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February 1, 2024

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

Re: Request for Information Regarding the Draft Interagency Guidance Framework for Considering the Exercise of March-In Rights, 88 FR 85593

Submitted electronically

Dr. Locascio:

The Association of American Medical Colleges (AAMC) appreciates this opportunity to comment on the request for information (RFI) on the draft Interagency Guidance Framework ("the framework") on the exercise of Federal march-in rights under the 1980 Bayh-Dole Act (PL 96-517).

The AAMC is a nonprofit association dedicated to improving the health of people everywhere through medical education, health care, medical research, and community collaborations. Its members are all 158 U.S. medical schools accredited by the Liaison Committee on Medical Education; 13 accredited Canadian medical schools; approximately 400 teaching hospitals and health systems, including Department of Veterans Affairs medical centers; and more than 70 academic societies. Through these institutions and organizations, the AAMC leads and serves America's medical schools and teaching hospitals and the millions of individuals across academic medicine, including more than 193,000 full-time faculty members, 96,000 medical students, 153,000 resident physicians, and 60,000 graduate students and postdoctoral researchers in the biomedical sciences. Following a 2022 merger, the Alliance of Academic Health Centers and the Alliance of Academic Health Centers International broadened the AAMC's U.S. membership and expanded its reach to international academic health centers.

The AAMC's member institutions conduct a substantial amount of research that is directly subject to the Bayh-Dole Act, including more than 60 percent of the extramural research funded by the National Institutes of Health (NIH), and generate many of the invention disclosures and patents arising from federally funded medical research. These inventions include drugs, devices, diagnostics, biologics (including mRNA vaccines), and other medical technologies. By enabling academic medical centers to negotiate directly with industry in licensing these inventions, Bayh-Dole has been instrumental in moving many discoveries into useful application and has made the United States the world's leader in medical innovation.

The AAMC has significant concerns with the draft framework, which we have considered in the context of the Administration's concerted efforts to reduce drug prices in the United States, as

framed in the White House statement announcing the framework.[1] The AAMC recommends that the framework be withdrawn for the following reasons:

1. The framework includes for the first time open-ended consideration of "marching in" on successfully commercialized inventions for reasons such as access or affordability of a marketed product. This runs contrary to the intent of Bayh-Dole to remove federal agencies as a party to licensing negotiations, development, and application and to refrain from interfering in those processes unless a patent holder fails to move the products of federally funded research into the market.

2. Implementation of the framework would make it less likely that private investors or industry would seek to license inventions by U.S. academic medical centers and universities, out of concerns that the title to an invention could be unilaterally transferred to a competitor or other organization. The guidance to agencies increases the speculative risk for private investment in academic intellectual property. The policy change could delay or preempt development of future innovations, including new drugs or vaccines.

3. The framework could incentivize private investors to collaborate preferentially with non-U.S. or non-federally funded institutions, as the title to resulting inventions would be perceived as more secure. This would be in direct opposition to Bayh-Dole's stated objective to foster U.S.-based development and manufacturing.

4. Crucially, the exercise of march-in rights over drug prices deemed by petitioners to be too high would not solve the systemic challenges of affordability or access to pharmaceuticals. This approach would seek to undermine the negotiated license agreement for inventions underlying pharmaceutical products without any parallel process to ensure that a subsequent licensee brings the product to market at a lower price. **Thus, the proposal is not a comprehensive or effective solution to the very real problem of drug affordability it seeks to address**.

5. The framework reverses two decades of policy on march-in, spanning multiple administrations, and appears to contravene the legislative record of the Bayh-Dole Act without analysis or explanation supporting this reversal. Rather than clarify expectations for agencies, it would instead likely deposit our member institutions in the middle of protracted litigation between their licensees and the Federal government.

For these reasons, the AAMC urges that the framework be withdrawn. No new guidance should be developed without more extensive engagement with the many affected communities, including academic scientists and inventors, the technology transfer community, private sector leaders and investors, and consumer and patient advocates. The current 60-day comment period should be the start of this engagement, not the penultimate step prior to finalization.

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[1] Biden-Harris Administration Announces New Actions to Lower Health Care and Prescription Drug Costs by Promoting Competition, Dec. 7, 2023. Available at: https://www.whitehouse.gov/briefing-room/statements-releases/2023/12/07/fact-sheet-biden-harris-administration-announces-new-actions-to-lower-health-care-and-prescription-drug-costs-by-promoting-competition/.

We further describe these concerns under certain questions posed by NIST in the RFI.

Question 1: Factors for consideration in exercising march-in

As the draft framework notes, the Bayh-Dole Act included several provisions designed to protect the public's interest, including the ability of federal agencies that supported research leading to a subject invention to march in and assert rights to the invention under certain delimited circumstances. The specificity of the march-in provisions reflected Bayh-Dole's primary objective: to ensure that inventions from federally supported research were brought to market and made publicly available as expeditiously as possible. The past four decades have demonstrated that Bayh-Dole has been remarkably successful in catalyzing academic-industry collaborations.

The proposed framework expands the criteria for march-in in ways that improperly expand the limited description of these rights in statute, including, for example, considerations of affordability or availability to different consumers or markets after a subject invention has been commercially developed. If the purpose of Bayh-Dole had been to influence the terms for marketing or distribution of a resulting product, then the Act would have included such specifications and Congress would not have presumptively removed agencies from being parties to the negotiations around an invention's licensing. Rather, the AAMC and many other organizations interpret the "reasonable" terms provision for march-in as ensuring that an inventor or licensee not "sit on" a technology or otherwise fail to actively seek its commercialization.

An invention arising from academic biomedical research is rarely available immediately for practical or clinical application. For example, a drug candidate must be further developed and tested even after it has been patented to determine its safety and effectiveness, to identify unanticipated side-effects, to determine how it is best administered, and to establish whether it can be scaled up for manufacture and distribution. This development process requires extensive preclinical and human testing, which takes years and typically relies on substantial financial investment from the private sector.

While federally funded academic research has led to many important drugs, it is less common for academic institutions to directly "develop" the drug. Instead, university inventions may form the basis for start-up organizations dedicated to bringing a promising compound or technique to human trials, usually in expectation that a successfully demonstrated technology will be purchased by a manufacturer. These start-ups, typically funded through a combination of academic institutional investment, private capital, and community support, are financially risky ventures. The AAMC is concerned that the framework, with its open-ended considerations for march-in on a successfully developed and marketed product, would make these investments unattractive for private investors. Pharmaceutical research and development investments are already highly risky as most pharmaceutical candidates fail. The added risk for investors would include the possibility that title to the underlying invention could be taken away or reassigned by a federal agency in a future action based on accessibility or affordability of the product. Investors might see this proposition as analogous to building a house on land to which they do not have clear title.

Question 4: Utilization of products developed from subject inventions

For decades, there have been calls to exercise march-in rights because of unacceptably high prices of pharmaceuticals that are based on intellectual property developed in federally supported academic research, usually through support from NIH. As the proposed framework notes, all those requests have been declined.[2] The AAMC shares the concerns of patients and families that pharmaceuticals should be accessible and affordable. Such costs also contribute to the strain on AAMC's member health systems. But we do not agree that march-in would be an effective or comprehensive remedy to the challenges relating to pricing or access to commercially available pharmaceuticals. Marketed pharmaceuticals typically incorporate a mix of patented or licensed technologies, often including trade secrets. March-in would only apply to the NIH-supported, university-developed patented components incorporated in the drug, not the privately held intellectual property. Re-licensing federally funded patents alone would in most cases be insufficient to enable a competing company to manufacture the drug. Even if it was an effective mechanism for addressing drug prices, exercise of march-in could not affect drugs developed without federal funding or off-patent drugs that nevertheless remain difficult for many patients to afford or access.

Question 5: Addressing gaps in technology

As the draft framework points out and as noted above, no agency has so far exercised its march-in rights, although there have been several unsuccessful petitions based on pharmaceutical pricing. The draft framework is inconsistent with prior decisions, which have occurred under several administrations based on their consistent interpretation of agencies' statutory authority under the Act. Further support for this interpretation includes statements by Senators Bayh and Dole themselves explicitly noting that the omission of reasonable price from the law was intentional.[3] The draft includes no analysis to explain or justify this reversal.

In closing, the AAMC reiterates our 2022 comments, submitted with five other higher education associations, in a letter to Health and Human Services Secretary Becerra about this very topic:

> We share the concerns of lawmakers and patients about the affordability and availability of medicines and our institutions are themselves impacted by rising drug costs. Universities, medical schools, and teaching hospitals are committed to making health care more accessible and equitable in our capacities both as medical providers and as scientific innovators. However, the use of Bayh-Dole march-in rights does not present an effective and comprehensive means to accomplish this objective…We, therefore, encourage lawmakers to pursue other more comprehensive solutions that ensure every American can afford quality care.[4]

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[2] A pharmaceutical-related march-in request was also at one time filed with the Department of Defense, which also funds biomedical research. https://www.keionline.org/wp-content/uploads/enzalutamide-march-in-royalty-free-Clare-Love-David-Reed-Army-4Feb2019.pdf

[3] Our Law Helps Patients Get Drugs Sooner, Washington Post, April 11, 2002. Available at: https://www.washingtonpost.com/archive/opinions/2002/04/11/our-law-helps-patients-get-new-drugs-sooner/d814d22a-6e63-4f06-8da3-d9698552fa24/

[4] AAMC and joint associations to Sec. Becerra, July 27, 2022. https://www.aamc.org/media/61966/download?attachment

We note that the AAMC's comments here are aligned with and are in addition to those in the joint letter we have submitted in response to this RFI with other organizations representing the higher education community. We urge careful review of those comments in addition to the concerns AAMC raises here, as well as the many letters from the individual academic institutions who have described the impact this framework would have on the viability and value of their own collaborations incentivized by the Bayh-Dole Act.

We are grateful for the opportunity to provide comments and for NIST's continuing engagement with the research community. Please feel free to contact me (hpierce@aamc.org) or my colleague, Stephen Heinig, Director of Science Policy (sheinig@aamc.org) with questions.

Sincerely,

Heather H. Pierce, JD, MPH
Acting Chief Scientific Officer

cc: David J. Skorton, MD, AAMC President and Chief Executive Officer