February 1, 2024

By Electronic Filing

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

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

Dear Director Locascio,

As a non-profit advocacy organization, FreedomWorks seeks to promote the values of limited government, social tolerance, and individual liberty within today's political discourse. With the objective of restoring common sense and competence to public policy and American political life, FreedomWorks envisions a future where growth and prosperity result in opportunity for all Americans.

Since 1980, the Bayh-Dole Act[1] has provided a uniform framework for the federal government that fosters innovation through the transfer of technology from public sector entities and federally funded institutions to the private sector. Under this framework, recipients of federal funding agreements such as universities may license patents to allow private sector entities to use inventions. A private sector entity can elect to retain ownership of an invention when certain contractual obligations are met.[2]

Before the enactment of the Bayh-Dole Act, as the Government Accountability Office notes, "[W]hen the government routinely retained the patents on federally sponsored inventions, only 5 percent of these patents were ever used in the private sector."[3] Noting the lack of development and innovation before the enactment of the Bayh-Dole Act, in May 1979, then-Comptroller General Elmer Staats wrote that the federal government's proclivity of taking ownership of patents was "impeding cooperative efforts between universities and the commercial sector."[4] This blocked the development and innovation of inventions.

This destructive approach pushed away private sector partners. "We found that hundreds of new compounds developed at university laboratories had not been tested and screened by the pharmaceutical industry," Staats wrote to Congress, "because manufacturers were unwilling to undertake the expense without some possibility of obtaining exclusive rights to further development of a promising product."

The Bayh-Dole Act includes "march-in rights" through which the federal agency facilitating a funding agreement between a public sector institution and a private sector entity that has retained ownership of a patent may force the private sector entity to grant a license.[5] However, the criteria for "march-in rights" are specific and narrow.

The *Draft Interagency March-In Guidance Framework* perversely changes the intent of the Bayh-Dole Act—which, as its sponsors in Congress, noted is "to spur the interaction between public and private research

---

[1] Pub.L. 96-517
[2] 35 U.S.C. §202
[3] https://www.gao.gov/assets/gao-09-742.pdf
[4] https://www.gao.gov/assets/109391.pdf – Staat was writing about the Department of Health, Education, and Welfare (HEW). HEW was renamed to the Department of Health and Human Services under the Department of Education Organization Act, which was enacted in October 1979, although the renaming officially took place in May 1980.
[5] 35 U.S.C. §203

so that patients would receive the benefits of innovative science sooner"[6]—into a price control scheme that, like other actions taken in recent years, will suppress innovation and inhibit the research and development of new vaccines and treatments by biotech and biopharmaceutical companies. Put simply, the *Draft Interagency March-In Guidance Framework* is bad policy that history has proven will fail.

We know the consequences of "reasonable pricing" from the past. The National Institutes of Health (NIH) and Public Health Service (PHS) inserted a "reasonable pricing clause" in Cooperation Research and Development Agreements (CRADAs) in 1989. The decline in CRADAs after the "reasonable pricing clause" was included in CRADAs was immediate, as private companies did not want to be subjected to what were effectively price controls.

The lack of participation from the private sector that was driven by the "reasonable pricing" scheme only hurt innovation. In April 1995, after studying the issue and hearing feedback from stakeholders, NIH Director Harold Varmus, M.D. terminated the "reasonable pricing clause." He explained, "An extensive review of this matter over the past year indicated that the pricing clause has driven industry away from potentially beneficial scientific collaborations with PHS scientists without providing an offsetting benefit to the public."

The NIH noted this experience with "reasonable pricing" in November 2021 and detailed that CRADAs increased by "four-fold" between FY 1996 and FY 2000 after the elimination of the "reasonable pricing clause" compared to FY 1991 and FY 1995, when the scheme was in place. As NIH explained, "We concluded that the primary stimulus for the increase in CRADAs most likely was the removal of the reasonable pricing clause[.]"

As noted, we have been here before. Unfortunately, no lessons have been learned, as evidenced by the *Draft Interagency March-In Guidance Framework*.

One of the questions to be considered under the *Draft Interagency March-In Guidance Framework* is, "Is the contractor or the licensee exploiting a health or safety need in order to set a product price that is extreme and unjustified given the totality of circumstances?" It also included other considerations, including, "It should be noted that in reviewing this question, the agency is not limited to reviewing price increases; the initial price may also be considered if it appears that the price is extreme, unjustified, and exploitative of a health or safety need."

The *Draft Interagency March-In Guidance Framework* does not include any definitions of "extreme, unjustified, and exploitative of a health or safety need." It does not include how such a price would be assessed or determined. It is ambiguous and, presumably, subjective to the whims of the federal agency.

The NIH has stated that "the extraordinary remedy of march-in is not an appropriate means of controlling prices."[7] That is a view that NIH has reiterated.[8] The Congressional Budget Office has noted, "Empirical studies find that public-sector research tends to increase private R&D rather than to decrease it—that is, they are complements, not substitutes. Several recent studies have associated increases in NIH-funded basic research with increased private R&D efforts. One study found that in the decade following an increase in NIH funding, private R&D spending grew by about eight times as much as the increase in that funding. Another study found that for every two NIH research grants, about one new private-sector patent was awarded."[9]

It is ironic that the Bayh-Dole Act was signed when the United States economy struggled to gain momentum after the uncertainty of the 1970s. Today, the United States faces even more serious challenges—post-pandemic uncertainty, international competitiveness from unfriendly nations, and reactionary approaches to public policy

---

[6] https://www.washingtonpost.com/archive/opinions/2002/04/11/our-law-helps-patients-get-new-drugs-sooner/d814d22a-6e63-4f06-8da3-d9698552fa24/

[7] https://www.techtransfer.nih.gov/sites/default/files/documents/policy/March-In-Norvir.pdf

[8] https://www.techtransfer.nih.gov/sites/default/files/documents/policy/March-in-xalatan.pdf

[9] https://www.cbo.gov/publication/57126

that cast aside evidence and history for political expediency and short-term partisan wins. Administrative actions, such as the *Draft Interagency March-In Guidance Framework*, will undermine the United States, exacerbate the existing sense of uncertainty, and make us less internationally competitive at a time when we need to unleash the forces of innovation.

Thank you for your consideration of these views.

Sincerely,

Adam Brandon
President
FreedomWorks