

United States Senate

WASHINGTON, DC 20510

March 4, 2024

VIA ELECTRONIC TRANSMISSION

The Honorable Dr. Monica Bertagnolli
Director
National Institutes of Health
9000 Rockville Pike
Bethesda, MD 20892

Dear Director Bertagnolli:

We write to express concern with the National Institute of Standards and Technology's (NIST) December 8th publication of draft guidance for how agencies should decide whether to exercise "march-in" rights to seize intellectual property related to federally funded research under the Bayh-Dole Act.¹ As you know, the public comment period for the draft framework ended on February 6th.

During your confirmation hearing for the role of Director of the National Institutes of Health (NIH), you stated that you would "follow all the laws of our land."² In this case, the laws are clear: the Bayh-Dole Act does not allow the NIH or any other agency to use march-in rights in response to a product's commercial pricing.

As even the Biden Administration acknowledges, no agency has ever used the Bayh-Dole Act in this way. Previous presidential administrations from both parties have repeatedly affirmed that agencies lack the authority to use the Bayh-Dole Act to seize patents on the basis of prices. Dr. Francis Collins, your predecessor as NIH Director who served in the role for 12 years spanning three presidencies, stated, "the Bayh-Dole Act does not appear to have been intended to be utilized in a fashion where the price is the obstacle."³ The bipartisan authors of the law in question, former Senators Birch Bayh and Bob Dole, also made clear that the law neither gives the government this authority, nor was it intended to. The Senators wrote that the law "did not intend that government set prices on resulting products," and "makes no reference to a

¹ U.S. Department of Commerce, National Institute of Standards and Technology, *Request for Information Regarding the Draft Interagency Guidance Framework for Considering the Exercise of March-In Rights* (scheduled for publication in the Federal Register on Dec. 8, 2023), <https://www.federalregister.gov/public-inspection/2023-26930/draft-interagency-guidance-framework-for-considering-the-exercise-of-march-in-rights>.

² United States Senate Committee on Health, Education, Labor, and Pensions, *Nomination of Monica Bertagnolli to be Director of the National Institutes of Health* (Oct. 18, 2023), <https://www.help.senate.gov/hearings/nomination-of-monica-bertagnolli-to-be-director-of-the-national-institutes-of-health>.

³ United States Senate Committee on Appropriations, Labor, Health and Human Services, Education, and Related Agencies Subcommittee, *Hearing on FY2017 National Institutes of Health Budget Request* (April 7, 2016), <https://www.appropriations.senate.gov/hearings/hearing-on-fy2017-national-institutes-of-health-budget-request>.

reasonable price that should be dictated by the government.”⁴ The Bayh-Dole Coalition, a diverse group including universities, small businesses, and non-profit organizations with interests in research and technology transfer, stated that this draft framework is a “stark departure from the government’s long-standing interpretation of the Bayh-Dole Act” that “would discourage critical public-private partnerships and prevent thousands of transformational discoveries from reaching consumers.”⁵ America’s universities and other research institutions, where the vast majority of NIH-funded research takes place, have all previously denounced efforts to use march-in rights to address drug prices, describing the concept as an “ineffective mechanism to reduce drug prices” that will “significantly undermine university innovation.”⁶

A short-sighted decision to exercise march-in rights would work against your stated goal and jeopardize patient access by discouraging individuals from partnering with NIH to develop new cures and treatments. Not only will this hurt patients, but it will also diminish the return the public gets on the investments Congress makes in NIH each year – something we should all seek to optimize.

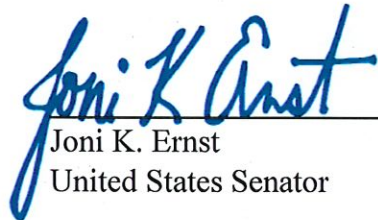
We share the bipartisan goal of wanting to lower drug prices for American patients and families. But using march-in rights to address drug prices would do more harm than good. Agencies, including NIH, should not abuse their authorities to illegally seize intellectual property, and in the process jeopardize the valuable public-private partnerships that make our biomedical research enterprise the best in the world.

Thank you for your attention to this matter.

Sincerely,



Bill Cassidy, M.D.
United States Senator



Joni K. Ernst
United States Senator



Roger Marshall, M.D.
United States Senator



Kevin Cramer
United States Senator

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

⁵ “Bayh-Dole Coalition Statement on Biden Administration’s Proposed March-In Framework,” (December 7, 2023) <https://bayhdolecoalition.org/bayh-dole-coalition-statement-on-biden-administrations-proposed-march-in-framework/>.

⁶ Letter to Secretary Xavier Becerra (July 27, 2022) (signed by the Presidents of the Association of American Universities, Association of Public & Land-Grant Universities, COGR, Association of American Medical Colleges, and Association of University Technology Managers, and the Executive Director of the Bayh-Dole Coalition).



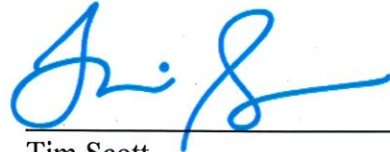
Ted Budd
United States Senator



Mitt Romney
United States Senator



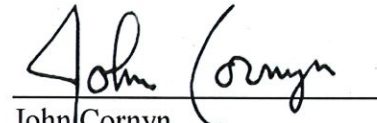
Marco Rubio
United States Senator



Tim Scott
United States Senator



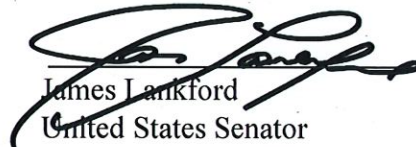
Markwayne Mullin
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John Cornyn
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Rand Paul
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James Lankford
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Roger F. Wicker
United States Senator



Shelley Moore Capito
United States Senator



Susan M. Collins
United States Senator



Tom Cotton
United States Senator

Copy:

The Honorable Xavier Becerra
Secretary of Health and Human Services

The Honorable Gina Raimondo
Secretary of Commerce

The Honorable Laurie Locascio
National Institute of Standards and Technology