

August 21, 2020

The Honorable Alex M. Azar II  
Secretary  
Department of Health and Human Services  
200 Independence Avenue, SW  
Washington, DC 20201

Dear Secretary Azar:

As leading state life sciences organizations from across the country, we write to express our strong concerns with troubling proposals that would allow the federal government to exercise “march-in rights” on innovative therapeutics or vaccines developed partially with federal funding. We caution that the misuse of march-in rights would discourage further investment into COVID-19 vaccines and therapeutics, and severely undermine the future of all innovative medicine development in the United States.

Our organizations represent biomedical innovators dedicated to researching, developing, and delivering innovative life-enhancing and life-saving treatments and cures, which provide value to the health care system and greater quality of life for patients and caregivers. In the past months, our member companies and research institutions have rallied around developing COVID-19 vaccines, therapeutics, and diagnostics, while pursuing groundbreaking innovation in many other areas, including gene, cell and other therapies for cancers and rare and infectious diseases. We are writing to underscore the importance of the *Bayh-Dole Act* in creating the partnerships that have enabled development of novel therapeutics just months after COVID-19’s emergence, as well as a robust pipeline of treatments and vaccine candidates in late-stage clinical trials.

The *Patent and Trademark Law Amendments Act of 1980* (more commonly referred to as the “Bayh-Dole Act” in recognition of its chief authors, former Senators Birch Bayh (D-Ind.) and Bob Dole (R-Kan.)), and subsequent amendments, established a new legal framework regarding patent rights, in which recipients of federal funding (such as universities, small businesses, non-profits and federal contractors, and grantees) could elect to take title to inventions they create as part of a federally funded research grant, and to engage in the commercialization process, such as licensing the invention to a company to try to develop it into a new product, rather than leaving ownership of inventions within the federal government. Prior to enactment of the *Bayh-Dole Act*, inventions were left to languish on government shelves, rather than being developed into new products and cures for diseases. In particular, a key goal of the *Bayh-Dole Act* was to enable the development and commercialization of new treatments and cures emanating from discoveries made by research institutions. Prior to the 1980s, industry was responsible for 100 percent of applied research. Today, thanks to the law, 25 percent of new medicines involve partnerships with research institutions<sup>1</sup>.

In spite of the undeniable success of the law, proposals keep surfacing to undermine the *Bayh-Dole Act* and misuse “the march-in” rights provision in the law to take away innovators’ intellectual property (IP) rights and control the prices of medicines. The “march-in” provisions of the *Bayh-Dole Act* are intended to be used in very limited circumstances by federal funding agencies to ensure that discoveries are turned into products, such as if the grantee or licensee to a patent “has not taken, or is not expected to take within a reasonable time, effective steps to achieve practical application of the subject invention.” March-in provisions are certainly not intended to be exercised by agencies to act as a price control mechanism for biopharmaceuticals or any other technologies derived from federally-funded research.

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<sup>1</sup> Association of University Technology Managers (AUTM)

This is not only a misread of the intention of the Bayh-Dole Act but introduces a stark disincentive to biomedical innovation at a time when the industry needs predictable and reliable IP protections to fight a global pandemic. The *Bayh-Dole Act* is widely hailed as a policy that fostered the creation of the biotechnology industry and spawned a whole generation of scientist-entrepreneurs. Indeed, the *Bayh-Dole Act* helped establish the biopharmaceutical industry as an important and thriving sector in the U.S. economy, creating jobs in all 50 states and representing a sizable portion of the nation's Gross Domestic Product. This innovative sector is responsible for about 1.9 million jobs across the U.S. and generates an economic output of approximately \$381 billion annually.<sup>2</sup> Our nation's innovation ecosystem has led to groundbreaking therapies and technologies to diagnose, treat and prevent conditions such as cancer, cardiovascular disease, diabetes, HIV/AIDS, chronic pain, Alzheimer's, Parkinson's Disease, and most recently, COVID-19.

Basing march-in on pricing considerations would go against the very aim of the *Bayh-Dole Act*, which is to stimulate the transfer of medical technology between academic institutions and commercial companies to bring new medicines and therapies to patients' bedsides. The government cannot encourage industry to bring products to market by licensing technologies and their associated patents, only to threaten to take them away once the product is commercialized – the result would be a return to the status quo prior to enactment of the *Bayh-Dole Act*, when taxpayer dollars were invested in research that had a minimal chance of ever reaching the market.

Today, the biomedical industry across the U.S. consists mainly of relatively small, entrepreneurial, and venture capital-backed firms that have yet to bring products to market. For these companies, intellectual property – predominantly in the form of patents – is typically their most valuable, and sometimes only, asset. An unreliable patent system would create significant uncertainty for the life sciences sector – especially for small and emerging companies, not to mention other IP-reliant sectors – and undermine incentives for future research. In fact, concepts like march-in and compulsory licensing mirror steps taken by countries that lag in innovative research—efforts that the U.S. government has long fought to stop. Such a change would dramatically undermine the promise of continued biomedical research, investment and innovation in the U.S.

While we agree that patient access to care is of critical importance, we strongly believe that the *Bayh-Dole Act's* march-in provisions should never be used to allow the federal government to set prices for biopharmaceutical products. To suggest otherwise is not only improper and inappropriate but runs fundamentally counter to calls for the biomedical industry to be our saving grace in this time of crisis. We urge you to oppose any efforts to undermine America's global leadership in biomedical innovation by implementing misguided march-in rights proposals. As you move forward, we stand ready to work with you to consider other proposals that will propel American innovation forward and deliver affordable, accessible and innovative therapies for patients who need them.

Sincerely,

Arizona Bioindustry Association (AZBio)  
Biocom  
BioCT  
BioFlorida  
BioForward Wisconsin  
BioKansas  
Bio Nebraska Life Sciences Association  
BioNJ

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<sup>2</sup> The Bioscience Economy: Propelling Life-Saving Treatments, Supporting State & Local Communities. TEconomy and BIO. June 2020

BioOhio  
BioUtah  
California Life Sciences Association (CLSA)  
Colorado BioScience Association (CBSA)  
Georgia Bio  
HealthCare Institute of New Jersey (HINJ)  
Idaho Technology Council (ITC)  
Illinois Biotechnology Innovation Organization (iBIO)  
Indiana Health Industry Forum (IHIF)  
Life Sciences Pennsylvania (LSPA)  
Life Science Tennessee  
Life Science Washington  
Massachusetts Biotechnology Council (MassBio)  
Medical Alley Association  
Michigan Biosciences Industry Association (MichBio)  
Missouri Biotechnology Association (MOBIO)  
Montana BioScience Association  
New Mexico Biotechnology & Biomedical Association (NMBio)  
NewYorkBIO  
North Dakota Bioscience Association  
North Carolina Biosciences Organization (NCBIO)  
Oregon Bioscience Association (OregonBio)  
Puerto Rico Bio Alliance  
RI Bio  
SCBIO  
South Dakota Biotech Association  
Texas Healthcare and Bioscience Institute (THBI)  
Virginia Biotechnology Association (VaBio)