



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 5, 2024

Re: [“Request for Information Regarding the Draft Interagency Guidance Framework for Considering the Exercise of March-In Rights”](#), Docket No.: 230831-0207, NIST–2023–0008

Dear Secretary Raimondo and Undersecretary Locascio:

On behalf of U.S. PIRG and our state affiliates¹, I welcome the opportunity to comment on the Request for Information relating to the National Institute of Standards and Technology (NIST) framework for the exercise of march-in rights under the Bayh-Dole Act.²

We applaud the important work of the Biden administration to address the high prices of prescription drugs, including implementation of the law allowing the Centers for Medicare and Medicaid Services to negotiate prices for certain drugs.³ Yet, to better ensure people in the United States can access essential medicine, more can and should be done to respond to the increasing prices of prescription drugs in our country. We applaud this step to build a framework which will serve to clarify how and when the federal government can license an invention that was funded by government dollars.⁴ Most importantly, the proposed framework makes it clear that an “unreasonable” price is an important factor to be considered in any decision to act on the funding agency’s power to use the government’s march-in rights as established under

¹ PIRG is a federation of independent, state-based, citizen-funded Public Interest Research Groups, and is part of The Public Interest Network, which operates and supports organizations committed to a shared vision of a better world and a strategic approach to social change. <https://pirg.org/about/>

² National Institutes of Health, *Bayh-Dole Regulations*, <https://grants.nih.gov/grants/bayh-dole.htm>

³ U.S. PIRG, *Lower prices coming for ten of the most expensive prescription drugs*, <https://pirg.org/updates/lower-prices-coming-for-ten-of-the-most-expensive-prescription-drugs/> August 29, 2023.

⁴ [35 U.S.C. 203](#).

Bayh-Dole Act. This important clarification will give agencies a clear pathway to use march-in rights when drug prices prevent the public from accessing innovative medicine emanating from public funding.

March-in has never been used, despite numerous petitions urging the federal government to intervene on behalf of patients who cannot access a prescription drug because of its high price.⁵

This framework is important to clarify that the price of a drug is a consideration in determining whether the funding agency should march-in. Too often, petitions brought on behalf of patients challenging the high price of medications developed using public funding have been denied because the price of the drug did not play a role in the funding agency's determination.

For example, in February 2022, we joined others in urging HHS to act on the petition submitted by four patients with prostate cancer to use the federal government march-in rights on patents for the prostate drug enzalutamide, marketed by Astellas under the brand name Xtandi.⁶ Patients with prostate cancer in the U.S. were facing costs as high as \$150,000 a year for treatment while patients in other countries were obtaining the medicine for under \$60,000 a year. The unreasonable price was a huge determinant of whether patients in the U.S. could access the medicine. We were disappointed in March 2023 to learn the Department decided not to utilize its rights under the Bayh-Dole Act to license the drug so as to introduce price competition and help patients get the medication on reasonable terms.

The federal government has a responsibility to enact a framework to ensure key elements of a law passed over 40 years ago can be used.

Over \$100 Billion of federal funds are distributed to outside entities every year to research and develop novel products, including important medicine.⁷ And yet, not once have march-in rights been utilized. There is a long history of haggling over what the law really means and how it should be used. The framework put forth in this RFI will be key to whether patients needing over-priced prescriptions will ever be able to benefit from the protections the Act intended.

The Bayh-Dole Act was written to solve the drug pricing predicament that exists today.

The Bayh-Dole Act was enacted so as to:

“..use the patent system to promote the utilization of inventions arising from federally supported research or development; to **encourage maximum participation of small business firms** in federally supported research and development efforts; to **promote collaboration between commercial concerns and nonprofit organizations**, including

⁵ KEI International, *Timeline regard Bayh-Dole march-in right requests*, <https://www.keionline.org/march-in-in-rights-timeline> accessed Feb. 4, 2024.

⁶ U.S.PIRG, *High cost of Xtandi, treatment for prostate cancer, could be solved using “March-In” rights*, <https://pirg.org/resources/high-cost-of-xtandi-treatment-for-prostate-cancer-could-be-solved-using-march-in-rights/>, Nov. 18, 2022.

⁷ National Center for Science and Engineering Statistics. *Survey of Federal Funds for Research and Development, 2021*. <https://nces.nsf.gov/surveys/federal-funds-research-development/2021>.

universities; to ensure that inventions made by nonprofit organizations and small business firms are **used in a manner to promote free competition** and enterprise without unduly encumbering future research and discovery; to promote the commercialization and public availability of inventions made in the United States by United States industry and labor; 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**; and to minimize the costs of administering policies in this area.” [*emphasis added*]⁸

Two key objectives of the Bayh-Dole Act is to “promote the utilization of patents” and “promote free competition.” There is no situation more ripe to meet these objectives than applying it to the way drug companies use patents to *prevent* the wide use of publicly-funded medical innovation. Bayh-Dole march-in rights should help patients access and use patented drugs by improving price competition through licensing those drugs to other companies. Drug companies use existing patents to keep competition out of the market so those large drug companies can keep their monopoly on the medicine and keep prices high. Pharmaceutical companies that have been targeted by march-in petitions are often engaging in anticompetitive patent strategies such as building patent thickets, encouraging product hopping and making pay-for-delay deals.⁹ Another objective of the Act includes promoting small business. Pharmaceutical companies that have been targeted by march-in petitions are not small businesses.

Anticompetitive strategies that keep drug prices high often mean patients can’t obtain these patented drugs. Two-thirds of U.S. adults rely on prescription drugs.¹⁰ And one in four Americans struggle to pay for their medications.¹¹ The financial burden of the high prices of prescription drugs is also a major concern for the annual budgets of our federal and state governments. And we are all paying these high prices even though U.S. taxpayers are underwriting much of the biomedical research with more than \$50 billion in annual investments through the National Institutes of Health.¹²

This state of affairs is the situation that the Bayh-Dole Act meant to address. With a well developed framework, we expect funding agencies to march-in on companies selling

⁸ [35 U.S.C. 200](#).

⁹ U.S. PIRG, *The Cost of Prescription Drug Patent Abuse*, <https://pirg.org/edfund/resources/the-cost-of-prescription-drug-patent-abuse/>, April 2023.

¹⁰ Emily Ihara, *Prescription Drugs*, Georgetown University Health Policy Institute, <https://hpi.georgetown.edu/rxdrugs/#:~:text=More%20than%20131%20million%20people,United%20States%20%E2%80%94%20use%20prescription%20drugs>

¹¹ KFF, *Poll: Nearly 1 in 4 Americans Taking Prescription Drugs Say It’s Difficult to Afford Their Medicines, including Larger Shares Among Those with Health Issues, with Low Incomes and Nearing Medicare Age*, <https://www.kff.org/health-costs/press-release/poll-nearly-1-in-4-americans-taking-prescription-drugs-say-its-difficult-to-afford-medicines-including-larger-shares-with-low-incomes/>, March 1, 2019.

¹² U.S. Senate HELP Committee, <https://www.sanders.senate.gov/wp-content/uploads/Public-Medicines-Report-updated.pdf>, June 12, 2023.

prescription medications where there is clear failure to make those medicines developed through taxpayer funding available “on reasonable terms.”

We fully support the clear inclusion of “price” in Criterion 1:

“(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.” [emphasis added]”

As demonstrated above, patients, insurers and federal and state governments are buckling under the high cost of prescription medicine that saves lives or helps people function at their best. A high price can unreasonably limit availability - when a patient can't meet their cost-sharing amount, when plans can't afford to cover the medicine without raising premiums which could price out employers and patients, when federal and state health programs can't balance their budgets because of the cost of medicine for the certain populations.

Criterion 2 underscores the importance of serving patient needs.

Criterion 2. Action is necessary to alleviate health or safety needs which are not reasonably satisfied by the contractor, assignee, or their licensees. In considering march-in based on criterion 2, agencies will seek a clear picture of the health or safety need that is not being reasonably satisfied.

We believe it is important, particularly to meet public health needs, to consider whether the high price of prescription drugs has made it difficult for patients with particular health problems to access the medicine for their population.

To improve the effectiveness of the proposed framework, we offer the following two recommendations:

1. **More clearly define elements to determine “reasonableness” of pricing.** Simply because some patients and some health plans can pay the existing price of a medicine does not mean it is a reasonable price. A broader scope of comparison and more clear examples should be included in the framework to assist agencies when looking at evidence to make their decision on whether a medication is available on “reasonable” terms. We recommend you consider adding considerations/evidence such as:
 - what other countries pay for the medication,
 - the impact on pricing with the introduction of a competitor/licensee (will it be more reasonably priced?),

- the overall impact of the current price, including the trend of its recent price increases, on the question of access as it relates to the public health of the patient population relying on that particular medication.
 - The overall impact of the price on, not just the patients needing the medications, but also payers like Medicare, Medicaid and private insurance too, where those high drug prices are paid through our premiums and tax dollars.
2. **Allow the public to have a role in march-in determinations.** The framework gives strong consideration to the evidence provided by the funding agency and to the “contractor” (in this case, the pharmaceutical company). But the end-user - the patient, payer or government entity - actually paying the price of the product, is not involved and has no clear opportunity to have their voice heard as an end-user. Participatory government is one of America’s founding principles. Patients, insurers, and state/federal government officials - those paying for the high-priced drugs - should be allowed an opportunity to weigh in on the evidence presented to the deciding party, including whether a price is “reasonable.”

Thank you for drafting the march-in framework to specifically include “price” in the consideration of “reasonable” terms and urge you to include our recommendations in the final version. We appreciate the department’s work and your commitment to make it clearer so agencies can step forward in confidence to help patients and the public by marching-in on overpriced medications.

Sincerely,



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