Business Roundtable

1000 Maine Avenue, SW, STE 500
Washington, DC 20024
202.872.1260
brt.org

February 6, 2024

The Honorable Secretary Raimondo
Secretary of Commerce
1401 Constitution Avenue, NW
Washington, DC 20230

The Honorable Laurie E. Locascio
Under Secretary of Commerce for Standards and Technology
National Institute of Standards and Technology
100 Bureau Drive
Gaithersburg, MD 20899

Re: Docket No.: 230831-0207 – Request for Information Regarding the Draft Interagency Guidance Framework for Considering the Exercise of March-In Rights

Dear Secretary Raimondo and Under Secretary Locascio:

On behalf of the CEO Members of Business Roundtable, we thank the National Institute of Standards and Technology (NIST) for the opportunity to comment on its *Draft Interagency Guidance Framework for Considering the Exercise of March-In Rights*.

Business Roundtable is an association of more than 200 CEOs of America's leading companies, representing every sector of the U.S. economy. Its members manage companies that support one in four American jobs and generate nearly one quarter of U.S. GDP.

Business Roundtable strongly opposes NIST's proposal to expand the ground for exercising march-in rights beyond the criteria outlined in the statute. The Bayh-Dole framework was developed to spur innovation and to ensure availability of products developed with federal support. NIST's proposal would undermine both objectives. It would decrease private incentives to partner with the federal government on the development of new products, resulting in less availability for the American public. Moreover, because the proposal is technology neutral, it would create a dangerous precedent, threatening the economic viability of future public-private partnerships.

Business Roundtable has long supported the Bayh-Dole Act and the public-private partnerships it enables. The intellectual property regime established under the Act propels new inventions, the adoption of new technologies and even the creation of new industries.

NIST's proposed reinterpretation of Bayh-Dole would encourage federal agencies to step in and exert control of private intellectual property rights. While the federal government does have limited statutorily defined march-in authority, it should not misuse this authority as a tool for government price-setting. If implemented, the proposed framework would be a major step backward for public-private collaboration and innovation in the United States.

As the Congressional Research Service stated in a 2016 report,[1] "No federal agency has ever exercised its power to march in and license patent rights to others [under Bayh-Dole].... [Some experts, including Members of Congress, believe that] march-in rights do not provide such broad authority, but rather are limited to [the] four circumstances identified in the statute. They are also concerned that use of march-in rights might discourage private investment in the often considerable effort needed to bring early-stage technologies to the marketplace." Indeed.

The draft guidance's proposed language would discourage, across all sectors, the investment and innovation by private sector companies necessary to transform early government funded research into products that benefit the American people. The impact of this dramatic change in policy would be felt across the U.S. economy and would compromise the United States' standing as the world's innovation leader.

This proposed NIST framework, if promulgated without change, likely would destabilize decades of bipartisan support for the current Bayh-Dole Act approach. The authors of the statute governing march-in rights have repeatedly and explicitly criticized the approach now being proposed by the Administration, saying that the Bayh-Dole Act "did not intend that government set prices on resulting products" and "makes no reference to a reasonable price that should be dictated by the government. This omission was intentional."[2]

Respected biomedical research leaders from previous Republican and Democratic Administrations have strongly opposed using this authority in the manner now being proposed, recognizing that it could have a devastating impact on research, development and commercialization. At a U.S. Senate Appropriations Committee hearing, Dr. Francis Collins, NIH Director at the time, warned "If we begin to use march-in in a very broad way…, it may in fact be substantial in terms of a loss of interest then in terms of industry participation in discoveries that NIH has supported."[3]

Indeed, the use of "reasonable pricing" clauses in NIH cooperative research and development agreements (CRADAS) until the mid-1990s resulted in such low industry interest in NIH research that Dr. Harold Varmus, NIH Director at the time, rescinded that requirement in 1995.
He stated that "An extensive review of this matter over the past year indicated that the pricing clause has driven industry away from potentially beneficial scientific collaborations … without providing an offsetting benefit to the public."[4]

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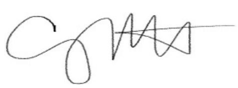
[1] March-In Rights Under the Bayh-Dole Act - Congressional Research Service
[2] Our Law Helps Patients Get New Drugs Sooner - The Washington Post
[3] Senate Appropriations Hearing, S.Hrg.114-160, April 7, 2016.
[4] NIH News Release Rescinding Reasonable Pricing Clause

While this framework will impact the entire economy, the Administration focused its announcement entirely on the effect of march-in rights on drug prices. In fact, this proposal will keep life-saving innovations sitting on the shelf of academic labs rather than leading to successful commercialization that can deliver cures for the benefit of patients. The Administration should instead work collaboratively with private sector innovators and self-insured employers to resolve concerns about affordability in health care.

Finalizing this Interagency Guidance Framework as currently proposed would severely undermine America's highly successful technology and innovation enterprise. It would also undercut other successful Administration efforts to promote American manufacturing, the onshoring of supply chains and technology leadership. Therefore, Business Roundtable requests that NIST withdraw this framework.

Thank you for the opportunity to provide feedback on the draft interagency guidance framework for march-in rights. Business Roundtable strongly urges NIST, the Department of Commerce and its partner agencies to pursue alternative pathways to address affordability without putting the intellectual property of America's innovators at risk.

Sincerely,



Corey Astill
Vice President, Health and Retirement Committee
Business Roundtable