Testimony of the Massachusetts Biotechnology Council (MBC) and the Biotechnology Industry Organization (BIO)

Hearing of the Massachusetts Joint Committee on Natural Resources and Agriculture
November 13, 2003

Regarding House Bills 3012:
The Prohibition of Open-Air Planting of Pharmaceutical Crops

On behalf of the members of the Massachusetts Biotechnology Council (MBC) and in conjunction with the Biotechnology Industry Organization (BIO), please accept this testimony in opposition to Massachusetts House Bill 3012. If passed, this bill would ban the open-air planting of pharmaceutical materials in plants. Beyond limiting a very promising area of research, this legislation would severely harm the state's reputation as a center of excellence for technology development.

Plant-based technologies hold significant potential for drug and industrial protein development. Traditional methods of producing pharmaceutical and industrial proteins are time and capital intensive. It can take up to 15 years and $800 million to research and develop one new drug product. Industrial proteins are revolutionizing manufacturing processes. In many cases, plant-based techniques offer a more expedient and economical way to mass-produce these proteins. Deriving medicines and industrial proteins from plants would allow researchers to increase supply and reduce production costs. In addition, plant-made production of pharmaceutical and industrial proteins holds distinct advantages over current production methods. Most proteins cannot be chemically synthesized, therefore previous production options were limited to mammalian or microbial cell cultures which are time consuming and expensive to develop.

Commodity crops are a natural choice for protein production due to extensive knowledge and familiarity with growing these plants. The evolution of production agriculture has enabled scientists develop significant knowledge of plant genetics, agronomics and environmental impact of many of the food crops we grow today. With this in-depth knowledge, scientists understand what is required for the successful development, confinement and extraction of proteins from a variety of crops. Biotechnology allows this to be achieved without the inherent risk of propagating contaminants that are possible in other methods.

Current federal regulatory guidelines dictate that pharmaceutical and industrial protein-producing plants 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 USDA 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's 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;

- the 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

- FDA Center for Food Safety and Applied Nutrition (CFSAN), and FDA Center for Veterinary Medicine (CVM), provide additional oversight as needed to ensure the safety of food and feed.

These regulations are comprehensive, rigorous and national in scope. MBC and BIO feel that researchers and consumers are best served by a strong, uniform regulatory system-not a patchwork of inconsistent guidelines that can vary widely from state to state.

House Bill 3012 will only serve to create confusion about a promising area of research and impede the commonwealth's effort to grow its life science industries. This legislation is reactionary and would only serve to harm the state's reputation as a center of excellence for technology development-a reputation that has attracted, grown and retained so many outstanding research organizations.

We appreciate the committee's consideration of our concerns and encourage committee members to oppose House Bill 3012.

*The **Massachusetts Biotechnology Council (MBC)**, founded in 1985, is a not-for-profit organization that provides services and support for the Massachusetts biotechnology industry. The MBC is committed to advancing the development of critical new science, technology and medicines that benefit people worldwide. Representing over 400 companies, academic institutions and service organizations involved in biotechnology and healthcare, the MBC works with public leaders to advance policy and promote education, while providing member programs and services.*

*The **Biotechnology Industry Organization (BIO)** is the national trade organization, based in Washington, DC, representing more than 1000 biotechnology companies, academic institutions and biotechnology centers in all 50 states and 33 countries. BIO members are involved in the research and development of health care, agricultural and environmental biotechnology products.*