired by Jim Rue and Keith Harcourt had ten standing members including three members from the State Board of Agriculture, three members from the Public Health Advisory Board, two scientists from Oregon public universities and two ex-officio members, the director of the Department of Agriculture and the administrator for the Office of Environmental Public Health.

> *The Committee noted that in sentence three the committee had not been "co chaired" but that there is a designated Chair (Jim Rue) and a designated Vice Chair (Keith Harcourt), they also noted that the "two ex-officio members" should be noted as non-voting members.*

The committee convened in November 2005 and met monthly through September 2006. During the first seven meetings, the committee heard detailed oral and/or written testimony from 12 academic and national institute scientists, state and federal regulatory officials, an economics consultant, and a representative of a non-governmental organization.[1] The speakers had diverse expertise and expressed a wide variety of views on the benefits and risks of biopharm crops.

> *The Committee asked that in sentence one the notation of "monthly" meetings be changed to "a total of 10 times" and at the end of the paragraph that the statement "All meetings were open to the public and non-government entities offered regular comment plus electronic submission of public comment was received." be added.*

The committee considered a number of formal recommendation options for the Governor of Oregon, ranging from a complete ban of biopharm crops to unqualified endorsement. The committee chose "endorsement, moderate scope" to indicate that it supports wisely chosen and carefully studied applications of biopharm technology in Oregon. The "moderate scope" choice option, however, reflected the committee's interest in substantial State of Oregon involvement in federal regulatory decisions about where and how biopharm crops may be grown in Oregon; how specific farmers, products, and markets for State products may be impacted; and because of the

[1] The presenters were Joseph Cortright, Impressa Consulting; Eric Flamm, FDA; Dr. Daniel Goldstein, MD, Monsanto; Prof. Richard Goodman, PhD, University of Nebraska; Douglas Gurian-Sherman, PhD, Center for Food Safety; Neil Hoffmann, PhD, USDA APHIS; Prof. Paul Jepson, Toxicology, Oregon State University; Dean Metcalfe, PhD, National Institute for Allergy & Infectious Disease, NIH; Prof. Carol Mallory-Smith, Crop Science, Oregon State University; Gary Marchant, Esq., Arizona State University; David Nunekamp, California Dept. Food and Ag;

complexity of this technology, the importance of substantial outreach/communication to the public about the scientific benefits and risks.

The Committee asked that there be an additional statement added to this paragraph that explained how difficult the decision-making process was do to the novelty, complexity, and limited public information of this particular subject. Also, to add a statement on the importance of communication on the benefits and risks of biopharming to the public.

The committee considered the particularly contentious issue of the use of food crops for biopharm products. In some cases, food crops are expected to be the safest and most economically efficient means for production because of advantages in storage, stability, consistency, purity, yield, and rapid scalability to meet highly diverse and customized medical needs, and changing demand (e.g., in response to disease epidemics). The economic efficiencies from use of field-grown food crops could also be substantial and enabling in cases where large scale and low cost production are critical (e.g., for an animal vaccine against bird flu).

The committee did not discuss changes to this paragraph.

The committee felt that applications in food crops should be reserved for products that have been through at least an initial safety assessment, as is currently now recommended by Food and Drug Administration (FDA), prior to large scale field trials and commercial use. Applications in food crops should also occur only in cases where similar products and efficiencies could not clearly be obtained in alternative non-food host crops in Oregon. Unless biopharm products have been judged to be presumptively safe for consumption by FDA, applications in food crops should require that very strict containment procedures are in place (examples include cultivation in locked greenhouses; use of fully sterile host varieties; large isolation distances from interfertile species; growth out of phenological synchrony with interfertile relatives; use of separate farm equipment; and strict monitoring and reporting). These, and other safeguards, are reflected in the current requirements for a permit for field trials of biopharm crops from United States Department of Agriculture's Animal and Plant Health Inspection Service (APHIS).

It was discussed that an emphasis should be added addressing the need for clear communication and criteria from FDA and USDA.

The committee recognizes that absolute containment of biopharm crops, whether grown in a normal greenhouse environment or in the field, is impossible to attain. This is a consequence of human error, theft, and movement of seeds and pollen via wind, water, or biological agents. However, it also recognizes that the low level adventitious presence of biopharmaceutical products that will occur in most cases from unintended dispersal is not likely to pose significant impacts on human or environmental health. Products for which adventitious presence would be likely to cause significant legal or safety issues (such as food crops with direct oral activity), or for which there are significant scientific uncertainties, should therefore not be grown without strict containment procedures in place.

The committee recognizes that the public signal sent by legislation or new rules about biopharm crops is more important in the near-term than are its effects on economics or safety, since no biopharm crops are currently proposed for production in Oregon. The committee believes that strongly restrictive laws or rules by the State might be viewed as a sign of hostility to biotechnologies generally, possibly limiting new biotechnology companies from starting here, or preventing established companies from considering relocation here.

The committee asked that there be an emphasis added to this section about the development of technology and that in order for Oregon to stay competitive in agriculture, new sciences should be considered and encouraged. Katy Coba offered to rewrite this section to include those specifics.

The committee concluded that a case-by-case regulatory approach, rather than a prescriptive or prohibitory approach, is warranted because of the enormous diversity in safety and benefits from different biopharm products, crop hosts, environments, and legal and regulatory frameworks. The committee therefore neither endorses nor rejects, all forms of biopharm technology. The committee also does not endorse or reject all applications of biopharm technology in food crops. The committee believes that a greater role for collaboration and oversight by the State of Oregon, with respect to Oregon-specific issues would be beneficial to Oregonians and our environmental and economic health. Therefore, the Oregon biopharmaceutical committee recommends the following to the Governor's Office:

- Encourage the exploration of beneficial applications of new technologies in Oregon, such as biopharmaceutical production, while protecting and maintaining public health, economical vitality and the environment.

  It was decided to add wording that would emphasize the current importance of Oregon agriculture. In addition that as long as Oregon continues to invest in research centers and technological development that bioindustrial/bioenergy should be considered as areas of investment.

- Collaborate with the United States Department of Agriculture's Biotechnology Regulatory Services (BRS) in the review and determination of permits to grow biopharmaceuticals in Oregon. The intent of collaboration is not to duplicate the efforts of APHIS, rather to allow the State to provide input on Oregon-specific issues and requirements.

- Formalize collaboration between BRS and the State of Oregon through a memorandum of understanding (MOU) or contractual agreement. The taskforce specifically recommends that any collaboration contain the following provisions:

  - As part of a state-federal cooperative, we recommend that information pertaining to the location, crop used, anticipated planting date and intended Plant Made

Pharmaceutical be disclosed to designated officials at the State before a trial permit is granted, and that appropriate authority be granted to the designated State Agency that would allow that Agency to maintain the level of confidentiality required to protect the confidential business information submitted to designated officials.

- All required protocols and tests conducted for bio-containment (such as sterilization techniques) and public health (such as allergencity tests) be disclosed to designated officials at the State before a permit is granted.

  Add sentences addressing monitoring and reporting, and the disclosure of the information to designated officials.

- Authorize the Directors of Agriculture and Public Health to modify, restrict or veto a permit for field trials in the State if deemed appropriate.

  The committee wanted to add a bullet that would outline the role of the Department of Ag and Public Health in the permitting process.

- Encourage the use of non-human food or animal feed crops for biopharmaceutical applications in outdoor environments when feasible. If human food or animal feed crops are selected, it is recommended that greenhouse production be utilized.

  Add to this section wording that an applicant proposing the outdoor growing of biopharmaceuticals using food crops must include a detailed justification for why outdoor growing is considered safe. Dr. Weasel and Dr Strauss indicated that they would help to rewrite this bullet.

- Require that upon permit approval for outdoor growth of biopharmaceuticals, applicants post a bond that would cover potential damages incurred from contamination or harm as a result of inadvertent release or the adventitious presence of the biopharmaceutical products in the environment.

  Add that the applicant must demonstrate financial responsibility to help cover any potential damages and require a mitigation plan for potential contamination.

- Authorize the Directors of Agriculture and Human Services through appropriate legislation to implement a state permitting system if the quantity or complexity of biopharmaceutical permit review becomes a resource burden. An application fee would cover the cost of staff time and resources spent reviewing permits.

  Add the need for a public communications plan that would address the application process, information on biopharmaceutical technologies, and also a plan for public comment on specific permits.

Public Comments

Rick North, Oregon Physicians for Social Responsibility asked if this proposed policy is to be submitted for legislation or is the intent for it to go through a rule process.

Katy Coba answered: First it is the intent for legislation to be sure we have all the regulatory authority for the process, second to be sure the issue of confidentiality is addressed statutorily, and finally to authorize the state to collect a permit fee to cover the costs. Katy added that if legislation did not go through that we would be able to do most of what's outlined in the policy document within the rule making process.

Meeting adjourned: 3:22 p.m.

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

Monday, September 25, 2006, 1-3 p.m.
Oregon Dept. Of Agriculture
635 Capitol St NE – Conf Room D
Salem, OR

If you would like this these minutes in an alternate format,
please contact Shannon Brubaker at (503) 986-4660.