

**Statement on Norvir March-in Petition**  
**Ted Poehler, Johns Hopkins University**  
**May 25, 2004**

Good Morning Dr. Rohrbaugh. Thank you for inviting me to speak here today.

When I was offered this opportunity, I did not immediately realize that I would be following Senator Birch Bayh to this podium. It is an honor to speak after such a distinguished public servant.

I am Ted Poehler, Vice Provost for Research at The Johns Hopkins University in Baltimore, Maryland. I am here as a representative of the Association of American Universities, which comprises (or “consists of”) 60 of the leading research universities in the United States as well as two in Canada.

At Johns Hopkins, we are keenly aware of our responsibility to bring the benefits of our research to the public as required under the provisions of the Bayh-Dole law. We vigorously defend that statute from any efforts to dilute its effectiveness. This statute is a cornerstone of our efforts to translate our theories and discoveries into actual products that benefit humanity.

For example, among many exciting inventions from Hopkins are those that come from work by Doctor Curt Civin on stem cell transplantation. Using an invented substance called CD34, Doctor Civin and his colleagues have aided the recovery of tens of thousands of cancer patients whose blood cells and bone marrow have been destroyed by cancer treatment.

Similarly, Doctor Bert Vogelstein has been working on pinpointing a patient’s risk for colorectal cancer through detecting the presence of mutations in the *APC* gene. Recently, Doctor Vogelstein’s work has led to the development of an early detection,

non-invasive test for colorectal cancer from a stool sample. This test, combined with early treatment, is greatly reducing the risk of death from this terrible disease.

These inventions and many others have helped countless patients through the transfer of technology to companies committed to making them accessible for clinical use. Bayh – Dole has been critical to these successes.

I am here to offer comments on behalf of AAU, Johns Hopkins and the academic research community on the pending petition for the government to exercise so-called “march-in” authority for Norvir, an HIV treatment drug manufactured by Abbott Laboratories.

The petitioners claim that Abbott Labs is charging too much for this life-saving prescription drug. They further assert that the government should exercise authority provided in the Bayh-Dole Act to march in and take title to the patent for Norvir... or license it to other companies that presumably would offer an identical drug at a lower price.

Bayh-Dole sets out how federally funded research inventions may be transferred to the private sector for further development and commercialization. The law was written to address a serious problem in our national research and development enterprise. Before its passage... fewer than five percent of the patents produced with government funding were making their way into the marketplace where they could contribute to the public good.

Bayh-Dole sought to solve this problem by providing an incentive to those closest to the basic science to seek partners to further invest in the development of that basic research. The hope was that, with this incentive, more new and marketable therapies and technologies would emerge.

The law allowed recipients of federal research support to hold title to inventions; at the same time, it imposed the obligation to market inventions for the public benefit.

An important underlying assumption was that those closest to the research would have the best understanding of potential applications. They, therefore, would be better able to market the invention than government officials in Washington.

The overwhelming evidence of patenting and licensing activity since 1980 is that this assumption was 100 percent correct. Indeed, it can be argued that today's thriving biotechnology industry in the United States is proof of this law's effectiveness.

March-in rights were retained by the government only as a means to ensure the prompt commercialization of inventions that resulted from federally supported research. They were intended to prevent companies from slowing... for commercial or competitive advantage... the development of new inventions. Under Bayh-Dole, the government has neither rights nor a role in the licensing or commercialization of new technologies developed in whole or in part with federal research support—so long as that commercialization occurs.

To be sure, there are serious challenges surrounding the accessibility and affordability of pharmaceuticals. But to use march-in rights to address drug pricing is a misapplication of the statute. Exercise of march-in rights in this case would likely have serious unintended and adverse consequences for future therapeutic development and technology transfer from government-funded researchers and institutions to the private sector. It's most likely that the result would be fewer therapies in the market place.

I began these remarks by acknowledging the honor of following Senator Bayh. Please allow me to quote from an April 11, 2002, *Washington Post* letter-to-the-editor written Senators Birch Bayh and Bob Dole:

Bayh-Dole did not intend that government set prices on resulting products. The law makes no reference to a reasonable price that should be dictated by the government. This omission was intentional; the primary purpose of the act was to entice the private sector to seek public-private research collaboration rather than focusing on its own proprietary research . . .

The ability of the government to revoke a license granted under the act is not contingent on the pricing of a resulting product or tied to the profitability of a company that has commercialized a product that results in part from government-funded research. The law instructs the government to revoke such licenses only when the private industry collaborator has not successfully commercialized the invention as a product.

We assert that the exercise of march-in rights by the government regarding Norvir could only arise from a misreading of the statute. It would represent a misapplication of the legal and regulatory systems that govern the transfer of technology from federally sponsored research to the private industry.

AAU institutions are committed to expanding knowledge and benefiting public health. We, therefore, take our role in the process of innovation seriously. We respect the taxpayer who funds in large measure the research that we do. We are acutely conscious of our obligation to place in responsible hands the discoveries and technologies we develop.

In many instances, the most efficient way to do so is to license an invention to a commercial entity willing to take the risk to invest further in a concept. This is exactly what the Bayh-Dole Act envisioned. It has been an unqualified success.

The exercise of march-in rights by the government on the basis of price would introduce a level of uncertainty into the commercialization process that would make these transactions far more difficult. The end result would be less successful technology transfer. The risk is that potentially lifesaving therapies never make it to the patient.

We therefore request that NIH reject this petition. Thank you again for this opportunity to speak today.