FINAL
Biopharming Ad Hoc Committee
September 25, 2006
Meeting Minutes

Present
Members: Katy Coba, Dr. Thayne Dutson, Bernie Faber, Dr. Keith Harcourt, Candace Mueller, Bob Shoemaker, Gail Shibley, Dr. Steve Strauss, and Dr. Lisa Weasel. Candace Mueller and Jim Rue were unable to attend.
Staff: Shannon Brubaker, Dr. Paul Cieslak, Dr. Don Hansen, Dr. Dan Hilburn, and Dr. Dave Stone.
Guests: Dalton Hobbs, Oregon Dept. Of Agriculture, Rick North, Oregon Physicians for Social Responsibility, Bruce Pokarny, Oregon Dept. Of Agriculture, Alex Pulaski, The Oregonian, David Rosenfeld, Oregon Health News, and Terry Witt, Oregonians for Food and Shelter.

Handouts: September 25, 2006 Meeting Agenda and Meeting Schedule, Final June 19, 2006 Meeting Minutes, Draft July 24, 2006 Meeting Minutes, Draft – Oregon Biopharmaceutical Committee Policy Statement & Recommendations Document, All public comment received as of 5 pm September 22, 2006.

Meeting called to order at 1:11 p.m.

Introduction and Opening Remarks

Keith Harcourt welcomed the members and invited introductions.

The July 24, 2006 meeting minutes were approved with no changes.

End of the Roadmap Review

Keith Harcourt, reminded the Committee that this is the last scheduled meeting although, if necessary, an additional meeting could be arranged to further discuss the public comments and the final proposal to the Governor.

Discussion of public comments on the draft biopharm policy and revisions to the policy.

The Committee discussed the comments submitted by the interested parties, stakeholders and citizens of Oregon.

This is a summary of the public comments:

Public comments submitted:

Con biopharm:	17*
Pro biopharm:	3
Mixed:	6
Comments only:	5

Unclear: 1

32

Comments from:

Oregon: 20
Other states: 7**
Unknown: 5

Issues raised:

Human Health concerns: 11 (32%)
Environmental concerns: 10 (31%)
Federal oversight deficits: 6 (19%)
Adverse economic impact: 6 (19%)
Corporate trust concerns: 6 (19%)
GM Bentgrass example: 6 (19%)
Use of public funds: 5 (16%)
Burdensome state involvement: 1 (3%)

Comments received by:

Citizens of Oregon
Organic farmers & gardeners
Physician
Former regulatory affair official from biotech co.
Irrigation consultant
Law Professor (U. Oklahoma)
Oregon Board of Pharmacy
Biology Professor (Santa Clara U.)
Immunologist (Salk Institute)
Center for Food Safety
Food Processors Association of America
Oregon Physicians for Social Responsibility***

*5 "con biopharm" comments were focused on the use of taxpayer dollars for biopharm and not necessarily against the technology itself
** Includes AZ (1), MS (1), CA (2), DC (2) and OK (1)
*** Co-signers on PSR comments include: Center for Food Safety, Consumers Union, Cornucopia Institute, Friends of the Earth, Organic Consumers Association, The Campaign to Label Genetically Engineered Food, Union of Concerned Scientists, New Seasons Market, NW Resistance Against Genetic Engineering, Oregon Association of Naturopathic Physicians, Oregon Nurses Association, Oregon Sierra Club, Oregon Tilth

Four additional comments were received after the summary was compiles – 2 from citizens of Oregon, 1-from Oregonians for Food and Shelter along with Biotech Industry Organization, and 1- from Grocery Manufacturing Association. Members were asked to review the submitted comments before the next meeting and have their comments submitted for the revised policy.

Below are the concerns the Committee discussed at the meeting, Keith asked that these concerns be addressed and included within the policy before the next meeting.

-Inclusion of "animal feed" with human food crops?

-Inclusion of by-products with biopharmaceuticals in regards to drift, adventitious presence, etc?

-Expansion of educational/contextual themes in document to 1) better communicate/educate general public, 2) address several public comments and 3) revisit the issue of "zero contamination"

-"Low presence" and risk issue and language (including whether to discuss the dose-response paradigm and allergic reactions)

-Review of language related to monitoring plan for any permits/applications

-Notation/reference to Early Food Safety Evaluation protocol by GMA?

-Consideration of changes within APHIS and relation to this document

-Strong, early statement that "Endorsement, Moderate Scope" does not imply endorsement of human food (and possibly animal fed crops) nor does it endorse outdoor planting

-Language explaining why field testing is necessary/desirable and consideration of scale in descriptions of field testing (i.e. terms such as large scale)

-Language stating that safety evaluations need to include most vulnerable/susceptible members of the population

-Language that emphasizes that public dollars/funds would not be used for biopharma

-Issue of liability and reverse-liability?

The Committee decided that there is a need for an additional meeting and requested Shannon to find options for dates and location. The next meeting should include discussion of the revised policy and conclude the Committee's work.

Public Comments

Terry Witt, Oregonians for Food and Shelter – expressed his appreciation of the efforts the biopharm committee has put forth. He agreed with Director Koba mentioned that though statutory changes might be necessary, a lot of this could be accomplished through the rule making process. Administrative rules would have the same legal standgin as a statute, with the exception that it could be changed much more readily. Also, Terri pointed out the example of the pesticide regulations at the federal level. The label which is the law is written in vary vague terminology, one of the labels used the terms *do not apply during windy conditions*. There was a lawsuit and the person in violation was fined for violation of the label and after going to court the circuit court judge ruled that the labeling language was unconstitutionally vague. How do you enforce *windy,* is it 3-5 mph? How do we define this or that, for example *large scale*, this could mean one thousand acres to one person and one hundred acres to another. Terri continued, not all

plants have the same mode of reproduction – for example if you do experimental plots with a hybrid corn you do not have to worry about certain things because it doesn't reproduce, it has to be bred every time, whereas, a plant that reproduces by rhizome you do not have to worry about pollen. Terri points out that it is a good approach to use a case by case review.

Rick North, Oregon Physicians for Social Responsibility – Expressed his appreciation for all the effort the Committee has put forth this last year. He stated that three times people have said to him regarding the memorandum of understanding (MOU), why should the federal government even do this, what's in it for them? Why should they give Oregon authority for something they do not have in the first place? It is a concern, and it gets back to the legal authority question which has come up a couple of times. He pointed out public comments that reflect that Oregon does have the right to do this, which contradicts comments from another member of the public. The best examples of this are states and locations that have already done it and have already taken the steps way beyond what Oregon is talking about, they have just said absolutely no genetically engineered organisms, which has gone beyond biopharm crops. We are on solid legal ground but Rick is concerned about the MOU and whether the feds are going to go for it. There is the concern that if the feds just don't agree with the state that they just won't sign.

Rick went on to say that this is drug production that is being talked about. Comparing this to conventional drug production, no one would suggest that in conventional drug production within a contained facility that it would be allowed if there were holes in the wall where the drug can get out, or that the ceiling was open so the drug could get out into the atmosphere or the floor was open so it could seep into the water supply…

Keith Harcourt, stated that the analogy was breaking down; these drugs do not come straight from the green house, something is harvested and sent to a facility which probably has some of the same physical features as conventional facilities.

Rick continued saying that these crops are grown outside which is where they are most likely to contaminate, out there in the open. They are not just drugs, they are untested drugs they have not gone through any clinical trials whereas, conventional drugs have. He concluded that when we are talking about biopharmaceuticals, there are a lot of unknowns.

Meeting adjourned: 3:22 p.m.

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

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