

February 4, 2010

The Honorable Kathleen Sebelius
Secretary of Health and Human Services
U.S. Department of Health and Human Services
200 Independence Avenue, S.W.
Washington, D.C. 20201

Dear Secretary Sebelius,

On behalf of the undersigned organizations representing American life sciences innovation, we are writing to express grave concerns about certain recommendations in the Secretary's Advisory Committee on Genetics, Health and Society's (SACGHS) *Report on Gene Patents and Licensing Practices and Their Impact on Patient Access to Genetic Tests*. We urge you to reject these recommendations and ensure that the fundamentals of the innovation system put in place nearly 30 years ago through the Bayh-Dole Act are preserved.

The U.S. leads the world today in life sciences research and development in large part because of the robust system for protecting intellectual property rights and the flexible technology transfer policies that exist in this country. Many companies have either spun out of universities or are developing products from university research. Often this initial research was funded by the National Institutes of Health (NIH), and transferred to companies for further research and development. It is through this collaboration fostered by the Bayh-Dole Act – and fueled by massive amounts of private investment – that research is translated into tangible medicines, diagnostic tests, and other healthcare-related products that are saving lives, improving diagnoses, and alleviating suffering for millions of people worldwide. The critical links in this chain are the availability and enforceability of patents to protect these investments, and a flexible system of technology transfer to foster commercialization.

This innovative collaboration is the envy of the world. It creates high-paying jobs throughout the United States of America – more than 7 million U.S. jobs are directly or indirectly the result of the flourishing life sciences industry. Governors across the country are busy trying to expand their university-industry partnerships to create biotechnology hubs in their States. President Obama has recognized this link as well – including \$10 billion in economic stimulus funds for the NIH to further promote research and technology transfer in the life sciences, much of it focused on genomic research.

The United States' success in this area has prodded other countries to take a page from the U.S. patent laws and the Bayh-Dole Act, with new biotech hubs sprouting up in various corners of the globe. The global competition is on, and the United States must preserve incentives for investment and innovation, particularly now during a time of continuing economic challenge. It is not the time to undertake or recommend policy changes that would undermine the foundations of American life sciences innovation.

Unfortunately, the SACGHS ignored the public comments by organizations with experience in patenting and technology transfer, as well as the thoughtful, dissenting views of several of its own Committee members and technical advisors. These serious omissions produced a report that contains certain recommendations that we believe would seriously hamper public/private collaborations and the commercialization of publicly-funded research. These unprecedented recommendations – based on limited anecdotal experiences and an internally contradictory evidentiary record – include exempting from infringement liability the use of gene patents for the purpose of developing and commercializing diagnostic tests, and promulgating regulations that would limit exclusive licensing of federally-funded inventions for genetic diagnostic purposes. By undermining the value of gene-based patents, these recommendations would chill future investment and innovation in this area, and would unfairly upset the investment-backed expectations of current patent owners and licensees.

We note that restrictive patenting and licensing practices with respect to federally-funded inventions – such as those now advocated by the SACGHS – were the norm before the passage of the 1980 Bayh-Dole Act. The negative effects of such policies were well documented at that time. They were the reason that federally-funded inventions languished on laboratory shelves, causing Congress to end these inefficient policies with overwhelming bipartisan support. After the passage of the Bayh-Dole Act, which allowed universities to patent and license with flexibility, the United States saw an incredible surge in commercialization of federally-funded research. This success put beneficial products into the hands of the tax-paying public, while creating thousands of jobs around university technology hubs across the country.

Here are some of the subsequent, documented impacts that have astounded the world since the passage of Bayh-Dole:

- Approximately 6,000 new U.S. companies have formed from university inventions;¹
- At least 4,350 new products are now on the market because of university patent licensing;²
- 5,000 active university-industry licensing partnerships are in effect, chiefly with small companies;³
- More than 153 new drugs, vaccines or in vitro devices have been commercialized from federally-funded research; incredibly, the Congress had found no instances of new drugs being developed from federal funding prior to 1980, when the federal government controlled patent rights in such inventions;⁴
- 50% of the members of the Biotechnology Industry Organization (BIO) surveyed in 2009 reported that their companies were founded based on in-licensed technologies;⁵ and
- 76% have licensing agreements with U.S. universities in place.⁶

¹ AUTM annual survey, 2006, available at http://www.autm.net/FY_2007_Licensing_Activity_Survey.htm.

² Ibid.

³ Ibid.

⁴ "The Contribution of Public Sector Research to the Discovery of New Drugs," Jonathan J. Jensen, Katrine Wyller, Eric R. London, Sabarni Chatterjee, Fiona E. Murray, Mark L. Rohrbaugh, and Ashley J. Stevens, presented at the BIO Technology Transfer Symposium, San Francisco, CA, October 28, 2009, available at <http://bio.org/ip/techtransfer/>.

⁵ BIO 2009 Member Survey, Technology Transfer and the Biotechnology Industry, available at <http://bio.org/ip/techtransfer/PDF.TECH.TRANSFER.PRESENTATION.10.25.pdf>.

⁶ Ibid.

Using very conservative estimates, and just for the years from 1996 to 2007, university licensing under Bayh-Dole realized:⁷

- A \$187 billion impact on the U.S. gross domestic product;
- A \$457 billion impact on U.S. gross industrial output; and
- 279,000 new jobs created in the U.S. from university inventions.

In light of the risks of going back to the pre-Bayh-Dole era, no compelling case has been made to warrant the Committee's recommendations. Indeed, the recommendations are based on claims of a crisis in the current system that does not exist, supported by selective assertions that do not hold up under scrutiny. If anything, the report's own case studies demonstrate that each situation is unique, and thus should be read to support flexibility in creating the terms of licensing agreements, rather than restricting an entire class of licenses by some general rule. We ask you to carefully consider the views and experiences of those who actually bring biomedical innovation to suffering patients, and to look closely at the case studies themselves, before making any decisions with respect to the Committee's recommendations.

We welcome efforts to improve patient access to genetic tests, and stand ready to work with you and other interested parties to do so. But we believe that the recommendations, if implemented, would unravel two sets of laws that are the foundation of life science innovation in this country – the patent system and the Bayh-Dole Act. This would do more harm to patients than good, by impairing the research, development and commercialization of the medicines and diagnostic tests of tomorrow.

We would welcome the opportunity to meet with you and your staff to further discuss this critically important matter. Thank you for your consideration of these views.

Sincerely,

[Signatories on following page]

⁷ The Economic Impact of Licensed Commercialized Inventions Originating in University Research 1996-2007, Roessner et. al., September 3, 2009, available at <http://bio.org/ip/techtransfer/>.

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