Final
Biopharming Ad Hoc Committee
April 24, 2006
Meeting Minutes

Present

Members: Dr. Thayne Dutson, Bernie Faber, Dr. Keith Harcourt, Candace Mueller, Jim Rue, Bob Shoemaker, Dr. Steve Strauss and Dr. Lisa Weasel. Gail Shibley was unable to attend.
Staff: Shannon Brubaker, Dr. Paul Cieslak, Chuck Craig, Dr. Don Hansen, Christina Hartman, Dr. Dan Hilburn, Joel Sherman and Dr. Dave Stone.
Guests: Dr. Eric Flamm, Food and Drug Administration; Rose Kachadoorian; Diane Lund, Oregon Health Forum; Dr. Gary Marchant, Arizona State University; Shawn Miller, Oregon Grocery Association; Rick North, Oregon Physicians for Social Responsibility; and Terry Witt, Oregonians for Food and Shelter.

Handouts: April 24, 2006 Meeting Agenda; Final February 27, 2006 Meeting Minutes; DRAFT March 27, 2006 Meeting Minutes; Article – From General Policy to Legal Rule: Aspirations and Limitations of the Precautionary Principle; Guidance for Industry Drugs, Biologics, and Medical Devices Derived from Bioengineered Plants for Use in Humans and Animals; and Biopharm Policy Options.

Meeting called to order at 1:04 p.m.

Introduction and Opening Remarks

Jim Rue welcomed the members and invited introductions.

The March 27, 2006 meeting minutes were approved once corrected to reflect that Dr. Kirstin Carroll did not attend the meeting.

Speaker Update
Dr. Charles Arntzen is scheduled to present at the May meeting. At the request of the Committee, the additional speaker for May will be one with opposing or similar views to those of Dr. Arntzen or a presentation by an immunologist/allergist pertaining to Genetically Modified Organisms (GMO's). Dependent upon the additional speaker for the May meeting, the immunologist/allergist may present at the June meeting.

Meeting Dates
Members discussed the need to reschedule the June 26 and the August 28 meetings. Members proposed that the June 26 meeting be rescheduled to June 19 and that a decision be finalized through e-mail. The rescheduling of the August meeting will be discussed at a future Committee meeting.

Action:
If unable to reschedule the June meeting, a recording of the meeting will be made available.

Dr. Eric Flamm, Food and Drug Administration
Dr. Eric Flamm provided a general overview of how the Food and Drug Administration (FDA) regulates foods and food crops.

Generally, there is very limited pre-market oversight of foods. Marketers, sponsors and developers of new foods are obligated to put only safe, wholesome and properly labeled food on the market. Pesticides and food additives (substances that could become a component of food or intended for use in food) must get FDA approval. Bioengineering falls into the category of a food additive because a greater range of substances can be introduced into the food through breeding.

The FDA has drafted an outline focusing on bioengineering that includes guidance for the industry and evaluations that would be needed to meet the legal responsibility of marketing wholesome properly labeled food. The FDA is recommending that they be involved at the research stage because of concerns with materials from the field trial getting into the food supply.

The U.S. Department of Agriculture's (USDA), Animal and Plan Inspection Service (APHIS) has oversight over field trials and commercialization of bioengineered crops including biopharmaceutical crops. The FDA relies on APHIS to keep the materials used in pharmaceutical crops out of the food supply.

Do legal pathways exist to facilitate approval of biopharmaceutical products for commercial use? What are they and what laws or regulations govern them?
Pharmaceuticals have to go through FDA approval regardless of how they are produced. The same laws for pharmaceuticals also apply for biopharmaceuticals.

What are the major risks/unknowns/costs for industry among these pathways?
The risk is unknown. The issue surrounding biopharmaceuticals is public

acceptance.

How is regulatory authority shared among FDA and other agencies?
APHIS and FDA share oversight of food safety. FDA approves pharmaceuticals.

How do the pathways differ from conventionally produced pharmaceuticals?
The pathways do not differ once through the purification stage.

A majority of pharmaceuticals produced by non-bioengineered plants are exempt from controlled substances based on certain criteria. Pharmaceutical crops will not be categorically exempt and will require an environmental assessment.

Do both APHIS and FDA do an environmental assessment at some point?
FDA does an environmental assessment at the Investigational New Drug (IND) stage and APHIS does an environmental assessment prior to deregulating crops. Dr. Gary Marchant indicated that APHIS also does an environmental assessment when a permit application is received.

Assuming that there will be some adventitious presence in food if biopharm crops are raised in outdoor environments, is there a legal allowance now, or could there be in the near future, for tolerances or other avenues so industries do not face "StarLink-like" risks and costs? What are they?
Dr. Flamm doesn't foresee any way the FDA could make across the board limits for Plant-Made-Pharmaceuticals (PMP) because it's the safety of the food that matters, not the amount in the food supply. For this reason, the FDA published early protein safety assessment guidelines.

Are there new developments toward the establishment of tolerances? Can tolerances be applied at the research stage in any form, prior to commercial approval of products?
If the FDA judges that a product is safe, there would be no need to set a tolerance. If the protein is proven to not be biologically active, and there are no digestibility issues or allergens or toxins, the protein is considered to be potentially harmless.

What are the legal precedents and framework under which legal/risk issues should be viewed for biopharmaceuticals? Does actual harm need to be proven, or is perception of harm adequate for legal damages?
From the FDA perspective, what matters most is potential harm. If there's accidental contamination but the product was found to not pose any risk, then there would not be any legal damage but if a review was not done and the product was

found to be harmful, then there could be some legal damage.

Dr. Gary Marchant, Arizona State University
Dr. Gary Marchant agreed with the information provided by Dr. Flamm and provided that in terms of the regulatory process, the state can veto the permit or include restrictions in addition to those set by the USDA.

New draft guidance for APHIS permits was distributed in March that provides guidance to companies for biopharmaceuticals.

With respect to legal issues and the risk involved, even if the FDA recognizes that a product is safe, there may still be consumers, plant processors or food manufacturers that think they were harmed and would in turn bring forth potential lawsuits causing economic harm. There is also the potential for litigation against farmers growing the same crop as those of the vendor.

Draft Policy Options Discussion
Members discussed the process the Committee is currently employing, next steps, changes, and content of the policy statement.

The final document is due September 25 which leaves the Committee only five months to produce a product. Members came up with the following suggestions:

- Adjust the process to weigh the benefits and burdens. While a lot has been discussed about risk, the Committee hasn't fully explored the benefits.
- Weigh the benefit, risk and legality of all the information presented.
- Provide outreach and the opportunity for the public to comment.
- Decide if the state needs to do anything based on federal regulation.

If part of the Committee's policy statement includes proposing legislation, the last day to submit information to the Office of the Legislative Counsel for drafting is July 14.

Action:
Technical staff will invite a speaker to one of the next few meetings to present the benefits of biopharming.

Public participation component – once a policy statement has been drafted, it will be posted to the web and the media will be notified. Interested parties will be provided the opportunity to get involved and comment.

Members were asked to decide which policy option they recommend. Time to discuss the options will be devoted at the May meeting.

- **Option A – No taskforce policy/action.**
- **Option B – Endorsement of biopharma.**
- **Option C – Complete ban of biopharma.**
- **Option D – Specific policy options.**

Public Comments

Rick North asked that the technical staff follow up with Dr. Flamm as to whether or not there are any biopharm crops in clinical trial. He also requested clarification on whether or not the state had veto power over APHIS. Rick also clarified that the Oregon Physicians for Social Responsibility does not oppose biopharmaceutical genetically modified crops, but the outside growing of the crops.

Terry Witt provided that he would like to see some sort of communication mechanism developed to educate the public on the biopharming issues but cautioned that polling the public may get skewed results and that rather than having the public debate the issue through this Committee, the issue should be debated through the legislative process. He also requested that the Committee be careful to not close Oregon down on any emerging technology that has potential benefits.

Meeting adjourned: 3:12 p.m.

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

Monday, May 22, 2006, 1-3 p.m.
Portland State Office Building, Suite 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.