

Congress of the United States
Washington, DC 20515

February 21, 2024

President Joseph R. Biden
The White House
1600 Pennsylvania Ave., NW
Washington, DC 20500

Dear President Biden:

The *Bayh-Dole Act*, enacted with your support in 1980, is a cornerstone of American innovation. The law has been the foundation of public-private partnerships that have driven our economy forward and improved public welfare, here and abroad, by turning federally-funded inventions into useful and widely available products. Importantly, it has allowed American universities—like the University of Delaware, North Carolina State University, Massachusetts Institute of Technology, Penn State University, and Arizona State University—and small businesses to commercialize products and be competitive in an increasingly global market.

Unfortunately, the draft guidance framework that the National Institutes of Standards and Technology (NIST) recently issued on the use of march-in rights under the *Bayh-Dole Act* threatens this system without achieving its stated objective of reducing prescription drug prices. We urge you to reconsider the proposal.

Four decades ago, Congress was able to come together and pass the bipartisan *Bayh-Dole Act* to solve a pressing problem: the need to turn discoveries made with government support into new products. Before the *Bayh-Dole Act*, the federal government owned and patented the advances arising from federally-funded research, but only about 5% of government-held patents were ever commercially utilized.¹ The *Bayh-Dole Act* allows universities and other federal funding recipients to protect their discoveries with patents that they, in turn, license to private companies that further invest funds to transform the discoveries into new commercial products. The law has more than exceeded expectations, creating new jobs and even new industries. *The Economist* described the *Bayh-Dole Act* as “[p]ossibly the most inspired piece of legislation to be enacted in America over the past half century,” observing that “[m]ore than anything, this single policy measure helped to reverse America’s precipitous slide into industrial irrelevance.”²

Since its enactment, the argument has been made that the *Bayh Dole Act*—and particularly its march-in provisions—can and should be used by the government to control prescription drug prices. For example, in 2002, some argued that the law’s provisions allows the government to “march-in” and force universities to license pharmaceutical patents to additional producers if a successfully commercialized drug was not “reasonably priced.”³ But the law’s authors, Senators Birch Bayh and Bob Dole, have made clear that Congress purposely *avoided* including such

¹ Mittal, A. K., *Federal Research: Information on the Government's Right to Assert Ownership Control Over Federally Funded Inventions* (2009), <https://www.gao.gov/assets/gao-09-742.pdf>.

² *Innovation’s Golden Goose*, *The Economist Technology Quarterly* (Dec. 14, 2002), <https://www.economist.com/technology-quarterly/2002/12/14/innovations-golden-goose>.

authority in the *Bayh-Dole Act*.⁴ Testifying at a public meeting that the National Institutes of Health held on the issue, Senator Bayh further explained that the proponents of using march-in rights to control prices had misinterpreted the law’s legislative history and that Congress would have to amend the law to allow “reasonable price” to be a factor in triggering march-in rights.⁵

But Congress has not chosen to amend the law, and for decades, the executive branch never suggested that it had the authority to override that decision. As recently as March 2023, your Administration rejected a petition seeking march-in based on price,⁶ joining every previous administration—Republican and Democratic alike—in denying petitions on that basis.

Given this long-standing precedent, we were surprised that NIST included “reasonable pricing” as a factor in its draft framework for considering the exercise of march-in rights. Proponents claim this change will help lower prescription drug prices, but that is simply not the case. Of the 361 pharmaceutical products that the Food and Drug Administration approved between 2011 and 2020, just five—fewer than 2%—could even be subject to full march-in rights.⁷ Thus, drug price changes prompted by successful march-in petitions will be negligible at best.

That leaves only the serious unintended consequences of NIST’s draft framework, which would apply to *all* types of technologies and products, not just pharmaceuticals.⁸ Under the proposed framework, entrepreneurial startups and small companies across industries—from green technology and precision agriculture to advanced computing and semiconductors—would be subject to march-in petitions challenging their pricing decisions by rival businesses and even our foreign competitors and adversaries, who could use this tool to cast a cloud over the companies that drive our economy. The increased risk of losing control over critical patents also threatens to deter the private investment necessary to commercialize products incorporating federally-funded research, preventing the public from benefiting from that research. The result would be to reverse the very advances the *Bayh-Dole Act* has achieved, and to disastrously disincentivize innovation.

³ Peter Arno & Michael Davis, *Paying Twice for the Same Drugs*, The Washington Post (Mar. 27, 2002), <https://www.washingtonpost.com/archive/opinions/2002/03/27/paying-twice-for-the-same-drugs/c031aa41-caaf-450d-a95f-c072f6998931/>.

⁴ Birch Bayh & Bob Dole, *Our Law Helps Patients Get New Drugs Sooner*, The Washington Post (Apr. 10, 2002), 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.

⁵ *Statement of Senator Birch Bayh to the National Institutes of Health* (May 205, 2004), available at <https://bayhdolecoalition.org/wp-content/uploads/2023/05/2004-Bayh-Statement-to-NIH.pdf>.

⁶ See National Institutes of Health March-In Response (Mar. 12, 2023), available at <https://bayhdolecoalition.org/wp-content/uploads/2023/05/NIH-rejection-Xtandi-marchin-12march2023.pdf>.

⁷ Gwen O’Loughlin & Suan Schulthess, *March-in Rights Under the Bayh-Dole Act & NIH Contributions to Pharmaceutical Patents* (Nov. 30, 2023), <https://vitaltransformation.com/2023/11/march-in-rights-under-the-bayh-dole-act-nih-contributions-to-pharmaceutical-patents/>; see Genia Long, *Federal Government-Interest Patent Disclosures for Recent Top-Selling Drugs*, 22 J. Med. Econ. 1261-67 (June 2019) (finding that less than 3% of patents covering the top-selling drugs from 2013-2017 were developed with government funding).

⁸ NIST, *Request for Information Regarding the Draft Interagency Guidance Framework for Considering the Exercise of March-in Rights*, [88 FR 85593](https://www.federalregister.gov/documents/2023/12/08/88-fr-85593) (Dec. 8, 2023).

NIST’s draft framework would have similarly dire consequences for U.S. academic research institutions, which help drive our innovation economy. Since 1996, technology transfer under the *Bayh-Dole Act* has supported 6.5 million jobs and contributed \$1 trillion to U.S. gross domestic product. In 2022 alone, university research and technology transfer resulted in 998 new startups and 7,739 U.S. patents.⁹ The draft framework would upend these public-private partnerships and chill private-sector investment in university intellectual property. The result: many valuable technologies would not move beyond the campus lab.

Critically, the NIST draft framework is also inconsistent with, and would undermine, initiatives intended to revitalize American manufacturing and bolster American technological innovation. These include programs under the bipartisan *CHIPS and Science Act* that use government funding to support early-stage research and development through public-private partnerships. They also include the Small Business Innovation Research and Small Business Technology Transfer programs that support innovation with public funding and lead to commercialization of those innovations under the *Bayh-Dole Act*.

American innovation is the envy of the world thanks in large part to the *Bayh-Dole Act*. The proposed NIST guidance attempts to change this landmark legislation’s long-established meaning without the consent of Congress. Such an action undermines the separation of powers enshrined in our constitutional system—all without even accomplishing its intended purpose of lowering drug prices. The draft framework will hamstring U.S. innovation to the advantage of our competitors and adversaries, and thus, we urge you to reconsider the NIST proposal.

Sincerely,



Christopher A. Coons
United States Senator



Thom Tillis
United States Senator



Darrell Issa
Member of Congress

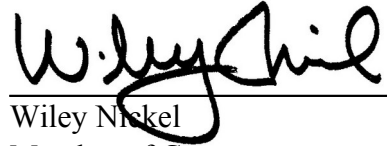


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⁹ Ass’n of Univ. Tech. Managers Infographic (2022), <https://autm.net/AUTM/media/Surveys-Tools/Documents/AUTM-Infographic-22-for-uploading.pdf>.



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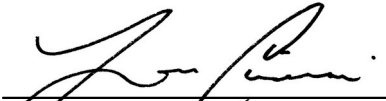
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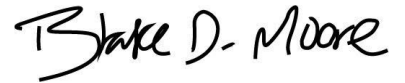
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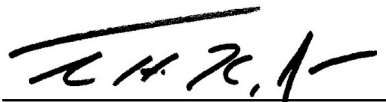
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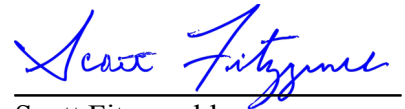
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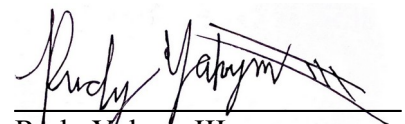
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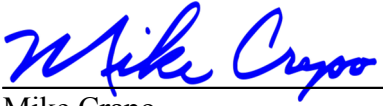
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