Americans for Prosperity
February 5, 2024

The Honorable Laurie E. Locascio
Under Secretary of Commerce for Standards and Technology
Director, National Institute of Standards and Technology
Department of Commerce
Washington, DC 20230

RE: Docket No. 230831-0207 — Request for Information Regarding the Draft Interagency Guidance Framework for Considering the Exercise of March-In Rights (NIST-2023-0008) [1]

Dear Under Secretary Locascio:

On behalf of more than three million AFP activists and supporters across the country, thank you for this opportunity to comment on NIST's request for information regarding the Biden-Harris Administration's proposed draft revisions of the factors that a federal agency may consider when deciding whether to exercise march-in patent confiscation rights under the Bayh-Dole Act.[2]

We respectfully request that the Administration withdraw this proposed guidance in its entirety because its provisions on prescription drug prices are not lawful and not in the public interest.

Executive Summary

1. Background. The Bayh-Dole Act of 1980 seeks, among other things, to ensure federally subsidized innovations are turned into actual products that benefit the public. To achieve this purpose, the Act authorizes the federal government to "march in" to confiscate a patent on a promising product that was developed with the help of taxpayer-funded research, and to lease it to someone else, when the product is found to be not "available to the public on reasonable terms."

[1] Federal Register, December 8, 2023, 88 FR 85593-85605, Docket No. 230831-0207, Document No. 2023-26930, RFI No. NIST–2023–0008, *https://www.federalregister.gov/documents/2023/12/08/2023-26930/request-for-information-regarding-the-draft-interagency-guidance-framework-for-considering-the.*
[2] The University and Small Business Patent Procedures Act of 1980, Public Law 96–517 (as amended), 35 § U.S.C. 200 et seq. Related documents: Executive Order 12591, Executive Order 14036.

2. Agency's Proposal. The agency proposes to revise the definition of "available to the public on reasonable terms" to include consideration of a product's price. Under these expanded definitions, if the federal government were to decide that a therapeutic invention is too expensive, it could confiscate the patent and lease it to someone else to sell it at a lower price.

3. The Proposal Is Unlawful. As a legal matter, this proposed expansion of federal power is not permissible. The Act's text and legislative history are clear: federal officials may *not* consider a product's commercial price when deciding whether to confiscate the patent.

4. The Proposal Is Harmful. As a policy matter, the proposal would amount to a form of backdoor government price controls, harmful and disruptive, both directly through march-in actions and indirectly through chilling effects on innovation and the reduced commercialization of breakthroughs. It would severely diminish inventor's incentive to create and market new products, with serious negative consequences for human life and well-being along with negative effects on American jobs and exports.

5. Better Approach — Patient-Driven Competition. The existing, limited grant of march-in power balances important public interests and accelerates the dissemination of publicly funded inventions. But it is a dangerous power. Expanding it to impose backdoor government price controls would lead to serious harm. Government confiscation of drug patents is the wrong way to increase competition and reduce prices. The right way is to give every American a Personal Option — a doctor-supported approach that makes health care more affordable, dependable, transparent, and hassle-free without government mandates or meddling.

1. Background

Congress enacted the Bayh-Dole Act of 1980 to stimulate innovation by encouraging the transfer of federally funded research from universities to the private sector. In doing so, it granted the executive a limited authority to exercise march-in rights, that is, patent confiscation rights, when certain conditions are not met.

As the agency explains:

> Bayh-Dole governs inventions made with Federal assistance. The Bayh-Dole Act outlines the rights of persons, nonprofit organizations, and small business firms ("contractors"), and, as set forth in Executive Order 12591, all contractors regardless of size and to the extent permitted by law, in "any invention of the contractor conceived or first actually reduced to practice in the performance of work under a funding agreement" ("subject invention") as well as rights retained by the government.
>
> One such right is the funding agency's right to require the contractor, an assignee, or exclusive licensee of a subject invention to grant a license to a responsible applicant or applicants, upon terms that are reasonable under the circumstances, and if the contractor, assignee, or exclusive licensee refuses such request, to grant a license itself (35 U.S.C. 203).

> This right, referred to as "march-in," can only be exercised if the agency determines that:
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> (1) action is necessary because the contractor or assignee has not taken, or is not expected to take within a reasonable time, effective steps to achieve practical application of the subject invention in such field of use;
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> (2) action is necessary to alleviate health or safety needs which are not reasonably satisfied by the contractor, assignee, or their licensees;
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> (3) action is necessary to meet requirements for public use specified by Federal regulations and such requirements are not reasonably satisfied by the contractor, assignee, or licensees; or
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> (4) action is necessary because the agreement required by section 204 has not been obtained or waived or because a licensee of the exclusive right to use or sell any subject invention in the United States is in breach of its agreement obtained pursuant to section 204.

2. Agency's Proposal

The agency proposes to add specific new text to its existing governmentwide march-in guidance beyond what is included in the statute. Importantly, the new text includes the following:

> If the contractor or licensee has commercialized the product, but *the price* or other terms at which the product is currently offered to the public are not reasonable, agencies may need to further assess whether march-in is warranted. Whether action may be needed to meet the needs of the Government or protect the public against nonuse or unreasonable use of the subject invention may include consideration of factors that unreasonably limit availability of the invention to the public, including *the reasonableness of the price* and other terms at which the product is made available to end-users. * * * 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. (Emphasis added.)

3. The Proposal Is Not Lawful

We think it clear that the proposed redefinition of the term "available to the public on reasonable terms" is not permissible under the Act. If the agency were to adopt it, it would be acting beyond its authority, for at least four reasons.

First, the statute says nothing about a product's price. The word "price" and its synonyms do not appear anywhere in the Act. And any suggestion that "extreme," "unjustified," or "exploitative" prices are a relevant consideration is likewise absent.

Second, on any plausible reading, the phrase "on reasonable terms" cannot be construed to refer to a producer's terms of sale. Rather, it obviously refers to the inventor's terms of license, that is, to the agreement by which the inventor licenses the product to be produced and commercialized.

Third, the underlying criterion on which the administration's proposal rests — lack of "practical application" of an invention — does not exist when an invention is being produced or used in a way that benefits the public, regardless of sale price. Thus, price cannot provide a ground for the government to march in on. The Act defines "practical application" to mean that an invention is being "manufactured," "practiced," or "operated" — in layman's terms, produced or used. If an invention is being produced or used, "practical application" is occurring, even if the price seems high in the view of federal officials. At the very least, the burden of proof must lie with the government to show that an invention's sale price prevents it from being manufactured, practiced, or operated. [3]

Fourth and finally, if the foregoing arguments are not persuasive, the agency must not overlook the public explanation of the Act's authors:

> Bayh-Dole did not intend that government set prices on resulting products. The law makes no reference to a reasonable price that should be dictated by the government. This omission was intentional; the primary purpose of the act was to entice the private sector to seek public-private research collaboration rather than focusing on its own proprietary research. … The ability of the government to revoke a license granted under the act is not contingent on the pricing of a resulting product or tied to the profitability of a company that has commercialized a product that results in part from government-funded research. The law instructs the government to revoke such licenses only when the private industry collaborator has not successfully commercialized the invention as a product. [4]

The Act's purpose is to ensure federally subsidized innovations are turned into actual products. It was not meant to, and does not authorize, federal officials to control or influence the prices of products.

4. The Proposal Is Not in the Public Interest

The proposal would suppress life-saving medical innovation, and harm patients, in at least six ways.

First, it would discourage private investment. The threat of march-in rights would discourage private companies from investing in the development of new drugs. Pharmaceutical research and

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[3] Section 203 of the Act declares that "The term 'practical application' means to manufacture in the case of a composition or product, to practice in the case of a process or method, or to operate in the case of a machine or system; and, in each case, under such conditions as to establish that the invention is being utilized and that its benefits are to the extent permitted by law or Government regulations available to the public on reasonable terms."
[4] Birch Bayh and Bob Dole, Letter to the Editor, *Washington Post,* April 11, 2002, https://www.washingtonpost.com/archive/opinions/2002/04/11/our-law-helps-patients-get-new-drugs-sooner/d814d22a-6e63-4f06-8da3-d9698552fa24/.

development require substantial financial investment and risk-taking. On average, it takes 10 years and $3 billion to bring a new drug to market, partly because drugmakers must test thousands of compounds to find one that works and partly because the federal government requires lengthy and expensive clinical trials to prove to its satisfaction the drug is safe and effective. Inventors who know their investment can be destroyed for arbitrary reasons are less inclined to pursue innovative research.

Second, it would discourage beneficial collaboration. The Bayh-Dole Act is widely viewed as fostering fruitful collaboration between academic researchers and private industry. But the prospect of march-in confiscations of a product based on price would strain these partnerships. Drug companies would be hesitant to collaborate with federally funded academic institutions if there were a risk the government could use that collaboration as a pretext to step in and alter the terms of their agreements.

Third, it would discourage beneficial risk-taking. Developing new therapies is a high-risk, high-reward endeavor. The potential for march-in rights based on something as hard to control as price upsets the delicate balance between the risks and the rewards of drug development. Manufacturers would become more conservative in their research choices, focusing on safer but less innovative projects to avoid the perceived threat of government intervention.

Fourth, it would delay access to innovative treatments. The actual use of march-in rights to control prices would lead to high-stakes legal battles, and thus to potentially years-long delays in bringing innovative treatments to market. Such fights would divert scarce resources and attention away from the critical task of getting life-saving therapies to suffering patients.

Fifth, it would diminish incentives for breakthroughs. Pharmaceutical research companies rely on the exclusivity granted by patents to recoup their substantial investments in research and development. The potential for arbitrary invocations of march-in rights would diminish the certainty of this exclusivity, and thus reduce the financial incentives for companies to pursue groundbreaking treatments for diseases with unmet medical needs.

Sixth and finally, it would put the U.S. at a competitive disadvantage. Medications are a top U.S. export. The global pharmaceutical industry is highly competitive, with companies from various countries vying intensely for market share. Pharma companies employ more than 300,000 Americans directly and millions of others indirectly. Imposing backdoor price controls through march-in rights would put U.S.-based pharma companies — the world's innovation leaders —at a disadvantage compared to their international counterparts, needlessly hobbling our economy and destroying jobs.

5. Better Approach — Patient-Driven Competition

Several previous administrations have been publicly exhorted to use march-in rights to control drug prices. In every case, they have said no. No administration has invoked march-in rights for the very good reason that doing so would have profound negative consequences for innovation

and public health. And no administration before now has attempted to expand the Act to make sale price a relevant criterion for patent confiscation.

The existing, limited grant of march-in power balances important public interests and accelerates the dissemination of publicly funded inventions. But it is a dangerous power. Expanding it to impose backdoor government price controls would lead to serious harm.

Government confiscation of drug patents is the wrong way to increase competition and reduce prices. The right way is to give every American a Personal Option — a doctor- supported plan that makes health care more affordable, dependable, transparent, and hassle-free without any government mandates or meddling. [5]

For these reasons, Americans for Prosperity respectfully requests that the Administration withdraw this proposed guidance in its entirety because its provisions on prescription drug prices are not lawful and not in the public interest.

Sincerely,
Brent Gardner
Chief Government Affairs Officer
Americans for Prosperity

[5] To learn more, visit personaloption.com.