

Before the

**National Institute of Science and Technology
Department of Commerce**

In the Matter of

**Request for Information Regarding the Draft Interagency Guidance Framework for
Considering the Exercise of March-In Rights**

Docket No. 230831-0207

Comments of

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About the Commenter

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Overview

The goal of any framework implementing Bayh-Dole Act march-in rights should be to reflect the public's right of reasonable access to federally funded inventions while preserving America's position at the forefront of innovation. The proposed framework is a positive step toward advancing the policy goals of the Bayh-Dole Act. The framework's explicit acknowledgement of price as a factor for agency consideration clarifies a long-standing debate and provides the possibility for an important safety net in infrequent cases when an essential medical product based on publicly-funded patented research is excessively priced. To improve the framework further, we recommend two targeted changes that clarify and align the framework with the text of the Bayh-Dole Act:

1. Realign the framework's "extreme, unjustified, and exploitative" language with 35 USC § 203(a)(2)'s "health and safety needs . . . not reasonably satisfied" language.
2. Realign the framework's "high pricing . . . unreasonably limiting availability" language with 35 USC § 203(a)(1)'s "unreasonable terms" language.

The Proposed Framework Clarifies the Policy Goals of the Bayh-Dole Act

The Bayh-Dole Act ("the Act") encourages innovation by defining federal policy regarding the commercialization of publicly funded research. The Act's three primary objectives are (1) to ensure inventions developed with federal funding are "used in a manner to promote free competition and enterprise without unduly encumbering future research and discovery," (2) to promote wider participation "in federally supported research and development efforts," and (3) to "protect the public against nonuse or unreasonable use of inventions."¹ The National Institute for Standards and Technology (NIST) and other agencies have diligently promoted the first two objectives. However, the third objective of protecting the public against nonuse has been relegated to the background. By clarifying the conditions needed to exercise march-in rights—especially conditions related to product pricing—NIST's proposed framework is a substantial step towards refocusing policy to achieve a central goal of the Act. While some aspects of the language in the proposed framework could be adjusted to meet the central goal even more directly, the current framework is an important achievement.

While the Act succeeds in securing private investor profits and promoting American innovation, funding agencies have failed to consider returns to all stakeholders. Given that substantial tax dollars are spent on research projects that do not lead to marketable products, taxpayers should benefit from the research that *does* succeed in producing inventions. Reasonable prices are the most direct and simple way for patients and consumers to benefit from these tax-funded inventions. Instead, Americans find themselves paying *even higher prices* than patients in other comparable high-income nations for medications resulting from their own government's research.

The Framework Correctly Recognizes that Price is a Relevant Factor for Use of March-in

The Public Has a Statutory Right of Reasonable Access to Federally Funded Inventions

Congress designed the Bayh-Dole Act to ensure the promotion of innovative collaboration and further public access on reasonable terms to innovations that receive federal funds. Persistent issues of drug affordability that can undermine product accessibility suggest a need to reassess how "reasonable terms" are defined in today's context, which includes pricing as a factor.

Without a guiding framework in place, history has shown that both the public and the government struggle to decide when and how march-in rights should be used. Since 1980, petitions to use march-in rights have been filed with the NIH for at least 6 different drug and device products but each time march-in rights have not been pursued.² In January 2021, NIST proposed a rule stating

¹ [35 U.S. Code § 200](#).

² Kesselheim, A. S., Tan, Y. T., Avorn, J. (2015). The roles of academia, rare diseases, and repurposing in the development of the most transformative drugs. *Health Affairs (Millwood)*, 34(2), 286–293. <https://doi.org/10.1377/hlthaff.2014.1038>.

that price could never be the sole factor triggering march-in.³ This resulted in over 80,000 comments and ultimately led to President Biden issuing an executive order directing the Secretary of Commerce, acting through the Director of NIST, to consider not finalizing the pricing provision.⁴ NIST wisely chose to heed this advice.

The deluge of comments to NIST, coupled with the executive order from the President, demonstrates the widespread interest in the role of price when weighing the option to march in. The Bayh-Dole Act is clear: for a subject invention to achieve practical application, its benefits must be made available to the public on *reasonable terms*. Reasonable terms include a reasonable price.⁵

We also applaud the heightened clarity provided by the framework, particularly its use of example scenarios, regarding the range of industries affected by the Act and the exercise of march-in rights. As evidenced by many of the comments on this framework and the 2021 proposed regulation changes, much of the discussion around march-in rights has focused on the healthcare industry and pharmaceutical pricing. Yet, this is not all that is at stake. Industries such as chemical producers, additive manufacturing, digital communications, and countless others also benefit from the current system of federal funding for privately-owned patents. These industries may also have instances of innovation failing to result in public benefit, which thoughtful exercise of march-in rights can alleviate.

Innovation Will Continue to Thrive Under this Framework

The proposed framework will have a negligible impact on the existing ecosystem of innovation. While critics of the framework will likely make claims that incentives to innovate will be diminished and innovation will therefore halt, these claims are unjustified. March-in is already a tool available to agencies. The framework simply clarifies factors to be considered in applying this existing discretionary power. It does not change the reality that march-in will only be employed in rare instances when a patent owner seriously abuses the public trust. In fact, in the more than 40

³ “Rights to Federally Funded Inventions and Licensing of Government Owned Inventions: A Proposed Rule by the National Institute of Standards and Technology on 01/04/2021.” *Federal Register*, www.federalregister.gov/documents/2021/01/04/2020-27581/rights-to-federally-funded-inventions-and-licensing-of-government-owned-inventions.

⁴ “Executive Order on Promoting Competition in the American Economy.” *The White House*, <http://www.whitehouse.gov/briefing-room/presidential-actions/2021/07/09/executive-order-on-promoting-competition-in-the-american-economy/>.

⁵ See Peter S. Arno & Michael H. Davis, “Why Don’t We Enforce Existing Drug Price Controls? The Unrecognized and Unenforced Reasonable Pricing Requirements Imposed Upon Patents Deriving in Whole or in Part from Federally Funded Research,” 75 *Tulane L. Rev.* 631, 644 n.69, 649–53 (2001) (explaining that the ordinary meaning of the words “‘reasonable terms’ have uniformly been interpreted to include price” in contexts including as a remedy to monopolistic markets); see also Jennifer Penman & Fran Quigley, “Better Late than Never: How the U.S. Government Can and Should Use Bayh-Dole March-In Rights to Respond to the Medicines Access Crisis,” 53 *Williamette L. Rev.* 1, 7–12 (2017) (finding “an abundance of evidence that the Bayh-Dole Act’s march-in provisions were devised to ensure that federally funded inventions be available to the public at reasonable prices”)

years since the Act’s passage, this tool has been invoked only a handful of times and has never been used.

Industries claim that exercising march-in rights will deter companies from engaging in government-funded research due to fears of losing control over their patents. In the pharmaceutical industry especially, this fearful perspective fails to fully consider the current operational dynamics of research and development. Increasingly, large drug companies rely on scientific collaboration and federal funds for successful innovation.⁶ There is scant evidence to suggest that the exercise of march-in rights, even based on pricing, would substantially deter collaborations with universities or other research entities. The pharmaceutical industry's reliance on public-private partnerships and federally-funded basic and translational science research indicates a more complex interaction than is often portrayed by industry executives. Therefore, inflated claims that this proposed framework will severely hinder innovation are unfounded.

In fact, there are many reasons to believe that industry incentives to invest in publicly financed research will remain strong, even under the current proposed march-in rights guidance. First, studies show that drugs with late-stage connections to publicly-funded research are of greater therapeutic importance than drugs without such a link.⁷ Drugs of greater therapeutic importance often earn substantial revenues for their sponsors.⁸ It is implausible to imagine that for-profit drug companies would systematically avoid investing in drugs with a high likelihood of earning substantial revenues simply because of the remote possibility that march-in rights—which have existed all along—could possibly be invoked if pricing is found to be unreasonable and serves to block patient access to the drug.

Indeed, similarly inflated claims were made when Congress initially debated the Bayh-Dole Act. Industries warned that march-in rights would disincentivize innovation and limit medical breakthroughs. The pharmaceutical industry now recognizes that the Act has had a positive impact on innovation, with the collaboration between government-funded university research and the pharmaceutical industry having led to numerous medications for patients.⁹ March-in rights have had a negligible impact on innovation, and this framework clarifying their scope is unlikely to substantially alter the status quo.

⁶ Sarpatwari, A., Kesselheim, A. S., & Cook-Deegan, R. (2022). The Bayh-Dole Act at 40: Accomplishments, Challenges, and Possible Reforms. *Journal of Health Politics, Policy and Law*, 47(6), 879–895. <https://doi.org/10.1215/03616878-10041247>

⁷ Nayak R K, Avorn J, Kesselheim A S. Public sector financial support for late stage discovery of new drugs in the United States: cohort study. *BMJ*. 2019; 367; <https://www.bmj.com/content/367/bmj.15766>.

⁸ Egilman AC, Rome BN, Kesselheim AS. Added Therapeutic Benefit of Top-Selling Brand-name Drugs in Medicare. *JAMA*. 2023; 329(15):1283–1289. <https://jamanetwork.com/journals/jama/fullarticle/2803804> (finding that *within Medicare, drugs with lower added benefit had lower net spending per beneficiary (median \$992 vs \$32,287)*).

⁹ “The Role of the Bayh-Dole Act in Fostering Technology Transfer and Implications for Innovation.” *PhRMA*, <https://www.phrma.org/-/media/Project/PhRMA/PhRMA-Org/PhRMA-Org/PDF/A-C/Bayh-Dole-Whitepaper-FINAL---21820.pdf>.

The pharmaceutical industry also reacted strongly against the Hatch-Waxman Act and subsequent amendments, claiming that patients would suffer due to a lack of investment in research and development if they were passed.¹⁰ Yet, since the passage of the Hatch-Waxman Act, the global pharmaceutical industry has experienced financial returns far exceeding other industries.¹¹ The pharmaceutical industry also reacted strongly against the passage of the Inflation Reduction Act in 2022, arguing that its system of Medicare drug price negotiation would destroy incentives for innovation. The CBO recently found that venture capital investments in pharmaceutical manufacturers have actually increased since the Inflation Reduction Act has passed.¹² The pharmaceutical industry and other interested parties will exaggerate the potential impact of any change to the current system. The reality is that innovation will continue to thrive because in each of these cases, as in the case of the proposed march-in rights guidance, policy changes are being made that are nuanced and supported by reasonable economic principles.

Perceived changes as laid out in the proposed march-in rights framework will likely have minimal impact on innovation. Patents are one of many tools to promote innovation. Direct government funding is another tool to positively impact innovation, and the Bayh-Dole Act recognizes that importance. The Act promotes the public funding of research and the corresponding march-in rights to ensure the public receives a fair return on its investment via reasonable access to publicly funded inventions. March-in rights are a necessary insurance policy against the worst abuses of public trust.

“Extreme, Unjustified, and Exploitative” Unnecessarily Deviates from Statutory Language

While this framework takes an important step in explicitly recognizing price as relevant, there are conspicuous mismatches in language between framework and statute. Left unaddressed, these mismatches could create new sources of confusion and inaction for funding agencies.

The Act’s march-in Criterion Two grants funding agencies the right to march in when “necessary to alleviate health or safety needs which are not reasonably satisfied[.]”¹³ The framework’s Criterion Two explanation raises the bar, asking in section V (under “Is a Statutory Criterion Met?”) whether a product’s price is “extreme and unjustified given the totality of circumstances[.]”

¹⁰ Robinson, Douglas A. “Recent Administrative Reforms of the Hatch-Waxman Act: Lower Prices Now in Exchange for Less Pharmaceutical Innovation Later?” *Washington University Law Quarterly*, vol. 81, no. 829.

¹¹ Ledley FD, McCoy SS, Vaughan G, Cleary EG. Profitability of Large Pharmaceutical Companies Compared With Other Large Public Companies. *JAMA*. 2020;323(9):834–843.

<https://jamanetwork.com/journals/jama/fullarticle/2762308> (finding that from 2000 to 2018, the median net income (earnings) expressed as a fraction of revenue was significantly greater for pharmaceutical companies compared with nonpharmaceutical companies (13.8% vs 7.7%)).

¹² “Additional Information about Drug Price Negotiation and CBO’s Simulation Model of Drug Development.” *Congressional Budget Office*, <http://www.cbo.gov/publication/59792> (finding that share of venture capital reaching pharmaceutical companies has been trending upward).

¹³ [35 U.S. Code § 203\(a\)\(2\)](#).

In a note following section V(a), the framework adds “exploitative” to the list of triggering descriptors. Not only is this heightened standard unfaithful to the statute, it is unnecessary. Patent holders subject to the Act have many existing substantive and procedural protections to ensure their rights are not unjustifiably infringed.

First, petitioners have the burden of proof in march-in proceedings. Second, existing regulations give contractors and licensees adequate notice, the “opportunity to appear with counsel, submit documentary evidence, present witnesses and confront such persons as the agency may present,” among other protections.¹⁴ Third, the framework’s explanation directs agencies to assess the scope and length of a health or safety need (section I), consult *and* agree with other agencies on necessary actions (section II), affirmatively link the product at issue to the need (section III), assess the existence of alternatives (section VI), and consult with the contractor to explore non-march-in alternatives (section VII). Section V’s totality-of-the-circumstances approach views price in the context of these other factors. There is no reason to add a non-statutory, higher “extreme, unjustified, and exploitative” price standard to the consideration.

An agency may determine in a given situation that only an “extreme” price would tip the scales towards march-in, but the statutory language grants broad discretion. This framework should inform agencies of their options and responsibilities, not artificially limit that discretion. Should agencies somehow begin to abuse their statutory march-in authority after more than 40 years of no action, Congress is able to adjust the right by amendment.

The Act’s march-in Criterion One grants funding agencies the right to march in when subject inventions are not “available to the public on reasonable terms.”¹⁵ The framework’s Criterion One explanation, in section IV(D)(a), asks agencies whether a contractor or licensee has “made the product available only to a narrow set of consumers or customers because of high pricing or other extenuating factors[.]”

The statutory focus is on the objective reasonableness of the terms themselves. The framework, however, restricts the issue of reasonableness only to situations when it causes patients and other consumers to change their purchasing decisions. Narrowing the inquiry’s scope precludes consideration of cases when consumers are faced with an excessive price but choose to pay it anyway. This is especially relevant in the pharmaceutical context, in which a patient may have no viable drug substitute, leading a rational patient to pay an objectively unreasonable price for a lifesaving drug. Agencies should not be asked to assume that a price is reasonable just because a high number of patients still pay it.

¹⁴ [37 CFR § 401.6](#).

¹⁵ [35 U.S. Code § 203\(a\)\(1\)](#), incorporating [§ 201\(f\)](#).

Keeping the language of both criteria faithful to the statute is more important than ever given current judicial uncertainty around *Chevron* deference and the resurgent Major Questions Doctrine. Though this framework is not an official rulemaking, its language will be a guidepost for future regulation, and applying non-statutory restrictions on the important issue of price may have harmful ripple effects that decrease the likelihood of agency march-in decisions surviving future judicial challenges.

The framework should stick to the statutory standard and encourage agencies to march in when subject inventions are priced in a manner that leaves reasonable patient or other consumer needs unsatisfied. Factors that could be considered include the drug's accessibility in relation to population needs, measures of cost-effectiveness, and its pricing relative to comparable medications and the same medication in other countries (e.g. Xtandi/enzalutamide priced three to five times higher in the US than other high-income nations). There is precedent for considering prices paid by foreign consumers. In a Senate report accompanying the fiscal year 2018 National Defense Authorization Act, the Armed Services Committee directed the Department of Defense to use march-in “whenever the price of a drug, vaccine, or other medical technology is higher in the United States than the median price charged in the seven largest economies that have a per capita income at least half the per capita income of the United States.”¹⁶

Conclusion

This framework is a major step in the right direction. The clear enumeration of price as a factor to be weighed for exercising march-in rights is exactly what is needed to best achieve the goals of the Bayh-Dole Act. To give the public the greatest possible opportunity to benefit from this framework, pricing concerns must be addressed in broader terms than what NIST has proposed. The framework should address subject inventions that are priced in a manner that leaves reasonable consumer needs unsatisfied.

¹⁶ *Senate Report 115-125*, Armed Services Committee, www.govinfo.gov/content/pkg/CRPT-115srpt125/pdf/CRPT-115srpt125.pdf.