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Laurie E. Locascio
Director
National Institute of Standards and Technology
U.S Department of Commerce
100 Bureau Drive
Gaithersburg, MD 20899

RE: NIST-2023-0008, Draft Interagency Guidance Framework for Considering the Exercise of March-In Rights

Dear Ms. Locascio:

On behalf of Emory University, we are pleased to offer comments in response to the request for information released by the National Institute of Standards and Technology (NIST) seeking feedback on the Draft Interagency Guidance Framework for Considering the Exercise of March-In Rights under the Bayh-Dole Act.

In 2023, Emory University was the proud recipient of over $684 million in federal research funding. While we are proud to steward these federal dollars, the output of this research does not accrue only to Emory—we have a team of staff to ensure that Emory research and innovations maximize benefit to humanity. When our research has the potential to innovate, Emory is committed to collaborating with researchers and industry to build and nurture partnerships that will move ideas from the lab to the marketplace in a fair and equitable manner. NIST's proposed framework would have a negative impact on our future ability to find partners for promising new innovations arising from our research community.

With this perspective in mind, we are pleased to offer feedback on the request for information and appreciate your consideration.

I. Recognition of Industry Partners in U.S. Drug Development

According to a 2018 report, funding provided by the National institutes of Health (NIH) "contributed to published research associated with every one of the 210 new drugs approved by the Food and Drug Administration (FDA) from 2010–2016," although federal agencies would not be

able to march in on most of these medications given the nature of NIH investment in these cases. This research involved more than $100 billion in grant funding focused on "basic research related to the biological targets for drug action rather than the drugs themselves."[1] The role of federal funding in research and drug development, while crucial, complements the industry investments. Despite these significant federal contributions, industry is the dominant source of research and investment for novel, FDA-approved medicines that are subject to Bayh-Dole regulations, contributing $44.3 billion toward patented drugs subject to the Bayh-Dole Act between 2011 and 2020, compared to the federal government's $276 million.[2]

This reality underscores one major issue with the proposed interagency framework on march-in rights. The concern NIST and its partner agencies should consider is that allowing the federal government to use its march-in rights would not have a demonstrable effect on high drug prices in the small percentage of drugs that are covered by federally funded inventions. There is usually a family of patents that eventually cover FDA-approved drugs. Issuing mandatory licenses to competitors of the company with the patent would likely be ineffective, as the company will often have other, non-federal patents covering the final product. Furthermore, the framework could have a chilling effect on future industry investment in drug research and development. There is a high failure rate in drug development, and patients need industry to continue to take that risk. Previous attempts to implement fair pricing requirements for NIH Cooperative Research and Development Agreements show investment avoidance in commercializing academic inventions, a decrease in NIH partnerships and an advantage for foreign biopharmaceutical markets.[3] Giving the government the ability to march in runs the risk of making these federally funded inventions too risky or expensive for development, and therefore investment, and will not contribute to the goal of lowering drug prices for consumers.

II. Importance of the Bayh-Dole Act's Constraints on March-In Rights

The proposed framework directly conflicts with the U.S. government's very own interpretation and application of the march-in provision of the Bayh-Dole Act over the last 43 years. Where the Bayh-Dole Act applies, it is intended to incentivize the private sector to license inventions to which early government-funded research contributed and develop them into potentially life-saving drugs. In his recent comments to the White House regarding the proposed framework, Sen. Thom Tillis acknowledged that "by allowing grant recipients such as universities to retain the title to the patents covering their inventions and enabling them to license the patents and the right to use those

[1] Ekaterina Galkina Cleary, Jennifer M. Beierlein, Navleen Surjit Khanuja, and Fred D. Ledley, "Contribution of NIH funding to new drug approvals 2010–2016," Proceedings of the National Academy of Sciences, February 12, 2018, https://www.pnas.org/doi/full/10.1073/pnas.1715368115.

[2] Gwen O'Loughlin and Duane Schulthess, "March-in rights under the Bayh-Dole Act & NIH contributions to pharmaceutical patents," Vital Transformation, November 30, 2023, https://vitaltransformation.com/wp-content/uploads/2023/11/march-in_v11_BIO-approved-30Nov2023.pdf.

[3] Ibid.

inventions to private sector partners, the Bayh-Dole Act has been hugely successful in facilitating the development of commercially available medical treatments and other products and maximizing taxpayer benefit for government-funded research."

While the Bayh-Dole Act gave the federal government march-in rights under an extremely limited set of circumstances, the framework must consider that those circumstances were never intended to regulate the price of any product subject to the law. Sen. Tillis also recognizes that "in the nearly four decades that the Bayh-Dole Act has been in place, [NIH] has denied every march-in petition based on pricing that has been submitted to the agency. In each case, NIH consistently concluded that the products subject to a march-in petition had reached practical application and met health or safety needs."

III. Impact of New Framework on Universities

The Bayh-Dole Act has a long history of established success in fostering innovation through collaboration between academia and industry. In the four decades since Bayh-Dole, all major universities have built expert patenting, licensing and technology transfer teams that facilitate the movement of federally supported inventions from their academic laboratories to industry. The Bayh-Dole Act provided a legal infrastructure for organizations, including and especially universities, with complementary skills and purposes to work together. Academic investigators often try ideas that do not work. In contrast, industry must focus on manufacturing and distribution of quality-controlled products at scale. This crucial partnership benefits not only the partner organizations, but also U.S. taxpayers and, ultimately, patients.

Giving the federal government a broader set of circumstances under which an agency can exercise its march-in rights through the inclusion, for the first time, of pricing criterion will have a detrimental effect on federally funded inventions. Universities will face increased scrutiny when they market these inventions to companies that are diligently assessing the risks associated with new technology when making investment decisions. Industry would also be discouraged from funding research at universities or sharing materials and data out of concern that pricing controls could ultimately be enforced via march-in rights. This hesitancy would impede the translation of groundbreaking research into tangible products, undermining the post-Bayh-Dole success of public-private partnerships. Industry may no longer view its collaboration with universities as mutually beneficial, but rather as a risky investment that could endanger their product lines and IP portfolios. Furthermore, the proposed framework could have a downstream effect on industry involvement in many of the programs that rely on industry collaboration with universities (e.g., ARPA-H).

Ultimately, Emory University is concerned that the proposed framework will increase barriers to federally funded research that benefits patients despite the vital lessons learned since enactment of the Bayh-Dole Act—including the impact of the law on global competition, as other countries replicate the law's success, and the COVID-19 pandemic that demonstrated the urgency and

importance of the partnerships among industry, the federal government and academia that the Bayh-Dole Act facilitated.

We appreciate your consideration of our comments on these topics. If you have any questions, please contact Jessica Davis, Assistant Vice President of Federal Affairs.

Sincerely,

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Associate Vice President of Research, and Executive Director for the Office of Technology Transfer