



April 18, 2005

The Honorable David Catania
Council of the District of Columbia
1350 Pennsylvania Avenue, N.W.
Room 110
Washington, D.C. 20004

Re: Opposition to the Prescription Drug Compulsory Manufacture License Act of 2005 (Leg. No. B16-0114)

Dear Councilmember Catania:

On behalf of the Biotechnology Industry Organization (BIO), we appreciate the opportunity to submit comments regarding our opposition to the Prescription Drug Compulsory Manufacture License Act of 2005 (“the Act”). This bill would authorize the compulsory licensing of prescription drugs that are still under patent by drug manufacturers. BIO strongly opposes this bill and any bill that provides for compulsory licensing of health related inventions.

We are particularly concerned with the impact this legislation could have on emerging biotechnology companies that do not have a product on the market. Biopharmaceutical product development, clinical trials and regulatory approval can take more than 10 years and cost more than \$800 million. Indeed, no industry spends more on research and development, and has a longer product development time-frame than the biotechnology industry. In spite of these challenges, investors who believe in the potential of the research continue to fund biotech research and development. These investors are taking significant risk that the investments will pay off with the development of a treatment, or new medicines and vaccines for intractable diseases. This type of funding is possible because of the ability of

companies to license according to their business models and the promise of free enterprise.

The requirements of the Act contradict existing federal law and are unconstitutional. Under the terms of the U.S. Constitution, a state or municipality can neither grant patents nor interfere with the rights that a federal patent confers on the patent holder. Moreover, the bill is in direct conflict with existing federal patent law. The federal patent system strikes the balance between exclusive use and public use that Congress deems necessary to encourage innovation and invention. State and local patent law is completely preempted by federal law.

The real world impact of compulsory licensing is wrought with unintended consequences. Compulsory licensing of biotechnology inventions would eliminate any incentive companies have to invest in biotechnology research and development. Indeed the potential threat of confiscation of patents to address national or global problems would make it difficult for companies to pursue development of products that are useful for the treatment of intractable diseases. For many biotechnology companies, patents are the only assets from which they attract the investment necessary to develop life-saving products. If there is a threat of compulsory licensing, not only will investors have to factor the inherent risk of failure, they will be forced to consider whether a product or a technology stands a risk of being taken by a state government or municipality.

The bill is based on the erroneous premise that compulsory licensing will increase access to pharmaceuticals. Confiscation and expropriation of intellectual property of biotechnology companies, universities and medical research institutes would be short-sighted. While there might be a temporary decrease in prices of existing product, the next generation of predictive tests, treatments and vaccines to address ever-mutating microorganisms would never materialize, because investors would be discouraged from supporting the necessary research and development.

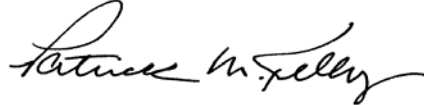
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Thank you for your consideration. If you have any questions or need additional information, please feel free to contact me at (202) 962-9200 or by email at pkelly@bio.org.

Sincerely,

A handwritten signature in black ink that reads "Patrick M. Kelly". The signature is written in a cursive style with a vertical red line to its right.

Patrick M. Kelly
Vice President,
State Government Relations
Biotechnology Industry Organization

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