February 6, 2024

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

Re: Comments in response to NIST's Request for Information Regarding the Draft Interagency Guidance Framework for Considering the Exercise of March-In Rights (Federal Register/Vol. 88, No. 235/Dec. 8, 2023)

Submitted electronically

Dear Director Locascio,

I am writing in response to the agency's *Request for Information Regarding the Draft Interagency Guidance Framework for Considering the Exercise of March-In Rights*. On behalf of the Council for Affordable Health Coverage (CAHC), I would like to express our opposition to the newly proposed framework.

CAHC is a broad-based coalition dedicated to ensuring universal access to affordable health coverage. We believe in promoting competitive, efficient, and transparent markets, supporting incentives for wellness and prevention, and improving patient choice, efficiency, and value.

CAHC knows the difficulty American patients face when buying the medicines they need. As an organization, we actively promote and develop policies that make health care more affordable. One area of concern is federal policies that slow or halt new products coming to market, as having multiple and innovative products introduced into the market fosters competition. Targeting the intellectual property protections and research incentives that Bayh-Dole codified is no way to lower prices but is a surefire way to lock in the status quo and high costs.

It is impossible to overemphasize the importance of the Bayh-Dole Act or its role in fostering American innovation. Before the bill was enacted in 1980, the United States lagged behind other first-world nations in developing innovative technologies. The government held the patents and licensing rights to all discoveries resulting from federally funded research. Funding agencies, however, had little incentive to encourage the commercialization of these discoveries.

The incentive problem was abstract, but the consequences were concrete. During the pre-Bayh-Dole era, the U.S. government held around 28,000 patents resulting from government-sponsored research. But it had licensed barely 5 percent of them for development.[1]

[1] https://www.gao.gov/assets/rced-98-126.pdf

The Bayh-Dole Act transferred to universities, federal labs, and businesses that received federal research funds the patent and licensing rights on their discoveries and inventions, empowering them to license them to commercial partners in exchange for royalty payments and other compensation. With the incentive structure corrected, tech transfer flourished. Between 1996 and 2020, the introduction of the new system led to the issuance of 126,000 new patents to research institutions and the creation of almost 17,000 startups.[2] The new system added $1 trillion to U.S. gross domestic product and contributed more than 200 life-saving drugs and vaccines to the healthcare system.[3]

Bayh-Dole's "march-in" provision allows the government to relicense patents in certain, limited circumstances, such as when licensees fail to make a good-faith effort to develop them. These rights were included as a fail-safe in the legislation to ensure federally backed inventions were reaching the marketplace. The government has never invoked this authority and has consistently rejected activist petitions that urge agencies to march in based on a successfully developed product's price.

The proposed framework reverses course, allowing federal officials to consider price as a trigger for march-in. This would threaten medical progress.

One objective of those promoting the proposed framework is to reduce drug prices. But march-in rights will prove to be an ineffective tool towards that goal.

Government march-in authority under Bayh-Dole is confined to patents resulting from federal funding. Because of the complexity of most pharmaceuticals, intellectual property underlying each product typically consists of multiple patents, many of them developed without the use of public funding. According to a 2023 study by Vital Transformation, which examined a cohort of 361 pharmaceutical products launched in recent years, only five depend solely on government-funded patents.[4] In other words, even the most aggressive efforts to reinterpret march-in rights would not affect 99 percent of drugs.[5]

Nevertheless, the mere threat of having to contend with march-in petitions would introduce a new element of uncertainty into biotech companies' investment decisions.

The historical record provides ample evidence of why the bureaucratic pursuit of a "fair" price for a product would discourage investment. When the National Institutes of Health (NIH) added a clause requiring "reasonable pricing" to its Cooperative Research and Development Agreements (CRADAs) in 1990, the number of CRADAs fell and stagnated.[6] After the NIH

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[2] https://autm.net/AUTM/media/Surveys-Tools/Documents/AUTM-Infographic-22-for-uploading.pdf, p. 1

[3] https://autm.net/AUTM/media/Surveys-Tools/Documents/AUTM-Infographic-22-for-uploading.pdf, p. 1

[4] https://vitaltransformation.com/wp-content/uploads/2023/11/march-in_v11_BIO-approved-30Nov2023.pdf, p. 19

[5] https://vitaltransformation.com/wp-content/uploads/2023/11/march-in_v11_BIO-approved-30Nov2023.pdf, p. 19

[6] https://www.techtransfer.nih.gov/sites/default/files/CRADA%20Q%26A%20Nov%202021%20FINAL.pdf, p. 3

eliminated the clause in 1995, investor confidence revived, and the number of partnerships soared.[7]

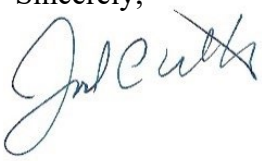
If the NIST finalizes the proposed framework, history will repeat itself. The framework fails to provide any specific criteria for officials to use in determining "reasonable" pricing.[8] This ambiguity of scale and scope would further decrease investor confidence.

If we want to increase the affordability of health care, we must embrace the system of innovation that drives it forward. It is important to note that the price of a new medication typically declines swiftly and sharply when its patents expire, and competitors can enter the market. Over time, this has been a source of trillions in savings for our healthcare system -- $408 billion in 2022 alone.[9]

But before patients can save money from generics, there must be novel drugs developed in the first place. Innovation is not a given -- it depends on the right policy environment.

The system works well as designed and currently implemented. For that reason, we urge you to withdraw the proposed framework.

Sincerely,



Joel C. White
President

[7] https://www.techtransfer.nih.gov/sites/default/files/CRADA%20Q%26A%20Nov%202021%20FINAL.pdf, p. 3

[8] https://www.federalregister.gov/documents/2023/12/08/2023-26930/request-for-information-regarding-the-draft-interagency-guidance-framework-for-considering-the#:~:text=The%20objectives%20for%20the%20Draft,determining%20whether%20to%20march%2Din.

[9] https://accessiblemeds.org/resources/press-releases/generic-biosimilar-drugs-generate-408-billion-savings-2022#:~:text=According%20to%20the%20analysis%2C%20the,approved%20generic%20and%20biosimilar%20drugs.