

My name is Michael Wach, and I am a Managing Director for Science and Regulatory Affairs with the Biotechnology Industry Organization, also known as BIO. BIO represents more than 1,200 biotechnology companies, academic institutions, state biotechnology centers, and related organizations in all 50 states and over 30 other countries. BIO members are involved in the research and development of health care, agricultural, industrial, and environmental biotechnology products.

I want to start by explaining to you what this technology really is. Even before humans cultivated plants for food, they used plants as a source of effective treatments and therapies, and we continue to find useful pharmaceutically active substances made by plants, but finding these substances is a haphazard process, largely based on luck. Plant-made pharmaceuticals are simply plants that have been engineered to produce specific proteins with known therapeutic value. These can be used by the medical community to combat life-threatening illnesses, including ailments such as diabetes, which affect millions of people. But these proteins could also treat diseases that affect only a few thousand people or fewer and which traditional drug manufacturing cannot address in a cost-effective way. In other words, pharmaceutical plants could make effective therapies available to people who simply will not be helped otherwise.

These materials are developed under rigorous rules administered by the United States Department of Agriculture, the Food and Drug Administration, and the Environmental Protection Agency to ensure that these plants don't enter the food supply, and they haven't. Plants producing pharmaceutical proteins are grown in field trials under very strict conditions set forth by the federal agencies. These requirements are based in science and consider the type of plant, the protein being produced, the location of the intended planting area, and crop handling procedures. Farm equipment that is used for these types of plants cannot be used for any food or feed crops. The field trials are inspected multiple times during and after the growing season to ensure that all regulations and permit conditions are being complied with. And all this is done with notice to the public and opportunities for public input. In addition to complying with the federal regulations, companies developing this technology are doing so responsibly to ensure the safety of the manufacturing process.

You might ask why use plants for this purpose. Developing a new drug and a cost-effective way to manufacture it is an enormously complicated process, and there is a great deal at stake—medically, technologically, and economically. The decision to use plants to make specific therapeutic proteins is not made cavalierly, and the decision is based on good science and good manufacturing.

First, producing therapeutic proteins in plants avoids contamination with human or animal pathogens, which can happen in systems using animal cells.

Second, the genetic engineering of plants has progressed to the point to where it is straightforward to move the right gene into the plant.

Third, plants are very good at making large amounts of protein very efficiently.

Fourth, the development of a pharmaceutical plant requires less investment of capital and labor, and production can be readily scaled up to meet increased demand.

Traditional means of producing therapeutic proteins cannot adequately meet current patient needs, and the needs of those suffering from rare diseases aren't met at all.

Without new technologies, such as pharmaceutical plants, more and more people will receive inadequate treatment, which is especially crucial in the developing world. Just to give one example, the World Health Organization estimates that by the year 2030, the number of people worldwide suffering from diabetes will double—that means 340 million diabetics. It is only through biotechnology that we are meeting our current insulin needs. We must have new technologies to meet the needs of the future.

Lastly, in addition to the potential opportunities this technology brings to Maine's industry and academic communities, this technology also provides opportunities for Maine farmers. Across the country, a small but growing number of farmers have found a new application for their land and their farming experience by managing small field tests of pharmaceutical plants, under contract to the developer, and under the

supervision of the federal government. Without making the citizens of Maine any safer, shutting the door on this technology will shut the door on those opportunities.

Thank you. I'll be happy to answer any questions you may have.