

July 17, 2024

The Honorable Monica M. Bertagnolli, M.D.
Director
National Institute of Health
9000 Rockville Pike
Bethesda, MD 20892

RE: Request for Information on *Draft NIH Intramural Research Program Policy: Promoting Equity Through Access Planning*.

Dear Director Bertagnolli:

On behalf of the CEO Members of Business Roundtable, we thank the National Institutes of Health Office of Science Policy for the opportunity to comment on its [*Draft NIH Intramural Research Program Policy: Promoting Equity Through Access Planning*](#).

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 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. Inherent in these partnerships is the need to get new technologies into the hands of consumers. This approach has proven successful for the economy, consumers, businesses, the government and scientific research. Business Roundtable opposes changes that would disrupt the current framework used to advance federal government funded research into cutting-edge technology.

Business Roundtable opposes the provision in the proposed program policy that would require licensees who succeed in bringing products to market to submit access plans and meet licensee requirements. This requirement would create a dangerous precedent, threatening the economic viability of future public-private partnerships.

While we appreciate that third-party intellectual property (i.e., patents solely owned by NIH's collaborators and partners) would be excluded from the scope of this policy, the draft policy's proposed language would discourage, across all sectors, the private sector partnerships with NIH that are necessary to transform early government-funded research into products that benefit the American people. In particular, NIH's proposal to introduce affordability as a factor would create barriers for new investment inconsistent with the statute. NIH has neither the statutory role nor the expertise to evaluate the complexity of pricing structures, health care

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coverage and reimbursement approaches. Further, the proposal's vague definition of affordability will create significant uncertainty that will discourage investment.

NIH's private sector partners are fully committed to advancing access, including equitable access across diverse populations. Unfortunately, this proposal, along with other proposals surrounding march-in rights, will not advance access but instead stifle innovation, reduce public-private partnerships and limit access to important technologies.

More broadly, Business Roundtable is concerned that expanded use of march-in rights could lead to more aggressive efforts by government to set prices. What constitutes a "reasonable" price may be reinterpreted by a future administration. Likewise, more types of products may be added. The expansive scope of the proposal will likely chill investment in many sectors beyond pharmaceuticals.

Finalizing this policy as currently proposed would undermine industry's willingness to partner with NIH on intramural research. It would also undercut other successful Administration efforts to promote American manufacturing, onshore supply chains and technology leadership. It is bad for patients, bad for innovation, bad for the economy and bad for national security; and it should be withdrawn.

Thank you for the opportunity to provide feedback on the proposed IRP policy. Business Roundtable strongly urges NIH to pursue alternative pathways to address access without placing additional burden on America's innovators.

Sincerely,

A handwritten signature in black ink, appearing to read 'Corey Astill', with a stylized, cursive script.

Corey Astill
Vice President, Health and Retirement Committee
Business Roundtable