



May 17, 2022

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

Dear Secretary Becerra,

On behalf of Biocom California, I write to respectfully ask you to uphold the standing precedent set by the Department of Health and Human Services (HHS) and not grant petitions that request the utilization of march-in rights on the basis of cost. The Bayh-Dole Act¹ created a mechanism to allow private entities to develop taxpayer-funded research and, in doing so, has transformed public-private partnerships and unleashed a new era of American innovation. While the Act does permit the government to “march-in” and take control of a patented invention in certain situations, the proposed use of march-in rights to exert control of the price of any licensed products is beyond the scope and intent of the law².

Biocom California is the largest, most experienced leader and advocate for California’s life science sector, which includes biotechnology, pharmaceutical, medical device, genomics and diagnostics companies of all sizes, as well as research universities and institutes, clinical research organizations, investors and service providers. With more than 1,500 members dedicated to improving health and quality of life, Biocom California drives public policy initiatives to positively influence the state’s life science community in the research, development, and delivery of innovative products. California’s life sciences industry generates over \$400 billion in annual economic activity, supports almost 1.4 million jobs, and increases labor income by \$131 billion per year³.

The Patent and Trademark Law Amendments Act of 1980, commonly referred to as the Bayh-Dole Act, in recognition of its authors, has had a tremendous impact on American innovation. The law gives intellectual property (IP) rights to recipients of federal grant funding, such as universities and small companies, allowing them to license their inventions so they can then be commercialized.

¹ Pub. L. 96-517

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

³ *Biocom California 2021 Economic Impact Report Databook.* <https://www.biocom.org/eir/>



Before 1980, the government had accumulated more than 25,000 patents and under 5 percent were commercially licensed⁴, leaving tens of thousands of inventions and innovations languishing. The Bayh-Dole Act corrected that imbalance by providing a pathway for government-funded research entities to partner with private companies to bring publicly funded innovations to the broader public.

Since its enactment, the Bayh-Dole Act has facilitated the creation of more than 480,000 inventions and 15,000 start-ups while supporting nearly six million new jobs⁵. Thanks to the law, approximately 300 new drugs and vaccines have been brought to market⁶.

Despite the monumental progress made over this 40-year span, proposals to undermine the law and exercise march-in rights to take away IP rights from innovators in a misguided attempt to dictate drug prices keep resurfacing. The March-in rights provisions of the law are reserved for instances where a licensee has *not* successfully commercialized a product, including lack of production by the licensee to meet the public need, failing to meet regulatory requirements, licensing ex-U.S. without approval, and in cases of alleviating a public health and safety need that the licensee cannot fulfill⁷. None of these circumstances mention the price of an appropriately commercialized product as a reason to march-in.

Additionally, the bill's sponsors, Senators Bayh and Dole, published an op-ed in the Washington Post in 2002 where they specifically stated, "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."⁸ Their words are as relevant in 2002 as they are 20 years later.

There have been six different attempts to invoke march-in rights due to a drug's price in the past⁹. These efforts span decades and several different administrations of differing political parties. All six times, these efforts have failed because the law does not allow for a price as a circumstance to exercise march-in rights.

The most recent proposal for exercising march-in rights is a drug for prostate cancer known as Xtandi. According to the sponsor, the federal government spent approximately \$500,000 on the initial discovery of the drug. Since that initial investment, the sponsor has invested more than \$1.4

⁴ *Information on the Government's Right to Assert Ownership Control Over Federally Funded Inventions*. US Government Accountability Office. July 2009. www.gao.gov/products/GAO-09-742

⁵ *Driving the Innovation Economy*. AUTM. https://autm.net/AUTM/media/Surveys-Tools/Documents/AUTM_FY2018_Infographic.pdf

⁶ *AUTM 2020 Licensing Activity Survey*. <https://autm.net/AUTM/media/SurveyReportsPDF/FY20-US-Licensing-Survey-FNL.pdf>

⁷ [35 U.S. Code § 203](#)

⁸ *Our Law Helps Patients Get New Drugs Sooner*. Washington Post. <https://www.washingtonpost.com/archive/opinions/2002/04/11/our-law-helps-patients-get-new-drugs-sooner/d814d22a-6e63-4f06-8da3-d9698552fa24/>

⁹ *March-In Rights Under the Bayh-Dole Act*. CRS. <https://www.everycrsreport.com/reports/R44597.html>

billion in research and development¹⁰, and private partners have spent over \$2.2 billion to commercialize Xtandi. This example highlights the tremendous investments made by the private sector once a technology has been transferred to study, test, gain regulatory approval, and eventually commercialize the product.

The consequences of failing to protect the intent of the Bayh-Dole Act may severely limit the appetite of private sector companies, and their risk-averse investors, to pursue the development and commercialization of products that stem from publicly funded research and revert to a pre-Bayh-Dole system that leaves important innovations on government's shelves.

Specifically, it would disproportionately harm small companies, which receive about 70 percent of university patent licenses¹¹ and create more than half of new drugs developed in this country. Small companies (under 250 employees) constitute the overwhelming majority of Biocom California's membership and contribute substantially to the California economy. Similarly, American universities would lose a significant revenue stream from licensing if their ability to transfer discoveries to the private sector¹², which would significantly slow down the pace of innovation.

Finally, the impact on California alone would be sizeable. California is the single largest recipient of grants from the National Institutes of Health, with over \$5 billion in Fiscal Year 2021¹³. California also received approval for more than 46,000 patents over the same time frame¹⁴. Granting the use of march-in rights for price concerns would have an outsized impact on California's innovation ecosystem.

Biocom California strongly urges you to maintain the precedent set by all previous administrations and deny these requests to use march-in rights based on the price of a product.

We appreciate the opportunity to provide these comments to you on behalf of our members and for your consideration of our request. Please contact Biocom California's Associate Manager for Federal Advocacy, Rick White at rwhite@biocom.org, for additional information or questions. We hope to engage further with you on this important matter and protect the vital progress made by the Bayh-Dole Act.

¹⁰ *Astellas Quote and Statement on the Bayh-Dole Act and XTANDI | February 9, 2022.*

<https://newsroom.astellas.us/Astellas-Quote-and-Statement-on-the-Bayh-Dole-Act-and-XTANDI-February-9,-2022>

¹¹ *Driving the Innovation Economy. AUTM.* https://autm.net/AUTM/media/Surveys-Tools/Documents/AUTM_FY2018_Infographic.pdf

¹² *How Using March-in Rights Would Threaten America's Research Universities. Information Technology & Innovation Foundation.* <https://itif.org/events/2022/03/29/how-using-march-rights-would-threaten-americas-research-universities>

¹³ *NIH Awards by Location & Organization, FY 2021.*

<https://report.nih.gov/award/index.cfm?ot=&fy=2021&state=&ic=&fm=&orgid=&distr=&rfa=&om=n&pid=#tab1>

¹⁴ *Number of patent grants in the United States in FY 2021, by state. Statista.*

<https://www.statista.com/statistics/256731/number-of-patent-grants-in-the-us-by-state/#:~:text=In%20the%20fiscal%20year%20of.patent%20grants%20in%20that%20year.>

Sincerely,

A handwritten signature in black ink, appearing to read "Joe Panetta". The signature is fluid and cursive, with a prominent initial "J" and a long, sweeping underline.

Joe Panetta
President and CEO
Biocom California