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United States Senate

COMMITTEE ON SMALL BUSINESS & ENTREPRENEURSHIP

WASHINGTON, DC 20510-6350

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February 6, 2024

The Honorable Xavier Becerra  
Secretary  
U.S. Department of Health and Human Services  
200 Independence Avenue, Southwest  
Washington, D.C. 20201

The Honorable Gina Raimondo  
Secretary  
U.S. Department of Commerce  
1401 Constitution Avenue, Northwest  
Washington, D.C. 20230

Dear Secretary Becerra and Secretary Raimondo:

On December 8, 2023, the U.S. Department of Commerce's National Institute of Standards and Technology (NIST) released a request for information (RFI) containing a new interagency guidance framework on patent march-in authority, after a joint review of the subject by the U.S. Department of Health and Human Services (HHS) and the U.S. Department of Commerce since spring of 2023.<sup>1 2 3</sup> In reviewing NIST's RFI on the proposed framework, we have serious concerns about its impact on small businesses. It is jarring to see the expanded range of possible circumstances in which the Administration seems intent on seizing patents held by small business owners— including those developed within the Small Business Innovation Research and Small Business Technology Transfer (SBIR-STTR) programs. Broad exercise of march-in authority under the Bayh-Dole Act could disincentivize small businesses from competing for federal research and development (R&D) dollars, discourage commercialization, and stifle America's innovation ecosystem at large.

Americans benefit from small businesses across our country devoting immense time and resources, through federal R&D programs like SBIR-STTR, to pursue technological

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<sup>1</sup> Reference to "march-in authority" refers to march-in rights as defined in the Bayh-Dole Act of 1980 (P.L. 96-517, § 6, codified at 35 U.S.C. § 203)

<sup>2</sup> Notice by the U.S. National Institute of Standards and Technology in the Federal Register, "Request for Information Regarding the Draft Interagency Guidance Framework for Considering the Exercise of March-In Rights." December 8, 2023. <https://www.federalregister.gov/documents/2023/12/08/2023-26930/request-for-information-regarding-the-draft-interagency-guidance-framework-for-considering-the>

<sup>3</sup> U.S. Department of Health and Human Services, "HHS and DOC Announce Plan to Review March-In Authority." March 21, 2023. <https://www.hhs.gov/about/news/2023/03/21/hhs-doc-announce-plan-review-march-in-authority.html>

breakthroughs. Yet, the proposed interagency framework on march-in rights envisions federal agencies standing ready to snatch and license out intellectual property developed by small and large businesses alike. In this regard, it jeopardizes a primary incentive for firms to transition scientific developments into commercial products. Exercising march-in authority could punish companies who wish to progress with their invention beyond basic R&D to commercializing their patented technology. Further, without the promise of secure ownership of intellectual property for those who acquire patents through the SBIR-STTR programs, fewer small businesses will be able to help federal agencies innovate to meet our nation's critical technology goals. Research efforts are likely to fail without the ingenuity and work ethic of the small business community. Finally, the framework may also produce a scenario where businesses take federal R&D grant money and *never* commercialize products, choosing to rely on the federal government to seize their intellectual property and license it to others to bring goods and services to market. This would keep real, growth-oriented startup companies from accessing SBIR-STTR awards and bankroll companies whose business model is to collect hundreds of SBIR-STTR awards with no desire to graduate from the program.

Considering the risks of the proposed interagency march-in framework, it is reasonable for SBIR-STTR companies to be concerned that this proposal will interfere with their commercial success. After all, the framework itself identifies a scenario where an SBIR company's rights to its own invention may be at risk under new guidance.<sup>4</sup> While this risk of march-in is not new, the Biden Administration is making a true mistake if it puts this authority in practice and even expands the scope of allowable justifications as is proposed under the draft framework.

On behalf of small businesses driving technological advancement across our country, we request answers to the following questions no later than February 20, 2024:

1. How are the interests of American small businesses, especially those participating in federally-funded R&D through programs like SBIR-STTR, accounted for in the current proposed framework for implementation of march-in authority?<sup>5</sup>
2. Do you expect the proposed guidance to trigger a formal analysis under the Regulatory Flexibility Act? If not, please explain why and provide formal documentation on the agency's justification.
3. Have you or do you plan to develop any mitigation strategies to counter the potential negative ramifications of the current proposed framework for implementation of march-in authority on innovative small businesses?

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<sup>4</sup> Notice by the U.S. National Institute of Standards and Technology in the Federal Register, "Request for Information Regarding the Draft Interagency Guidance Framework for Considering the Exercise of March-In Rights." December 8, 2023.

<sup>5</sup> Notice by the U.S. National Institute of Standards and Technology in the Federal Register, "Request for Information Regarding the Draft Interagency Guidance Framework for Considering the Exercise of March-In Rights." December 8, 2023.

Americans, and particularly SBIR-STTR companies, deserve clarity on how this proposed framework would impact their efforts to pioneer new technologies.

Sincerely,



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Joni K. Ernst  
Ranking Member



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Marco Rubio  
Member



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Ted Budd  
Member



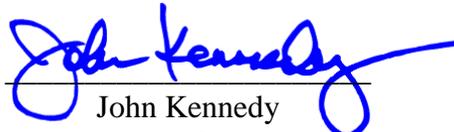
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Todd Young  
Member



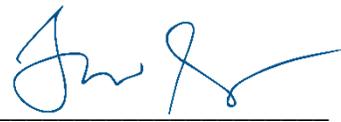
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James E. Risch  
Member



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John Kennedy  
Member



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Tim Scott  
Member

CC: The Honorable Isabel Casillas Guzman, Administrator, U.S. Small Business Administration