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Oregon Department of Agriculture
Biopharm Comments
c/o Plant Division
635 Capitol Street, NE
Salem, OR 97301-2532

cc: biopharm-comments@oda.state.or.us

Dear Oregon Biopharm Ad Hoc Committee:

My name is Joseph Mendelson and I'm the Legal Director for the Center for Food Safety in Washington, D.C. The Center for Food Safety (CFS) is a non-profit membership organization dedicated to protecting human health and the environment from the proliferation of harmful food production technologies and by promoting organic and other forms of sustainable agriculture. CFS represents over 40,000 members including many members in the state of Oregon.

I have been an attorney working in the field of agricultural and environment law for more than fifteen years. During that time I have predominately focused my legal work on the federal and state regulation and oversight of agricultural biotechnology. This work has been recognized in legal journals, other scholarly publications and throughout the national and international media I have brought numerous cases against the federal government challenging its failure to sufficiently regulate the testing and commercialization of genetically engineered crops. Most recently, I served as counsel in the case of Center for Food Safety, et al v. Veneman, ___ F.Supp.2d ___, 2006 WL 2348109 (D.HI Aug. 10, 2006), in which a federal court determined that the United States Department of Agriculture actions in overseeing field trials of genetically engineered pharmaceutical producing plants (i.e. biopharm crops) violated Federal environmental laws and was wholly inadequate.

My organization has already signed onto the response by Oregon Physicians for Social Responsibility, and I concur with those opinions expressed in that letter. Herein, I'd like to provide additional information that should prove helpful to the state's deliberations.

First, I appreciate Oregon's leadership in addressing biopharmaceutical crop issues. There are significant questions involved with these crops and it's to your credit that you are taking action before serious

problems arise. It appears clear that you have determined a need for the state to supplement federal actions in order to protect human health, the environment and the agricultural interests of farmers and food processors.

One question that may arise is whether the state can assume authority that exceeds the federal government in approving and regulating these crops. Although there are no guarantees that an action won't be challenged, the short answer is yes. There have already been numerous examples and legal precedents demonstrating such state oversight of genetically engineered (GE) plants and animals.

The most obvious examples are actions that states and localities have already taken that go beyond federal authority. For instance, Marin, Trinity and Mendocino counties in California have adopted laws banning the planting of any GE crops. The city of Arcata, CA has voted to do the same.

In 2001, Maryland passed legislation banning the raising of any GE fish unless they were in ponds or lakes not connected to any other waterways. In 2003, California enacted a moratorium on growing GE fish in Pacific Ocean waters over which the state has jurisdiction. In 2005, Alaska passed a law requiring the consumer food labeling for all genetically engineered fish. All in all, at least nine states, including Oregon, have either passed legislation or developed state regulations to address the impacts associated with GE fish by limiting or banning their use. See Or. Admin. Rule 635-007-0595 (2004).

Moreover, Oregon itself has already acted to set state-based conditions that restrict the field testing of some GE crops. The state has limited the locations where GE bentgrass may be field tested by establishing a Bentgrass Control Area in Jefferson County. See Or. Admin. Code 603-052-1240 (2006). Unfortunately, this restriction has not prevented GE versions of creeping bentgrass from escaping their test plot locations and establishing themselves in the Crooked River National Grassland. See Reichman, et al, *Establishment of Transgenic Herbicide-Resistant Creeping Bentgrass (Agrostis stolonifera L.) In Nonagricultural Habitats*, MOLECULAR ECOLOGY (2006).

To date, not one of the myriad of state-based laws or regulations addressing oversight of GE crops has been challenged in court or struck down. See CFS, *A New View of U.S. Agriculture* (2006) (providing a comprehensive list of state laws and regulation addressing agricultural biotechnology). Indeed, the Congressional Research Service (CRS), which provides legal advice to members of the U.S. Congress, was asked to assess the legality of state actions to regulate GE crops. In a 2004 response to the question of the constitutionality of a Vermont bill to place a state-wide moratorium on the planting of all GE crops, CRS replied that the proposed Vermont law would survive any potential constitutional challenge: "There is undoubtedly a growing trend among states to legislatively address GE agribusiness issues. States will likely be able to regulate in this area unless or until Congress addresses the issue in a way that would preempt state efforts." Memorandum from Stephen R. Viña, Congressional Research Service to Hon. Bernard Sanders (Aug. 25, 2004). Although the opinion applied only to Vermont, legal precedents cited by the CRS would apply to any state.

The main legal issue in question is federal preemption of state action. Such preemption can be either express or implied. In express preemption, congressional intent is explicitly stated in statute. In implied preemption, congressional intent is implicitly contained in the statute's structure or purpose. At least two types of implied preemption have been recognized by courts: field preemption and conflict preemption. Under field preemption, the scheme of federal regulation is so pervasive that it is

reasonable to infer that Congress left no room for states to supplement it. In conflict preemption, compliance with both federal and state regulations is a physical impossibility, or state law stands as an obstacle to the accomplishment and execution of the full purpose and objectives of Congress.

Regarding express preemption, neither Congress nor any of the three federal agencies (EPA, FDA, and USDA) with primary responsibility for regulating genetic engineering in the United States have directly spoken as to whether states may regulate the liability issues surrounding the dispersal of genetically engineered seeds or traits.

On implied preemption, Congress has not passed any comprehensive agricultural biotechnology laws. Federal agencies have only piecemeal addressed the issue through the authority of previously existing laws that deal with plant pests, food safety and pesticide use. As a result, there is no congressionally created scheme of federal regulation pervasive enough for a court to make a reasonable inference that the States were not intended to supplement the existing piecemeal regulation.

Regarding damages, Oregon has every right to require a biopharm company to assume financial responsibility for economic harm caused by a contamination incident. State liability legislation seeks to provide a legal remedy for the pollution caused by a patented product and does not interfere with the patent itself. Protecting the resources of the state from such pollution is well within the traditional domain of state police powers. Federal patent law does not have the purpose of extending patent protection to the extent that it shields someone harmed by the patented product from seeking redress.

Finally, some may question whether some of your recommendations could violate the “Commerce Clause” of the Constitution, which expressly delegates the authority to regulate interstate commerce from states to Congress. Your proposed restrictions of biopharm crops, in my opinion, could not be challenged successfully on these grounds.

First, there is no differential treatment that benefits an in-state company at the expense of an out-of-state company. Any restrictions would apply equally to both. Furthermore, companies may still move freely across the state’s border, as long as proper safety precautions are followed. Finally, the Oregon regulations you are proposing are safety and environmental based-regulations and would not affect any commercial financial transactions that would occur regarding biopharm crops. Indeed, since no biopharm crops have ever been approved, there are no commercial sales.

Second, as stated in the CRS analysis, “the (Supreme) Court routinely upholds regulation of threats to crops, livestock and public health.” As noted in Maine v. Taylor (1986), “As long as a state does not needlessly obstruct interstate trade or attempt to ‘place itself in a position of economic isolation,’ it retains broad authority to protect the health and safety of its citizens and the integrity of its natural resources.” There is no attempt by Oregon to totally ban the growing of biopharm crops, but to place restrictions so as to protect health, environmental and agricultural interests of the state.

In sum, Oregon should have no fear on proceeding with significant state regulatory actions over and above what is currently provided by the federal government.

Thank you for the opportunity to provide input.

Sincerely,

/s/

Joseph Mendelson III
Legal Director