

July 27, 2022

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

Dear Secretary Becerra,

On behalf of the undersigned organizations, which represent research universities, colleges, medical schools, teaching hospitals, research and scientific organizations, and technology transfer professionals at those institutions across the country, we want to share our concerns about recent calls made in a June 23, 2022, bicameral Congressional letter to you for your department to reinterpret federal law in a misdirected bid to lower prescription drug prices.¹ The members of Congress calling for this action cite as authority provisions of the 1980 Bayh-Dole Act on march-in rights and government use of patented discoveries. Although our associations fully share the widespread public concerns about the high costs of prescription drugs and therapeutics, we write to urge you to reject such calls. They are contrary to the language and clear intent of the Bayh-Dole Act and are likely to decrease innovative research with no clear evidence such a reinterpretation will have any actual impact on reducing drug prices.

If the Department of Health and Human Services grants these lawmakers' request to invoke the government use license and/or march-in rights provided under the Bayh-Dole Act (35 USC 202 and 203), private-sector firms will be less willing to license universities' intellectual property. Introducing the possibility of retroactive revocation of exclusive rights and compulsory licensing by government decree could shake investor confidence, drying up critical venture funding needed to commercialize new technologies and bring them to market. The inevitable result would be that some valuable and potentially lifesaving research outputs would not move beyond the lab.

Before 1980, the federal government retained title to almost all patents developed by university researchers who received federal funding. During this period, fewer than 250 patents were issued to U.S. universities yearly, and the government only licensed about 5% of its 30,000 patents to firms looking to perform additional research and development to commercialize the discoveries. The remaining patents sat on the proverbial government shelf, collecting dust -- meaning that the U.S. government and the American people received essentially nothing in return for their investment in these inventions.²³

¹ <https://www.warren.senate.gov/imo/media/doc/Bicameral%20Letter%20Urging%20HHS%20to%20Lower%20Drug%20Prices%20FINAL1.pdf>

² <https://bayhdolecoalition.org/wp-content/uploads/2021/02/Memo-To-Foster-Innovation-Biden-Administration-Must-Protect-Bayh-Dole.pdf>

³ <https://bayhdolecoalition.org/wp-content/uploads/2021/02/Memo-To-Foster-Innovation-Biden-Administration-Must-Protect-Bayh-Dole.pdf>

That changed with the passage of the Bayh-Dole Act. By enabling universities to license their patents to the private sector and companies to invest their money and expertise to bring those inventions to market, this landmark legislation not only gave universities the right to retain title to the patents on their inventions arising from federal grants, but it also highlighted the obligation of these universities to diligently commercialize discoveries resulting from federally sponsored research.

This arrangement has spurred the creation of thousands of products, including over 200 new medicines such as gene therapies for rare diseases, revolutionary cancer treatments, and a once-a-day pill for HIV.^{4 5 6} Behind the rapid development of COVID-19 vaccines lay decades of university research into mRNA technology. According to a recent survey by AUTM in 2020, U.S. universities were issued 8,706 U.S. patents, spun off 1,117 startup companies, and inked 10,050 licensing and option agreements. Their previous research also yielded that more than 900 new commercial products reached consumers that year.⁷ Between 1996 and 2017, U.S. universities and nonprofit patent licensing activity contributed up to \$865 billion to U.S. GDP.

Some have argued that HHS has the authority to invoke the Bayh-Dole Act's march-in rights to intervene and grant a new license to patents that arise from federally funded research when the list price of a marketed product is above some undefined threshold. This is a misinterpretation of the law's plain language, intent, and forty-two-year history. March-in rights are intended to assure the commercialization of government-funded inventions. The Bayh-Dole Act never mentions or suggests that pricing is a consideration or criterion as to whether a product is reasonably available to the public, nor has "government use" ever been accepted to cover such a broad claim of authority under the government use license.

Ultimately, while our organizations believe that actions need to be taken to control drug pricing, the use of the march-in for this purpose represents a misuse of this government authority. As former Senators Birch Bayh and Bob Dole confirmed in 2002, they never intended for the government to use the march-in provision of their eponymous legislation as a price control mechanism.⁸ The statute deliberately omits any mention of "reasonable price." For this reason, the National Institutes of Health has declined all previous petitions to use march-in rights to lower drug prices.

We share the concerns of lawmakers and patients about the affordability and availability of medicines and our institutions are themselves impacted by rising drug costs. Universities, medical

⁴ https://autm.net/AUTM/media/Surveys-Tools/Documents/AUTM_FY2018_Infographic.pdf

⁵ <https://autm.net/about-tech-transfer/better-world-project>

⁶ <https://bayhdolecoalition.org/wp-content/uploads/2021/02/Memo-To-Foster-Innovation-Biden-Administration-Must-Protect-Bayh-Dole.pdf>

⁷ <https://autm.net/AUTM/media/Surveys-Tools/Documents/FY20-Infographic.pdf>

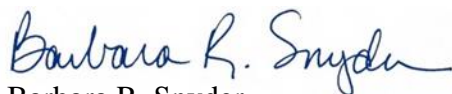
⁸ https://www.washingtonpost.com/archive/opinions/2002/04/11/our-law-helps-patients-get-new-drugs-sooner/d814d22a-6e63-4f06-8da3-d9698552fa24/?itid=ik_inline_manual_11

schools, and teaching hospitals are committed to making health care more accessible and equitable in our capacities both as medical providers and as scientific innovators. However, the use of Bayh-Dole march-in rights does not present an effective and comprehensive means to accomplish this objective, in no small part because it would only impact drugs for which clear connections to federal research investments were made. We, therefore, encourage lawmakers to pursue other more comprehensive solutions that ensure every American can afford quality care.

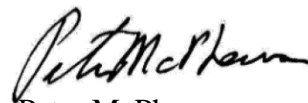
In addition to being an ineffective mechanism to reduce drug prices, such an action would significantly undermine university innovation and the benefits it delivers to the American people and indeed, as in the case of COVID-19 vaccines, the entire global community. If the government can order compulsory relicensing of patents, private investment will go elsewhere, and promising innovations will once again waste away as was the case prior to the passage of the Bayh-Dole Act.

The Bayh-Dole Act plays a pivotal role in fostering scientific innovation and economic growth. We support you as you carry out your obligation to uphold the intent of the law and the beneficial legal framework it creates.

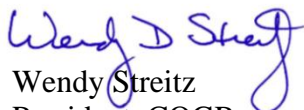
Respectfully,



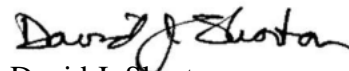
Barbara R. Snyder
President, Association of American Universities



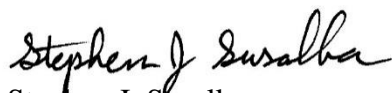
Peter McPherson
President, Association of Public and
Land-grant Universities



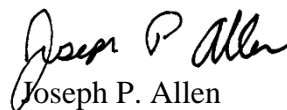
Wendy Streitz
President, COGR



David J. Skorton
President and CEO, Association of
American Medical Colleges



Stephen J. Susalka
Chief Executive Officer, AUTM



Joseph P. Allen
Executive Director, Bayh-Dole
Coalition