**Testimony of the Biotechnology Industry Organization**
**to the Oregon Senate Environment & Land Use Committee**

**Regarding Senate Bill 570: The Oregon Genetically Engineered Pharmaceutical and Industrial Crop Act**

April 8, 2005

On behalf of the members of the Biotechnology Industry Organization (BIO), please accept this testimony in opposition to Oregon Senate Bill 570. If passed, this bill would ban—for a four year period—the outdoor production of pharmaceutical and industrial materials in any plants that may be used for food or feed. Examples of prohibited plants would include corn, alfalfa, rice, and safflower. In addition to limiting a very promising area of biomedical research, this legislation would severely harm the state's reputation as an emerging center of excellence for technology development.

***The potential of plant-based technology is enormous.*** Traditional methods of producing pharmaceutical and industrial proteins are time- and capital-intensive. In many cases, plant-based techniques offer a more expedient and economical way to mass-produce these proteins. Nature offers a more flexible way to respond to these needs than do brick-and-mortar facilities.

Plant-made production of pharmaceutical and industrial proteins holds distinct advantages over current production methods. Many proteins are difficult or impossible to synthesize with traditional chemistry. Therefore, previous production options were limited to mammalian or microbial cell cultures, which are time consuming and expensive to develop. Plant-based technologies can result in increased supply, reduced production cost and increased investment in research—not just development. These benefits of

plant-based technology are shared by consumers, specifically patients who could have increased access to life-saving treatments for a wide variety of diseases.

***Commodity crops are a natural choice for protein production due to extensive knowledge and familiarity with growing these plants.*** Understanding of a plant's genetics, agronomics and environmental impact is crucial in the successful development, confinement and extraction of these proteins. Plants used for pharmaceutical and industrial protein production are selected based on the specific target protein and scientists familiarity with that plant's system. Again, all this can be achieved without the inherent risks often associate with traditional production methods, *i.e.*, fermentation, mammalian cell culture.

In compliance with current federal regulatory guidelines, pharmaceutical or industrial protein-producing plants must be grown and processed separately from food and feed crops. After harvest, the plant material is processed to separate and purify the proteins, which are then delivered to manufacturers. In addition, the seeds to grow protein-producing plants are available only to those with an appropriate U.S. Department of Agriculture (USDA) growing permit, and cannot be purchased off-the-shelf at a local seed store.

***Stringent U.S. Department of Agriculture and Food & Drug Administration (FDA) requirements already exist to regulate the production of plant-based proteins.*** The USDA regulates plant-made pharmaceuticals during development and field production while FDA regulates the evaluation, production and distribution of pharmaceutical products. Several agencies within USDA and FDA further regulate and monitor plant-made pharmaceuticals:

- USDA Animal and Plant Health Inspection Service (APHIS) oversees the process from seed through grain, including the transport and release of the seed in a greenhouse or field;
- States participate with USDA Animal and Plant Health Inspection Service (APHIS) in the permitting and inspection;

- FDA Center for Biologics Evaluation and Research (CBER) and FDA Center for Drug Evaluation and Research (CDER), regulate biologic products/devices, including plant-made pharmaceuticals; and

These regulations are comprehensive, rigorous and national in scope. Researchers and consumers are better served by a strong, uniform regulatory system than a state-based patchwork of inconsistent guidelines.

***Senate Bill 570 will only serve to create confusion about a promising area of research and impede the state's effort to grow its life science industries.*** This legislation is reactionary and would only serve to harm the state's hard earned reputation as an emerging center of excellence for technology development and could undermine important research efforts in the state in all areas biotechnology.

We appreciate the committee's consideration of our concerns and encourage committee members to oppose Senate Bill 570.

Respectfully submitted,

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*BIO represents more than 1,100 biotechnology companies, academic institutions, state biotechnology centers and related organizations across the United States and 31 other nations. BIO members are involved in the research and development of healthcare, agricultural, industrial and environmental biotechnology products.*