Congress of the United States
Washington, DC 20515

[[DATE]]

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 [include 4-6 additional universities from signer states]—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Unfortunately, the draft guidance framework that the National Institutes of Standards and Technology (NIST) recently issued on the use of march-in rights threatens this system without achieving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. 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."[1]

Critics have long asserted that the *Bayh Dole Act*—and particularly its pricing mandates—has not been properly interpreted and enforced. For example, in 2002, some argued that one of the law's provisions allowed the government to "march-in" and force universities to license pharmaceutical patents to additional producers if a successfully commercialized drug was not "reasonably priced."[2] Testifying at the only public meeting that the National Institutes of Health held on the issue, Senator Bayh explained that the critics had misinterpreted the law's legislative history and

[1] *Innovation's Golden Goose*, The Economist Technology Quarterly (Dec. 14, 2002), https://www.economist.com/technology-quarterly/2002/12/14/innovations-golden-goose.

[2] 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/.

that reasonable pricing could only be a factor in triggering march-in rights if Congress amended the law to provide a statutory definition of "reasonable price."[3]

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,[4] joining every previous administration—Republican and Democratic alike—in denying petitions on that basis.

Given this long-standing administration position, 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 march-in rights.[5] 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.[6] 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 resulting in the disastrous effect of disincentivizing innovation.

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.[7] 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.

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[3] *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.

[4] *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.

[5] 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).

[6] NIST, *Request for Information Regarding the Draft Interagency Guidance Framework for Considering the Exercise of March-in Rights*, 88 FR 85593 (Dec. 8, 2023).

[7] Ass'n of Univ. Tech. Managers Infographic (2022), https://autm.net/AUTM/media/Surveys-Tools/Documents/AUTM-Infographic-22-for-uploading.pdf.

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, as well as the Small Business Innovation Research and Small Business Technology Transfer programs that support innovation with public funding and 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.

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[[SIGNATURES]]

CC:
U.S. Department of Commerce Secretary Gina Raimondo
U.S. Department of Health and Human Services Secretary Xavier Becerra
Under Secretary of Commerce for Standards and Technologies Laurie E. Locascio