Final
Biopharming Ad Hoc Committee
June 19, 2006
Meeting Minutes

Present
Members: Katy Coba, 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, Chuck Craig, Dr. Don Hansen, Dr. Dan Hilburn, and Dr. Dave Stone.
Guests: Angela Crowley-Koch, Oregon Physicians for Social Responsibility; Oregonian; Dan Floyd, Oregon Grocery Association; David Harry, Outreach Biotechnology – OSU; David Rosenfeld, Oregon Health News; and Terry Witt, Oregonians for Food and Shelter.

Handouts: June 19, 2006 Meeting Agenda and Meeting Schedule, Final April 24, 2006 Meeting Minutes, Draft May 22, 2006 Meeting Minutes, Article – Can we Predict or Avoid the Allergenic Potential of Genetically Modified Organisms? by Gerhard Oberrmeyer and Fatima Ferreira, Questions – Comments on the Possibility of Allergic Reactions related to Biopharm Crops by Dr. Richard Goodman University of Nebraska and Biopharm Policy Options.

Meeting called to order at 1:10 p.m.

Introduction and Opening Remarks

Jim Rue welcomed the members and invited introductions.

The May 22, 2006 meeting minutes were approved with no changes.

Roadmap

Jim Rue, gave an overview of the upcoming meetings, he clarified to the Committee that in order to have a policy drafted by the end of September that there should be some guidance to staff by the end of the meeting on the direction the Committee wants to go. A draft policy could then be ready for the August meeting. The draft policy will then be posted on the internet for public comment which will close before the September meeting; September's meeting should be a final discussion on the policy.

Dr. Dean Metcalfe, Chief of th Laboratory of Allergic Diseases, National Institute of Allergy and Infectious Disease.

Dr Metcalfe, was given three questions of concern to answer, as follows:

1) Do you believe that the differences ion glycosylation of proteins between plant species used as hosts, or between human/animal and plant hosts, present serious concerns for allergy or auto-immune diseases as a result of adventitious presence?

   No, as a general rule Dr, Metcalfe doesn't. We are constantly taking on proteins from multiple sources, including plant, insect, viruses and bacteria. All of these organisms that are constantly being ingested, have proteins of various glycosylation. If there is going to be a difference in that kind of thing that's going to lead to an auto-immune disease and we could identify we would have probably seen it. Remember that when you eat anything or even just breath you are taking in all of these organisms all of the time. You are not excluded from those so, Dr. Metcalfe finds that as a theoretical possibility it is very low.
2) In particular, do you believe that production of human or animal derived anti-bodies or vaccines in biopharm crops might present new and significant allergy or auto-immune problems as a result of adventitious presence?

   Dr. Metcalfe feels that what really needs to be done is to do a vaccine assessment like you do with any vaccines and as we well know that some vaccine attempts over the years have actually been destructive, some have lead to Demyelinating Syndromes, some have made common viral infections become worse, so any vaccine or biological product that is engineered into a plant or animal must be extracted and studied by all of the usual techniques to make sure that the vaccine is not going to be harmful. Many vaccines cannot be taken orally or the vaccines require active immunity so it is unclear how many vaccines can be made that you could eat in an apple or banana's that are really going to have a major effect on changing the immune system. So this has to be looked on a case by case basis, because those proteins are engineered to create an immune response you have to make sure that the immune response, particularly in very close to human models, is not harmful. This is different than allergenicity because the product is being designed to affect the immune system.
3) Please comment, in general, on your view of the value, benefits, and risks of biopharm crops – including whether you agree or disagree with the statement of

there should be no outdoor-grown food crops used for biopharm products, of any kind.

Dr Metcallfe feels that this is an extreme position if you look at the problems worldwide that people are faced with now. Standard ways of engineering crops, as far as increased productivity, have really reached their limit and either we have to figure out a way to get population under control, or we have to increase yield and you can do so by a lot of these engineering techniques. You can also get away from using pesticides and other agents of that sort in some of these situations. There is no question that you can do a lot of good things by using engineered crops. On the downside you have to be aware of the safety risks and make an assessment on each crop on the varied possibilities that you are concerned with, everything from gene drift, facilitating weed growth, to whether or not it induces an improper immune response. It is one of those situations where you don't throw out the technology because of concerns. We should do risk assessments to be safe. That kind of idea of zero tolerance isn't going to work.

We do not want to get complacent, but you certainly do not want to stop technology growth on the basis of concerns that are hard to substantiate in terms of something may happen. Another practical problem is that many places in this world, like China, are going to go ahead anyway so you have to find a way to deal with that. We should not let down our guard and should be sure there is a guided analysis on each product to make an informed decision.

(Note: the above statements are only the views of Dr. Metcalfe on bio-technology not the views of any government entity.)

Taskforce Policy Dialogue

Jim Rue reviewed the options explaining that each option can combine details that are in a different option. He explained that from the discussions he has heard he feels that the Committee is leaning more toward Option D, which could include a more limited scope, a moderate scope, or a strict scope. He requested that the Committee come up with some guidance to the staff so that the process toward drafting a policy can occur before our next meeting in July.

Guidance to staff is as follows:

• Consider the possibility of using the Department of Ag's current statutory authority to approach this in a Control Area Order fashion.
• Consider the case-by-case approach. If there is a permit submitted to the USDA to do biopharma then what will the states response be.
• Keep in mind the issues of confidentiality, currently the state does not have the right to kepp some information confidential. It may take a statutory change to allow this type of information to be withheld.
• Fees will need to be a critical portion so there is appropriate funding for oversight, review and monitoring.
• The state should establish an agreement with the USDA that clearly defines the roles of the state and federal government in regards to the biopharma crops. Staff should review the existing agreement between the Colorado Dept. of Ag and the USDA for specifics.
• The state's policy might require the permitee to pay for monitoring of adventitious presence on a wide scale, to help provide assurance to the markets that the levels are low or at zero presence.
• Existing state quarantines, such as European corn borer, can help to determine if the plant species is allowed in to our state. These may be considered as Oregon specific guidelines.

Staff asked the members of the Committee to send them via email their list of primary concerns and principles so that they can be compiled into a summary.

Public Comments

Terri Witt, Oregonians for Food and Shelter stated that he agrees with Katy on the confidentiality issue and that needs to be strongly considered as a part of this issue. The Committee should also consider that there may be some differences to look at in the biotechnology realm from the production end as well as from the developing end, because there may be some differences in terms of the way you would regulate it. We need to be sure that we do not preclude research and development at OHSU, PSU or OSU where it should be encouraged. The Committee should also look at the position the state has taken on Nanotechnology and use some of that as a model, because there is support for that technology which raises a lot of concerns but also a lot of benefits.

Angela Crowley-Koch, Physicians for Social Responsibility stated that in regards to the speaker's opinion of whether growing of plants for biopharma should be indoor or outdoor that he never answered the question. Also she commented on an example concerning a retinal disease that could be noticed long-term but not

immediately. This relates to an earlier statement about there were no allergies that had been noticed. So then the question becomes, has there really been any tests? Keep in mind that while there haven't been substantiated complaints, safety hasn't been proven or non allergy development.

Dr. Strauss pointed out that there have been some studies done.

Meeting adjourned: 3:24 p.m.

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

Monday, July 24, 2006, 1-3 p.m.
Portland State Office Building
800 NE Oregon St – Room 120B
Portland, OR

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