Congress of the United States
Washington, DC 20515

May 1, 2024

The Honorable Gene L. Dodaro
Comptroller General of the United States
U.S. Government Accountability Office
441 G Street, NW
Washington, DC 20548

Dear Comptroller General Dodaro:

We write to request that your office conduct a study on the impact—should it be implemented—that the National Institute of Standards and Technology's (NIST) proposed framework for exercising march-in rights under the *Bayh-Dole Act* would have on drug prices for Americans, U.S. innovation, and national interests.

The *Bayh-Dole Act* is a cornerstone of American innovation policy. The law has been the foundation of public-private partnerships that have driven our economy forward and improved public welfare, here and abroad, by incentivizing turning federally-funded inventions into useful and widely available 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 new industries while allowing American universities to be competitive in an increasingly global market.

In December 2023, NIST issued a request for public comment on a draft framework directed to the use of march-in rights under the *Bayh-Dole Act*.[2] NIST's proposed framework— contrary to the language and intent of the *Bayh-Dole Act*—would allow agencies to consider "reasonable pricing" as a factor for determining whether to exercise march-in rights (however, what constitutes "reasonable pricing" is undefined in the draft framework).

Although the proposed framework was developed with the laudable objective of reducing prescription drug prices, the facts tell a different story. A March 2024 National Bureau of Economic Research empirical study on the feasibility of using *Bayh-Dole Act* march-in rights to lower drug prices found that NIST's proposed framework will have limited impact—only 2.5% of all drug products approved by the Food and Drug Administration between 1985 and 2022 could

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

even be subject to full march-in rights.[3] Several studies over the past decade have similarly concluded that successful march-in petitions would do little to lower drug prices.[4]

Moreover, the draft framework applies to all types of technologies and products, not just to pharmaceuticals.[5] Thus, the draft framework has the potential to harm innovation across a wide range of technologies that are important to the U.S. economy, including green technology, precision agriculture, semiconductors, and advanced computing.

The draft framework garnered more than 50,000 public comments, many of which urged NIST to withdraw the proposal because it will severely hamstring U.S. innovation.[6] The leading U.S. trade association for generic and biosimilar prescription drug manufacturers, for example, opposed the draft framework, explaining that it will not bring generics or biosimilars to the market more quickly and, instead, is likely to undermine generic and biosimilar development.[7] Public health and patient-focused advocacy groups also opposed the draft framework, raising concerns over its likelihood to disincentivize American innovation.[8] Importantly, universities and associations pointed to the lack of evidence supporting the need for the framework and urged NIST to study the potential negative consequences before implementing it.[9]

We are concerned that implementing the draft framework is likely to have negative consequences for U.S. innovation and global competitiveness, the public-private partnerships that the *Bayh-Dole Act* created, and the U.S. economy. Therefore, we request that you prepare a study on the below questions designed to determine the impact of the draft framework on U.S. prescription drug prices, U.S. innovation, and U.S. national interests. We recommend interviewing those who have

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[3] Lisa Larimore Ouellette & Bhaven N. Sampat, *The Feasibility of Using* Bayh-Dole *March-In Rights to Lower Drug Prices: An Update* (Mar. 2024), https://www.nber.org/papers/w32217.

[4] 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).

[5] NIST, Draft Framework RFI.

[6] *See, e.g.*, Former U.S. Department of Commerce Officials, Comment on Draft Framework RFI, https://www.regulations.gov/comment/NIST-2023-0008-0598; Ass'n of Am. Med. Colleges, Comment on Draft Framework RFI, https://www.regulations.gov/comment/NIST-2023-0008-0554; Nat'l Venture Capital Ass'n, Comment on Draft Framework RFI, https://www.regulations.gov/comment/NIST-2023-0008-0620.

[7] The Association for Accessible Medicines, Comment on Draft Framework RFI, https://www.regulations.gov/comment/NIST-2023-0008-0779.

[8] *See, e.g.*, Am. Cancer Society Action Network, Comment on Draft Framework RFI, https://www.regulations.gov/comment/NIST-2023-0008-0690; Nat'l Health Council, Comment on Draft Framework RFI, https://www.regulations.gov/comment/NIST-2023-0008-0776.

[9] *See, e.g.*, Stephen Susalka, CEO of AUTM, Comment on Draft Framework RFI, https://www.regulations.gov/comment/NIST-2023-0008-46361; Rice Univ., Comment on Draft Framework RFI, https://www.regulations.gov/comment/NIST-2023-0008-0612; Georgetown Univ., Comment on Draft Framework RFI, https://www.regulations.gov/comment/NIST-2023-0008-0819; Univ. of N.C. at Chapel Hill, Comment on Draft Framework RFI, https://www.regulations.gov/comment/NIST-2023-0008-0640.

studied the impact of march-in rights on technology transfer; those who have studied the impact of march-in rights on drug pricing; universities; businesses (both large and small) that have had experience with federal funding and/or licensing federally funded inventions; and investors, such as venture capitalists.

1. To what extent did NIST conduct any analyses to assess the potential economic impact of the *Draft Interagency Guidance Framework for Considering the Exercise of March-in Rights*? Including any impacts on:

    a. U.S. economic growth, competitiveness, technology leadership, and innovation climate;

    b. The pricing and accessibility of products and innovations resulting from federal research funding (including pharmaceuticals);

    c. Universities and research institutions; and

    d. U.S. businesses and manufacturers.

2. To what extent does NIST's assessment reflect the full range and uncertainties of potential effects of changes to march-in rights, including effects identified by stakeholders and experts? For example:

    a. Financial impacts on researchers and licensees;

    b. Attractiveness of federal research funding; and

    c. National security concerns, including potential exploitation of the draft framework by foreign entities.

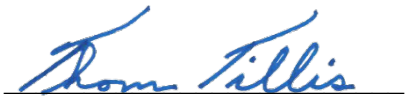
3. To what extent does NIST's draft framework provide clarity for potential licensees and investors when they are making licensing and investment decisions (e.g., on the interpretation of "reasonable price," among other things)?

4. What impact do stakeholders, scholars, economists, and other interested parties expect NIST's draft framework to have on the American economy and economic competitiveness, the U.S. health care system and the availability of innovative medicines, health outcomes for Americans, the U.S. innovation ecosystem and technological leadership, and the use and value of intellectual property in the U.S?

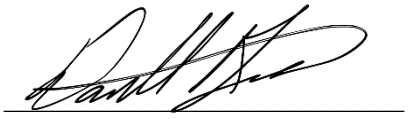
Thank you in advance for your consideration of this request. If you have any questions regarding this inquiry, please contact our offices.

Sincerely,

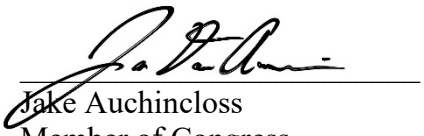
Christopher A. Coons
U.S. Senator



Thom Tillis
U.S. Senator



Darrell Issa
Member of Congress



Jake Auchincloss
Member of Congress