The Honorable Gina Raimondo
Secretary of Commerce
Washington, DC 20230

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

February 6, 2024

Public Citizen Comments Re: Docket No.: 230831-0207, "Request for Information Regarding the Draft Interagency Guidance Framework for Considering the Exercise of March-In Rights"

Dear Secretary Raimondo and Undersecretary Locascio,

Public Citizen is a nonprofit consumer advocacy organization with more than 500,000 members and supporters. The Access to Medicines program advocates for access to prescription drugs in the United States and internationally. We write you today to express our support for strengthening and finalizing the Interagency Guidance Framework for Considering the Exercise of March-In Rights.

Despite the indispensable role the United States government and our public institutions play in biomedical research and development,[1] too often medicines are priced out of reach for patients. In the United States, prescription drug corporations routinely charge prices three times as high as those they charge in other wealthy countries.[2] Three-in-ten Americans report not taking their medicine as prescribed due to costs.[3] High prices of medicines and hormones like insulin that millions of people throughout the country need to stay alive have led to rationing, and ultimately death.[4] Black, Hispanic, and lower-income patients bear a disproportionate share of the burden of difficulty affording prescription drugs.[5]

Exorbitant drug prices also put an enormous strain on the coffers of public health programs, and consequently public tax dollars. Of the more than $400 billion spent on retail prescription drugs in 2022,

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[1] Rahul H. Nayak, Jerry Avorn, & Aaron S. Kesselheim, *Public sector financial support for late stage discovery of new drugs in the United States: cohort study*, 367 BMJ l5766 (2019). https://www.ncbi.nlm.nih.gov/pmc/articles/PMC6812612/

[2] Assistant Secretary for Planning and Evaluation (ASPE), U.S. Department f Health and Human Services, *International Prescription Drug Price Comparisons: Estimates Using 2022 Data.* (February 2024), https://aspe.hhs.gov/sites/default/files/documents/277371265a705c356c968977e87446ae/international-price-comparisons.pdf

[3] Ashley Kirzinger, Alex Montero, Grace Sparks, Isabelle Valdes, & Liz Hamel, *Public Opinion Prescription Drugs and Their Prices*, KFF (Aug. 21, 2023), https://www.kff.org/health-costs/poll-finding/public-opinion-on-prescription-drugs-and-their-prices/

[4] Bram Sable-Smith, *Insulin's High Cost Leads to Lethal Rationing*, NPR (Sept. 1, 2018), https://www.npr.org/sections/health-shots/2018/09/01/641615877/insulins-high-cost-leads-to-lethal-rationing

[5] Lunna Lopes, Marley Presiado, and Liz Hamel, *Americans' Challenges with Health Care Costs*, KFF (Dec. 21, 2023), https://www.kff.org/health-costs/issue-brief/americans-challenges-with-health-care-costs/

nearly $135 billion came from Medicare and $45 billion from Medicaid.[6] Additionally, more than $150 billion more are estimated to be spent on nonretail drugs each year.[7]

The Administration is making significant progress in tackling our nation's drug pricing crisis through implementation of Medicare drug price negotiation, inflationary rebates, and other provisions of the Inflation Reduction Act, but far more is needed to provide relief to all patients facing unbearably high prescription drug prices, including people with private insurance and those without insurance.

Instances of patients and public health programs facing drug corporation price gouging on medicines that were invented wholly or in part with the support of taxpayer dollars are particularly egregious. Thankfully, the U.S. government holds an array of tools to help protect the public interest and ensure people get access to the medicines they need, and that the federal government and taxpayers are not ripped off, particularly with regard to these sorts of medicines.[8]

The Bayh-Dole Act is a key area of U.S. law "to promote utilization of inventions arising from federally supported research and development," including prescription drugs and other medical inventions.[9] One of its core policies is to provide ownership of federally-supported inventions to grant recipients and contractors while preserving rights for federal funding agencies to protect and advance the public interest, including by "ensur[ing] that the Government obtains sufficient rights in federally supported inventions **to meet the needs of the Government and protect the public against nonuse or *unreasonable use* of inventions**" (emphasis added).[10]

Through $50 billion in annual investments, the U.S. government and taxpayers undergird the biomedical R&D upon which new drugs rely.[11] Experts in pharmaceuticals and intellectual property law have identified that around 11% of newly approved drugs rely on at least one patent that discloses government rights, including the right to march-in, stemming from an inventor making an invention in the performance of work under a federal funding agreement.[12] Additionally, researchers have shown that medicines invented with public sector financial support are more likely to receive approval through expedited development or review pathways, and to be first in class, indicating they are potentially of greater therapeutic

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[6] Centers for Medicare and Medicaid Services, National Health Expenditure Tables, https://www.cms.gov/data-research/statistics-trends-and-reports/national-health-expenditure-data/nhe-fact-sheet (last visited Feb. 5, 2024).
[7] IQVIA, *The Use of Medicines in the U.S. 2023: Usage and Spending Trends and Outlook to 2027,* (May 2, 2023), https://www.iqvia.com/insights/the-iqvia-institute/reports-and-publications/reports/the-use-of-medicines-in-the-us-2023
[8] Letter from Harvard Medical School/BWH PORTAL: Program On Regulation, Therapeutics, And Law & Yale Law School GHJP: Global Health Justice Partnership to Senator Elizabeth Warren, https://www.warren.senate.gov/imo/media/doc/2022.4.20%20Letter%20to%20Warren%20on%20Drug%20Pricing%20Executive%20Authorities.pdf (last accessed Feb. 6, 2024).
[9] 35 U.S. Code § 200, Bayh-Dole Act Policy and Objective.
[10] *Id*.
[11] United States Senate, Health, Education, Labor, and Pensions Committee Majority Staff, *Public Investment, Private Greed*, (June 12, 2023), https://www.sanders.senate.gov/wp-content/uploads/Public-Medicines-Report-updated.pdf
[12] Ledley FD, Cleary EG (2023) NIH funding for patents that contribute to market exclusivity of drugs approved 2010–2019 and the public interest protections of Bayh-Dole. PLoS ONE 18(7): e0288447. https://doi.org/10.1371/journal.pone.0288447

importance than drugs that were not invented with public funds.[13] Thus, the application of march-in rights and other public interest protections under the Bayh-Dole Act have profound implications for access to medicines and drug pricing for patients and consumers.

Unfortunately, despite numerous petitions presented over the 40-plus year history of the Bayh-Dole Act, not once has a federal agency exercised its right to march-in and license competition to remedy price gouging (which constitutes a failure of the owner of a subject invention to make that invention available to the public on reasonable terms), or otherwise.

We applaud the administration for articulating through this guidance that price, indeed, is a factor in exercising march-in rights, which more accurately reflects a plain reading of the statute and the intent of legislators who passed the Bayh-Dole Act into law. While recognition of price as a factor represents a paradigm shift from positions held by previous administrations, still, the guidance is inappropriately restrictive and narrowly construes conditions under which agencies might initiate march-in proceedings.

Below, we outline several recommendations to provide clarity and more closely align the proposed guidance with statute while advancing the public interest objectives of the Act.

1) Include international pricing disparities as a major consideration for exercising march-in rights.

The first statutory criterion for using the march-in authority allows the government to march-in when the patent holder has not achieved "practical application," which means to manufacture the invention and "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**" (emphasis added).[14] Price gouging U.S. patients and consumers for an invention made with public, taxpayer dollars is a clear failure to make such an invention available on reasonable terms, and it would defy the plain reading of the statute to suggest otherwise.

Dozens of academic experts in pharmaceutical and intellectual property law agree that "pricing alone should provide sufficient grounds for exercising march-in rights."[15] In a 2022 letter, they confronted the most common arguments against the Act's application to price; the following quotes the letter at length:[16]

> Based on the plain text of the statute, excessive pricing alone should provide sufficient grounds for exercising march-in rights. Section 203(a)(1) permits march-in licenses if the patent holder has not effectively achieved "practical application" of the drug, which § 201(f) defines as, *inter alia*, making the drug "available to the public on reasonable terms." Years after the Bayh-Dole

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[13] Rahul H. Nayak, Jerry Avorn, & Aaron S. Kesselheim, *Public sector financial support for late stage discovery of new drugs in the United States: cohort study*, 367 BMJ l5766 (2019). https://www.ncbi.nlm.nih.gov/pmc/articles/PMC6812612/

[14] 35 U.S. Code § 203; 35 U.S. Code § 201(f)

[15] Letter from Harvard Medical School/BWH PORTAL: Program On Regulation, Therapeutics, And Law & Yale Law School GHJP: Global Health Justice Partnership to Senator Elizabeth Warren, https://www.warren.senate.gov/imo/media/doc/2022.4.20%20Letter%20to%20Warren%20on%20Drug%20Pricing%20Executive%20Authorities.pdf (last accessed Feb. 6, 2024).

[16] *Id*.

Act's enactment, former Senators Birch Bayh and Bob Dole (who were then working for Washington firms that lobbied for pharmaceutical manufacturers) argued that Congress did not intend "reasonable terms" to cover excessive pricing. But the text of the statute contradicts this interpretation. The statute's plain text matters more than a single newspaper op-ed expressing subjective intent of individual lawmakers, particularly when that intent is expressed years *after* the law has already been passed. Moreover, there were numerous, *contemporaneous* examples from debates around the passage of the Act that clearly link the Act's march-in provisions with the need to control prices and promote accessibility to the public.

Price is a crucially important element of the terms of a transaction, and providing goods or services only at excessive prices is offering only unreasonable terms. This interpretation is supported by federal court cases interpreting other statutes discussing the meaning of "reasonable terms." Reviewing the reasonableness of prices is well within the competence of both courts and agencies, as illustrated by other aspects of patent law, contract law, utilities regulation, and more. Finally, other industry representatives have argued that the government's failure to *exercise* march-in rights means that those rights do not exist. Yet, as the Supreme Court has long held, "[t]he fact that powers long have been unexercised well may call for close scrutiny as to whether they exist; but if granted, they are not lost by being allowed to lie dormant."

We applaud the Biden administration for recognizing this key reality in the proposed framework, particularly as the previous administration actively sought to deny the application of march-in rights to pricing.[17] However, we are concerned that the current framework does not adequately encompass clear instances of unreasonable pricing, and could leave U.S. patients and taxpayers at continued risk of pricing abuses.

Currently and mistakenly, the practical application section of the framework seems to only mention instances in which unreasonable pricing for end users is also unreasonably limiting the availability of the invention. But the Bayh-Dole Act states clearly that the *reasonableness of the terms* of availability is at issue; not whether the resulting availability to end users of the invention is reasonable. Focusing only on how available a taxpayer funded invention is, without any consideration of whether the invention is available on reasonable terms to the public, impermissibly eliminates language in the statute and narrows the scope of the public interest protections. Take, for example, a taxpayer funded drug priced hundreds or even thousands of dollars more per month in the US compared to other countries, incurring significant financial burdens to Americans in terms of out-of-pocket costs and insurance premiums. Because insurance coverage helps make the drug available, an agency may refrain from marching-in, even though the terms on which the drug is available to the public is patently unreasonable given the public's funding of the drug.

[17] Docket No.: 230315-0076, *Rights to Federally Funded Inventions and Licensing of Government Owned Inventions*, https://www.federalregister.gov/documents/2023/03/24/2023-06033/rights-to-federally-funded-inventions-and-licensing-of-government-owned-inventions

President Biden and White House officials have made statements that express intention for a broader application of march-in right to pricing abuses:[18]

"Today, we're taking a very important step toward ending price gouging so you don't have to pay more for the medicine you need."

– President Biden[19]

"When drug companies won't sell taxpayer funded drugs at reasonable prices, we will be prepared to let other companies provide those drugs for less. […] If American taxpayers paid to help invent a prescription drug, the drug companies should sell it to the American public for a reasonable price."

– Lael Brainard, National Economic Advisor, White House[20]

We recommend adding language clarifying that "reasonable terms" explicitly includes consideration for the price and other terms at which a subject invention is sold in the United States, reflecting total costs incurred by public agencies, including by Medicare, Medicaid, and by other public and private payers, including private insurance providers, and end users.

Further, we recommend the framework express that pricing disparities between the United States and other high-income countries (HICs) for subject inventions should be a major consideration taken by agencies in their assessments of whether to exercise march-in rights. Additionally, the guidance can set forth a clear pricing standard, which would both help ensure that agencies do not fail to exercise march-in rights when doing so is necessary to protect the public interest, and provide clarity to patent holders on what is likely to constitute price gouging grounds for an agency to march-in.

The NIH and other agencies have been petitioned repeatedly[21] to exercise march-in rights on the basis that the owner of a taxpayer-funded invention (or inventions) is charging patients and consumers in the United States prices in gross excess of those charged in other high-income countries.

For example, in 2004, the NIH was petitioned to exercise march-in rights to license generic competition for ritonavir, an important HIV treatment, when Abbott Laboratories increased the U.S. commercial price by 400%, resulting in employers, insurers and patients paying five to ten times more than their counterparts in other high-income countries.[22] More recently, prostate cancer patients petitioned the NIH

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[18] Also noted in the December 19, 2023 letter to Secretary Becerra from Robert Sachs, renewing appeal of the NIH rejection of the Xtandi march-in petition. https://www.keionline.org/wp-content/uploads/sachs-becerra-121923.pdf

[19] The White House, *President Biden is Taking Important Steps to Combat Price Gouging*, (Dec. 7, 2023), https://www.youtube.com/shorts/ENDURMtyKeo

[20] Robert J Sachs, Clare M Love, Eric Sawyer, *Letter to Sec. Becerra Re. Appeal of NIH decision rejecting petition for HHS to exercise Federal rights in patents on Xtandi in order to address price discrimination against US cancer patients*, (Dec. 19, 2023), https://www.keionline.org/wp-content/uploads/sachs-becerra-121923.pdf

[21] Timeline regard[ing] Bayh-Dole march-in rights requests. Knowledge Ecology International. https://www.keionline.org/march-in-rights-timeline

[22] Statement of James Love, President, Essential Inventions, Inc. at the NIH Meeting on Norvir/Ritonavir March-In Request, May 25, 2004. https://www.essentialinventions.org/legal/norvir/may25nihjamie.pdf

to march-in on patents for enzalutamide (brand-name Xtandi) due to Astellas and Pfizer setting a price in the United States 3-5 times those charged in other wealthy countries.[23]

A policy recently formalized and announced by the Administration for Strategic Preparedness and Response (ASPR) at the Department of Health and Human Services offers a conservative standard that could also constitute an obvious violation of the practical application requirement, serving as a clear indication of when an agency should consider licensing competition to remedy unreasonable pricing. [24] Specifically, ASPR is standardizing the practice of including a fair pricing requirement in its contracts supporting clinical development by including a most favored nation clause, which states that a commercialized product must have a list price equal to or less than its price in comparable global markets.[25]

In reference to this ASPR most favored nation pricing policy, President Biden stated:[26]

"It's a simple principle. You shouldn't pay the highest price in the world for drugs that your tax dollars have already helped create."

Public Citizen believes the principle articulated by President Biden is just as applicable to medicines and other federally-funded inventions as it is to medicines with clinical trials supported by ASPR. Thus, it would be appropriate to articulate a pricing benchmark in the march-in framework that aligns with the fair pricing policy championed by President Biden and ASPR.

Not only should United States patients and taxpayers not be subjected to the highest prices in the world for drugs our tax dollars have helped create, but U.S. patients and taxpayers should get *by far* the best deal for medicines we pay to invent. It should be indisputable that charging us more than people in other high-income countries constitutes failing to make a product relying on a taxpayer-funded invention available to the public on reasonable terms.

Specifically, we recommend including language on page 11 of the framework, in the section addressing the practical application criterion, which states:

> **"Agencies may also give strong consideration to whether action may be needed to meet the needs of the Government or protect the public against unreasonable use of the subject invention in the form of excessive pricing."**

To provide additional clarity, in section IV of the practical application criterion section of the framework, it should set forth this corresponding standard:

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[23] Clare Love and Robert Sachs letter to Secretary Becerra. November 18, 2021. https://www.keionline.org/wp-content/uploads/Love-Sachs-HHS-Xtandi-Request-18Nov2021.pdf

[24] The White House, *Fact Sheet: Biden-Harris Administration Announces Dozens of Pharma Companies Raised Prices Faster than Inflation*, Triggering Medicare Rebates, (Dec. 14, 2023), https://www.whitehouse.gov/briefing-room/statements-releases/2023/12/14/fact-sheet-biden-harris-administration-announces-dozens-of-pharma-companies-raised-prices-faster-than-inflation-triggering-medicare-rebates/

[25] *Id*.

[26] The White House, *Remarks by President Biden on Progress to Lower Prescription Drug Costs*, (Dec. 14, 2023), https://www.whitehouse.gov/briefing-room/speeches-remarks/2023/12/14/remarks-by-president-biden-on-progress-to-lower-prescription-drug-costs/

"Is the product utilizing the subject invention being sold or offered for sale in the United States at a price that is greater than the lowest price available in other high-income countries?"

While we strongly believe the most-favored nation standard is most appropriate for inclusion in this guidance, we do not believe or intend to suggest through these comments that international pricing disparities are the only ways in which a product should be considered excessively priced and not available on reasonable terms. In some instances, particularly in cases where the patent holder has already made enormous revenues far greater than any private investment it has made in the medicines, including with consideration for risk entailed in development, a reasonable price may be substantially lower than what a most favored nation requirement would allow. In other words, this and other examples presented in the framework *should not* be considered exhaustive.

That said, as a less preferred alternative to the above suggestion, the framework could also provide additional clarity on price through setting forth the following standard, a form of which was unanimously supported by members of the Senate Armed Services Committee in 2018,[27] and which is yet more conservative than the most favored nation standard:

"Is the product utilizing the subject invention being sold or offered for sale in the United States at a price that is greater than the median of the lowest prices available in other high-income countries?"

Clarifying a greater scope of the practical application criterion for price through adding suggested language on international pricing disparities is essential to maximizing the value of the framework in protecting consumers and taxpayers against price gouging for government-funded medicines and other inventions.

2) Guide agencies to consider whether to exercise march-in rights in context of other legal authorities, including the Bayh-Dole paid-up license and "government use" patent licensing authority.

The final section of the framework (before the scenarios) asks, "Would march-in support the policy and objective of Bayh-Dole, considering the specific case and broader context?"[28] Two specific questions it presents to provide agencies broader context are, "What intellectual property, in total, is needed to make the product in question?" and, "Does making the product or performing the service also require use of intellectual property that was not government funded and is not subject to Bayh-Dole?" The framework continues, "For example, if only one of several patents necessary to produce a product is subject to march-

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[27] Knowledge Ecology International, *Senate Armed Services Committee directive on use of Bayh-Dole rights for DoD funded drugs*, (July 17, 2017), https://www.keionline.org/23404
Specifically, the Senate Armed Service Committee directive stated: *The committee directs the Department of Defense (DOD) to exercise its rights under sections 209(d)(1) or 203 of title 35, United States Code, to authorize third parties to use inventions that benefited from DOD funding 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.*

[28] *See* National Institute of Standards and Technology, Department of Commerce, *Request for Information Regarding the Draft Interagency Guidance Framework for Considering the Exercise of March-In Rights*, 88 Fed. Register 85593, 85600 (Dec. 8, 2023).

in, that likely weighs against march-in, since other licensees would need separate permission to use several other patents before they could make the product. On the other hand, if all the intellectual property needed to produce the product is a subject invention(s), that might result in a different licensee being able to produce product quickly or efficiently."

The framework is correct to pose questions about the practical impact of using march-in rights, but it is misguided in suggesting that it will typically only be appropriate to march-in when all the intellectual property implicated by a product is comprised of subject inventions. Rather than guide agencies to consider whether march-in rights *alone* are sufficient to change market conditions for a particular product, it should inform agencies to consider march-in rights alongside other legal authorities.

There are at least two related licensing authorities agencies could wield alongside march-in rights to best advance the public interest.

"Government use" patent licensing allows the federal government to use or manufacture any patented invention, or for a third party to do so on its behalf, without license of the patent owner, in exchange for reasonable compensation to the patent holder.[29] Reasonable compensation has typically been found by courts to require payment of a "reasonable royalty," with royalties that lead to major savings compared to the pre-license monopoly price.[30] The § 1498 authority has previously been used by federal agencies and the government to procure low-cost generic versions of patented medicines, and leveraged to secure brand-name drug discounts.[31] Legal experts have concluded that § 1498 could also be used to enable purchase of lower-cost generics by private entities reimbursed by Medicare and Medicaid, since those benefits would accrue primarily to these federal programs in the form of reducing costs or expanding coverage for beneficiaries.[32]

In addition to march-in rights, the Bayh-Dole Act provides federal agencies with an "irrevocable, paid up license to practice or have practiced for or on behalf of the United States any subject invention throughout the world[.]"[33] Like march-in rights, the Bayh-Dole paid-up license is limited to subject inventions, but like § 1498, the practice of the patented invention must be for or on behalf of the United States. However, in contrast to march-in and § 1498, no compensation to the patent holder is required under the Bayh-Dole § 202 license.

In the scenario described in the guidance and presented above, under which there are multiple patents on a drug, but not all of them are for subject inventions implicated by march-in rights, an agency could rely on § 1498 to authorize a generic manufacturer to use the non-Bayh Dole patent(s) to manufacture that drug for direct federal purchasers like the Department of Veterans Affairs and the Department of

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[29] 28 U.S. Code § 1498(a)

[30] Letter from Harvard Medical School/BWH PORTAL: Program On Regulation, Therapeutics, And Law & Yale Law School GHJP: Global Health Justice Partnership to Senator Elizabeth Warren, https://www.warren.senate.gov/imo/media/doc/2022.4.20%20Letter%20to%20Warren%20on%20Drug%20Pricing%20Executive%20Authorities.pdf (last visited Feb. 6, 2024).

[31] *Id*.

[32] Letter from Harvard Medical School/BWH PORTAL: Program On Regulation, Therapeutics, & Law And Yale Law School GHJP: Global Health Justice Partnership to Senator Elizabeth Warren, https://www.warren.senate.gov/imo/media/doc/2022.4.20%20Letter%20to%20Warren%20on%20Drug%20Pricing%20Executive%20Authorities.pdf (last visited Feb. 6, 2024).

[33] 35 U.S. Code § 202(c)(4)

Defense, as well as health programs reimbursed by the government, including Medicare and Medicaid.[34] Moreover, while march-in regulatory processes are exhausted, agencies could make a dramatic difference in pricing and access through exercising the § 202 paid-up license to facilitate reasonable prices for Medicare, Medicaid and their beneficiaries.

To remedy this involuntary license authority myopia, we recommend the final guidance adopt the following language:

> **"If march-in rights may not be sufficient to allow another party to manufacture a product, such as when only one of several patents necessary to produce a product is subject to march-in, would public access to the subject invention on reasonable terms be advanced if march-in rights were exercised alongside other authority, such as 'government use' patent licensing under 28 U.S. Code § 1498?"**
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> **"Agencies may consider whether other licensing authority, such as 'government use' patent licensing under 28 U.S. Code § 1498 or the 'paid up license' under 35 U.S. Code § 202, can be exercised alongside march-in rights to protect the public against nonuse or unreasonable use of a subject invention."**

3) Consider more broadly the impact of excessive prices on whether health and safety needs are not reasonably satisfied, as well as unmet health and safety needs globally.

The second criterion of the march-in statute authorizes agencies to march-in when "action is necessary to alleviate health or safety needs which are not reasonably satisfied by the contractor, assignee, or their licensees[.]"[35] Excessive pricing of medicines can prevent public health and safety needs from being satisfied, and numerous march-in petitions have been presented to the federal government on this basis.

For example, march-in petitioners alleged government action was necessary because Abbott's pricing of ritonavir threatened the health and safety of people living with HIV/AIDS.[36] The latanoprost petition asked the government to march-in, in part based on the health and safety needs criterion, because poor and elderly Americans could not afford Pfizer's discriminatory pricing.[37] At the time of the petition, latanoprost

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[34] While § 1498 provides clear authority that agencies and the guidance should not ignore, it is also important to consider that in some cases, it may be possible for a generics manufacturer to design around non-Bayh-Dole secondary patents when the government holds rights on the primary patent or patents. In fact, researchers have noted that patents resulting from public sector financial support are disproportionately on key properties of a drug's product or substance. *See* Rahul H. Nayak, Jerry Avorn, & Aaron S. Kesselheim, *Public sector financial support for late stage discovery of new drugs in the United States: cohort study*, 367 BMJ l5766 (2019).

[35] 35 U.S. Code § 203(a)(2)

[36] Essential Inventions, Inc., Petition to Use Authority Under Bayh-Dole Act to Promote Access to Ritonavir, Supported by National Institute Of Allergy And Infectious Diseases Contract No. Ai27220 (Jan. 29, 2004), https://www.essentialinventions.org/legal/norvir/norvir-29jan04petition.pdf

[37] Letter from James Love, President, Essential Inventions, & Sean Flynn, Counsel, Essential Inventions, to Tommy Thompson, Secretary, Department of Health & Human Services (Jan. 29, 2004), https://www.essentialinventions.org/legal/xalatan/xalatan-29jan04petition.pdf

was the most commonly used medicine for treating glaucoma; consumers who could not afford it risked going blind without access.[38]

While the draft framework correctly acknowledges that price is implicated by the health and safety needs criterion, its consideration of price seems narrower than what plain reading of the statute would permit. Specifically, in the context of second march-in criterion, the framework asks agencies to consider, "Is the contractor or licensee exploiting a health or safety need in order to set a product price that is extreme and unjustified given the totality of circumstances?" The guidance presents a corresponding example in scenario 6, under which a company takes advantage of increased demand for a mask during a respiratory virus pandemic to sharply increase price and potentially does not have adequate supply to meet demand.

The "extreme and unjustified" language and the scenario provided suggest a considerably higher threshold for action than demanded by statute, which asks the simple question of whether health and safety needs are not reasonably satisfied. High price could very well pose a barrier to health and safety needs even if they are not "extreme and unjustified" in the broader context of excessive pharmaceutical prices in the United States that have become commonplace. The drug industry's standard practice of charging U.S. consumers exorbitant sums contributes to three in ten Americans rationing medicine due to cost.[39] In the context where treatment rationing driven by high prices is the norm, it is not clear what would be required to meet the "extreme and unjustified" standard proposed in the framework. Furthermore, widespread drug rationing demonstrates that price can prevent health and safety needs from being met, even as manufacturing supply of a product is not in shortage.

To ensure that the framework allows sufficient space to allow agencies to respond to the failures of patent holders to meet health and safety needs through excessive pricing, we recommend inclusion of the following language in the section on criterion 2:

> **"Is the contractor or licensee setting a product price that unreasonably contributes to members of the public not accessing a subject invention that could alleviate health and safety needs?**
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> ***It should be noted that in reviewing this question, the agency may consider whether an intermediary purchaser has put forth access restrictions in response to the product price. For example, if in response to a high product price set by a contractor or licensee, a private provider of health insurance coverage puts a drug on a formulary tier with high cost-sharing, or puts in place step-therapy or other prior authorization requirements that are not based on medical necessity, the agency may consider the resulting access restriction as directly following from the pricing of the contractor or licensee."***
>
> **"Is the ability of any public program to fulfill its mission to serve health and safety needs unreasonably impeded by the product price set by the contractor or licensee?"**

Additionally, in some instances, contractors may not be reasonably satisfying health or safety needs outside of the United States. The march-in statute does not limit consideration for health and safety

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[38] *Id*.

[39] Ashley Kirzinger, Alex Montero, Grace Sparks, Isabelle Valdes, & Liz Hamel, *Public Opinion on Prescription Drugs and Their Prices*, KFF POLLING (Aug. 21, 2023), https://www.kff.org/health-costs/poll-finding/public-opinion-on-prescription-drugs-and-their-prices/.

needs to those that exist in the United States. Moreover, global access to biomedical inventions can have an impact on health in the United States, and some publicly-supported technologies may be supported specifically to meet health needs outside the United States.[40] Therefore, we also recommend the following language with relation to the health and safety needs criterion:

> **"Is the contractor, assignee, or licensee failing to offer a product for sale outside the United States in a territory where it is needed to serve unmet health or safety needs?**
>
> **"Is the contractor, assignee, or licensee offering a product for sale in a territory outside the United States, but only at a price that unreasonably prevents health or safety needs from being met?**
>
> ***In reviewing this question, agencies should consider the available resources that have been allocated by the United States, other countries, and other global health donors to meet the particular health or safety need that is addressed by the subject invention in each territory with particular consideration for impacts in low- and middle-income countries. March-in licenses may be limited, where necessary, to permit licensees to serve the affected population outside the United States."***

4) Provide public transparency into what patents and products include inventions resulting from public funds.

While the Bayh-Dole Act requires inventors to disclose in patent applications whether the patent covers an invention that was first conceived or actually reduced to practice in the performance of a funding agreement,[41] more transparency from agencies into the patented inventions they fund and related commercialized products is needed.

For example, HHS currently makes publicly available a list of vaccines and therapeutics based on licenses of HHS-owned inventions, including which agency-owned patents have been licensed with relation to particular products.[42,43] Conversely, information on what inventions are made under federal grants in the iEdison database is kept secret.[44] As a result, identifying what vaccines and therapeutics have benefited from federally-funded inventions ranges from onerous, in the case of small molecule drugs, to extraordinarily difficult and labor intensive even for individuals with expertise, in the case of biologics.

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[40] It is also worth mentioning that the domestic manufacturing preference only requires the recipients of exclusive licenses for use or sale of subject inventions *in the United States* to manufacture products embodying the subject invention (or produced through use of the subject invention) substantially in the United States. *See* 35 U.S. Code § 204.

[41] 35 U.S. Code § 201(e)

[42] *HHS License-Based Vaccines & Therapeutics,* NIH TECHNOLOGY TRANSFER, https://www.techtransfer.nih.gov/reportsstats/hhs-license-based-vaccines-therapeutics (last visited Feb. 6, 2024).

[43] This public transparency follows from a recommendation included in a recent Government Accountability Office (GAO) report, titled: "NIH Should Publicly Report More Information about the Licensing of Its Intellectual Property." See GAO, BIOMEDICAL RESEARCH: NIH SHOULD PUBLICLY REPORT MORE INFORMATION ABOUT THE LICENSING OF ITS INTELLECTUAL PROPERTY (Oct. 2020).

[44] Robert Cook-Deegan, Aaron S. Kesselheim, & Ameet Sarpatwari, *Updating the Bayh-Dole Act March-in Rights and Transparency*, 327 JAMA NETWORK VIEWPOINT 923 (2022).

At a minimum, the framework should guide agencies to disclose publicly, in a clear and accessible format, the same information the government currently provides for vaccines and therapeutics based on licenses of HHS-owned inventions, including:

- **Product name and description**
- **Date of marketing approval**
- **Date of first commercial U.S. sale**
- **Funding agency**
- **U.S. patent numbers of the patents with government rights (and related patent applications disclosing government rights[45])**

Good governance relies on accountability, and accountability demands transparency. Public transparency into patents and products resulting from public funds would deliver much needed 'public accountability for public dollars'[46], including through providing the public with vital information to help ensure agencies protect the public interest in inventions made with taxpayer dollars.

5) Ensure complete and accurate disclosure of the government interest in patents for government-funded inventions.

The ability of agencies to protect the public interest through march-in and other rights requires full disclosure by grantees of where government rights stemming from the Bayh-Dole Act attach. But NIH support is not consistently disclosed by its grantees in associated patents.[47] In a recent analysis of patents with application dates in years 2012 through 2021, the GAO found, "incomplete reporting as well as underreporting of NIH support in patent government interest statements."[48] The GAO noted its findings were consistent with those of previous studies that showed evidence of underreporting of federal funding in patents, including one academic study that found government interest statements were missing in 20-40 percent of biomedical patents issued between 1980 and 2007, including some associated with FDA-approved drugs.[49]

It is not possible for agencies to fulfill their obligations to protect the public against nonuse or unreasonable use of subject inventions if they do not have accurate information on which technologies they hold rights, nor for the public to provide accountability.

We therefore recommend the framework concurrently guide agencies to periodically review patents and applications filed by grantees and related institutions to ensure grantees do not fail to disclose government interests. If a grantee fails to disclose government rights or does not make a correction to

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[45] Patent applications are not currently included on the HHS-licensed products list.
[46] Robert Cook-Deegan, Aaron S. Kesselheim, & Ameet Sarpatwari, *Updating the Bayh-Dole Act March-in Rights and Transparency*, 327 JAMA NETWORK VIEWPOINT 923 (2022).
[47] Knowledge Ecology International, *Failure to Disclose U.S. government Bayh-Dole rights in patented inventions*, BAYH-DOLE, https://www.keionline.org/bayh-dole/failure-to-disclose (last visited Feb. 6, 2024).
[48] GAO, NATIONAL INSTITUTES OF HEALTH: BETTER DATA WILL IMPROVE UNDERSTANDING OF FEDERAL CONTRIBUTIONS TO DRUG DEVELOPMENT (April 2023).
[49] *Id*.

include government rights where a failure to disclose has been identified, agencies should consider retaining title to the subject invention.[50]

6) Ensure timeliness and responsiveness in petition responses.

Current regulations setting forth procedures for exercising march-in rights provide timelines for agencies and contractors to take various actions relating to considering whether to exercise march-in rights and their proceedings.[51] But there is no deadline provided for agencies to respond to petitioners requesting exercise of march-in rights, nor is there any requirement that agencies respond substantively to the issues that petitioners argue warrant their use. As the December 19, 2023 letter from prostate cancer patients to Secretary Becerra renewing the appeal of HHS's refusal to exercise march-in rights on on enzalutamide patents noted: "NIH took 16 months to issue a perfunctory decision ignoring the provision of the Bayh-Dole Act requiring US taxpayer funded inventions to be made available to the public 'on reasonable terms.'"[52]

To ensure petitions for agencies to exercise march-in rights do not languish before agencies while the public is being harmed through nonuse or unreasonable use of a subject invention, we recommend the framework guide agencies within 30 days after receiving a petition to exercise march-in rights to begin consultations set forth in 37 C.F.R. § 401.6 (a)(1), or to respond to petitioners with a clear explanation of why the agency has decided the evidence presented in the petition does not warrant such consultation. If an agency moves forth with consultation with the contractor and at any subsequent stage decides not to pursue march-in rights, the agency should provide a clear explanation to petitioners for that decision.

7) Promote procedural transparency in march-in proceedings; do not provide more opacity than required under law.

The draft framework incorrectly asserts in a footnote that "All portions of the march-in proceeding are closed to the public and are held confidential (35 U.S.C. § 202(c)(5))." The statute referenced in this footnote reads:

> *(c) Each funding agreement with a small business firm or nonprofit organization shall contain appropriate provisions to effectuate the following:*
>
> > *[…] (5)The right of the Federal agency to require periodic reporting on the utilization or efforts at obtaining utilization that are being made by the contractor or his licensees or assignees: Provided, That any such information as well as any information on utilization or efforts at obtaining utilization obtained as part of a proceeding under section 203 of this chapter shall be treated by the Federal agency as commercial and financial information obtained from a*

[50] 37 C.F.R. § 401.14
[51] 37 C.F.R. § 401.6
[52] Letter from Robert J. Sachs, Clare Love, & Eric Sawyer to Xavier Becerra, Secretary, Department of Health and Human Services (Dec. 23, 2023), https://www.keionline.org/wp-content/uploads/sachs-becerra-121923.pdf.

person and privileged and confidential and not subject to disclosure under section 552 of title 5.

Repeatedly, the statute limits what information is protected as privileged and confidential to that which relates to "utilization or efforts at obtaining utilization."

The regulation governing march-in proceedings is similarly limited (emphasis added):[53]

> *Any portion of the march-in proceeding, including a fact-finding hearing that involves testimony or evidence* ***relating to the utilization or efforts at obtaining utilization*** *that are being made by the contractor, its assignee, or licensees shall be closed to the public, including potential licensees. In accordance with 35 U.S.C. 202(c)(5), agencies shall not disclose any such information obtained during a march-in proceeding to persons outside the government except when such release is authorized by the contractor (assignee or licensee) or otherwise required by law.*

As noted by Knowledge Ecology International,[54] while utilization is not defined by statute, the definition of "practical application" clarifies that "utilization" of an invention is a separate concept from whether "its benefits are […] available to the public on reasonable terms."[55] The regulation also provides an exception for release of information relating to utilization when such release is authorized by the contractor or otherwise required under law. Complete opacity of march-in proceedings goes far beyond the limited confidentiality for information on utilization and efforts at utilization required under law and would go against the public interest in transparency.

To ensure fairness in march-in proceedings, the framework should remove this errant footnote and instead guide agencies to make proceedings and related documents fully public and transparent, and only redact information insofar as it relates to utilization and efforts at utilization, as required under law. Additionally, petitioners and other members of the public should be permitted to participate in proceedings.

8) Provide a greater balance of questions for agencies to assess whether exercising march-in rights would advance the policy and objectives of the Bayh-Dole Act.

The third overarching question presented in the framework asks agencies to evaluate whether using march-in rights would support the policy and objectives of Bayh-Dole. We agree that this is an appropriate consideration and that many of the questions put forth in this section of the framework are appropriate, particularly pertaining to the question: "Would march-in help achieve practical application, alleviate health or safety needs, meet public use requirements, or meet manufacturing requirements."

But the balance of questions in the section may inordinately prejudice agencies against using march-in rights. Section 2 of these comments provided some suggested language to increase balance:

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[53] 37 C.F.R. § 401.6

[54] See JAMES LOVE, LUIS GIL ABINADER, BROOK K. BAKER, KNOWLEDGE ECOLOGY INTERNATIONAL, COMMENT ON TRANSPARENCY OF MARCH-IN PROCEEDINGS (NIST–2023–0008) (2024)

[55] 35 U.S. Code § 201

"If march-in rights may not be sufficient to allow another party to manufacture a product, such as when only one of several patents necessary to produce a product is subject to march-in, would public access to the subject invention on reasonable terms be advanced if march-in rights were exercised alongside other authority, such as 'government use' patent licensing under 28 U.S. Code § 1498?"

"Agencies may consider whether other licensing authority, such as 'government use' patent licensing under 28 U.S. Code § 1498 or the 'paid up license' under 35 U.S. Code § 202, may be exercised alongside march-in rights to protect the public against nonuse or unreasonable use of a subject invention."

When an agency refuses to use the legal tools it has to protect the public interest, then those inclined towards abuse will likely believe they can act with impunity. Incorporating the following questions into the framework would provide further balance by considering the consequences of failing to exercise march-in rights:

"Would failure to exercise march-in rights risk encumbering future public access to the benefits of subject inventions on reasonable terms?"

"Would failure to exercise march-in rights risk health and safety needs not reasonably being satisfied by contractors with subject inventions more frequently?

"Would failure to exercise march-in rights risk contractors breaching domestic manufacturing requirements pursuant to section 204 more frequently?"

Finally, the entire purpose of march-in rights is to act as a check against corporate or other private abuses of the public interest with relation to publicly-funded inventions, or as the Bayh Dole Act policy and objective statement states: "to ensure that the Government obtains sufficient rights in federally supported inventions to meet the needs of the Government and protect the public against nonuse or unreasonable use of inventions".[56] Policymakers did not include these rights just for agencies to fail to exercise them in the face of abuse. Further, it is even more unlikely that policymakers would have wanted these public interest protections to yield to private industry concerns about their future ability to abuse publicly funded technologies. March-in rights are considered for use only in instances where the public-private agreement has been violated by the contractor, assignee, or licensee.

Just as the Patent and Trademark Office should not inappropriately grant patents because it is concerned about its relationship with patent applicants, agencies should not inappropriately refrain from using march-in rights out of concerns of "the potential chilling effect on […] relationships with industry", and we therefore recommend that this language be removed from the framework.

If the framework retains the "chilling effect" language on page 22, it should at least be balanced with countervailing questions, such as:

"How much revenue has the manufacturer obtained through sales of products which include the subject invention? Is this amount greater than privately incurred research and

[56] 35 U.S. Code § 200

development expenses related to the drug? Is this amount greater than privately incurred research and development expenses, with consideration for the risk incurred in such private investments? If so, how much greater? What are the marginal costs of manufacturing and distributing the product compared to the price at which it is made available for sale? How much revenue would the manufacturer be likely to receive in its own future sales and through royalties from march-in licensees?"

9) Consider the Bayh-Dole Act domestic manufacturing preference when evaluating potential licensees for the exercise of march-in rights.

The draft framework guides agencies to ask questions about alternative licensees and their capacity. We support that inquiry but suggest there are additional factors beyond the timing of production, marketing capacity, and price.

When considering alternative licensees for sale of the subject invention in the United States, agencies should evaluate whether such licensees would be able to comply with the requirement of section 204 that the invention be substantially manufactured domestically. While the section 204 requirement only expressly applies to *the exclusive right* to sell in the United States, agencies should retain this preference while considering march-in licensees, when possible.[57]

Additionally, agencies should also consider other factors, including but not limited to whether a potential licensee currently allows employees a collective voice at work or do they waste resources combatting efforts to unionize? Do they pay a living wage? Do they have a record of bringing historically underrepresented groups into the manufacturing sector? Such criteria are in line with the Biden Administration's whole-of-government approach to using its leverage to support workers who are organizing and pro-union employers; such criteria are also in line with this administration's promise of "invent it here, make it here."

This concludes Public Citizen's comments on the Draft Interagency Guidance Framework for Considering the Exercise of March-In Rights. Thank you for the opportunity to provide feedback on the administration's vital work to protect the public interest in publicly-funded inventions.

Cc: The Honorable Xavier Becerra, Secretary of Health and Human Services

Dr. Monica M. Bertagnolli, Director, National Institutes of Health

Neera Tanden, Director, Domestic Policy Council, White House

[57] Inability to identify a domestic manufacturer licensee after reasonable efforts should not prevent licensing to another responsible applicant or applicants.