Congress of the United States

Washington, DC 20515

June 9, 2023

The Honorable Gina Raimondo
Secretary
Department of Commerce
1401 Constitution Ave, N.W.
Washington, D.C. 20230

The Honorable Xavier Becerra
Secretary
Department of Health and Human Services
200 Independence Avenue, S.W.
Washington, D.C. 20201

Dear Secretary Raimondo and Secretary Becerra,

We are writing to request information about the Interagency Working Group for Bayh-Dole (Working Group) and to urge the Working Group to move swiftly to lower drug prices for Americans. We are deeply disappointed that the Department of Health and Human Services (HHS) rejected the petition to march-in on the prostate cancer treatment enzalutamide, also known by its brand name Xtandi, which was developed with taxpayer dollars yet costs as much as six times more in the United States than in peer countries.[1] In its response to petitioners, HHS completely ignored the central question posed in the petition: whether the drug's high price violates the statute's requirement that the invention be made available to the public on "reasonable terms."[2] We are pleased that the Working Group will consider price in its evaluation of the Administration's march-in authority, but we are concerned that there have been no public updates about the Working Group's membership, process, timeline, or scope of work in the more than two months since it was first announced.

Americans pay two to three times more for brand-name prescription drugs than individuals in peer countries.[3] Last summer, Congress passed overdue drug pricing reforms to help older adults afford their medications by empowering Medicare to negotiate some drug prices for the first time, limit price spikes, and cap out-of-pocket costs.[4] Though this represents critical progress, more must be done to curb excessive drug prices, including for the more than 200 million Americans who are not on Medicare.[5] The

[1] U.S. Department of Health and Human Services, "HHS and DOC Announce Plan to Review March-In Authority," press release, March 21, 2023, https://www.hhs.gov/about/news/2023/03/21/hhs-doc-announce-plan-review-march-in-authority.html; The American Prospect, "A Big Miss on Drug Prices," David Dayen, March 22, 2023, https://prospect.org/blogs-and-newsletters/tap/2023-03-22-nih-drug-prices-xtandi/.

[2] Knowledge EcologyInternational, "HHS and NIH reject the Xtandi March-in petition," James Love, March 21, 2023, https://www.keionline.org/38536; 35 U.S.C. 201(f).

[3] Letter to Secretary Becerra and Acting Director Tabak from Clare M. Love, Eric L. Sawyer, and Robert Sachs of Universities Allied for Essential Medicines, February 3, 2022, https://www.keionline.org/wp-content/uploads/Love-Sachs-Sawyer-UAEM-Letter-Xtandi-Pfizer-Contract-3Feb2022.pdf.

[4] Kaiser Family Foundation, "Explaining the Prescription Drug Provisions in the Inflation Reduction Act," Juliette Cubanski, Tricia Neuman, and Meredith Freed, January 24, 2023, https://www.kff.org/medicare/issue-brief/explaining-the-prescription-drug-provisions-in-the-inflation-reduction-act/.

[5] U.S. Census Bureau, "Health Insurance Coverage in the United States: 2021," Katherine Keisler-Starkey and Lisa N. Bunch, September 2022, p. 4, https://www.census.gov/content/dam/Census/library/publications/2022/demo/p60-

Biden Administration can use its existing authority to step in on behalf of all Americans and rectify pharmaceutical industry abuses that have allowed drug prices to skyrocket, and it can do so without waiting for permission from Congress. As your agencies work together to "develop a framework for implementation of the march-in provision,"[6] we urge you to consider the following:

Consider whether a drug is priced higher in the United States than other high-income countries in the definition of "reasonable terms."[7] Of the seven march-in petitions filed since 1980, all of them have been rejected by the National Institutes of Health (NIH)[8] despite provisions under the *Bayh-Dole Act* (Bayh-Dole), codified at 35 U.S.C. 203, that allow the federal government, in certain cases, to grant licenses to a "responsible applicant" for inventions developed with federal funds.[9] The government may exercise this taxpayer protection authority when "action is necessary to alleviate health or safety needs" or when an invention's benefits are not "available to the public on reasonable terms" per the plain text of the statute.[10] And as legal experts have repeatedly concluded, a product's price plays a critical role in determining whether it is reasonably available to the public.[11] "[T]he words 'reasonable terms' have uniformly been interpreted [by courts] to include price."[12] Or put another way, "if a drug company is not charging a reasonable price for a drug, or if its pricing harms public health by substantially restricting access to the drug, the federal government is well within its rights to ensure the availability of cheaper generic versions."[13] Legal experts from Yale Law School, Harvard Medical School, and Columbia Law School have declared these tools to be "integral, longstanding, and legitimate parts of our patent systems."[14] To ensure these tools are exercised and have a clear standard to trigger their use, the NIH and other health technology funding agencies should consider adopting a standard wherein a subject invention is not considered available on reasonable terms if the list price of a prescription drug that includes the

278.pdf.

[6] U.S. Department of Health and Human Services, "HHS and DOC Announce Plan to Review March-In Authority," press release, March 21, 2023, https://www.hhs.gov/about/news/2023/03/21/hhs-doc-announce-plan-review-march-in-authority.html.

[7] 35 U.S.C. 201(f).

[8] Congressional Research Service, "March-In Rights Under the Bayh-Dole Act," August 22, 2016, https://www.crs.gov/Reports/R44597; U.S. Department of Health and Human Services, "HHS and DOC Announce Plan to Review March-In Authority," press release, March 21, 2023, https://www.hhs.gov/about/news/2023/03/21/hhs-doc-announce-plan-review-march-in-authority.html.

[9] 35 U.S.C. 203.

[10] 35 U.S.C. 203(a)(2); 35 U.S.C. 201(f).

[11] *See, e.g.*, Peter S. Arno & Michael H. Davis, *Why Don't We Enforce Existing Drug Price Controls?*, 75 Tulane L. Rev. 631 (2001); Center for American Progress, "Enough Is Enough: The Time Has Come to Address Sky-High Drug Prices," Topher Spiro, Maura Calsyn & Thomas Huelskoetter, September 2015, https://cdn.americanprogress.org/wp-content/uploads/2015/09/15131852/DrugPricingReforms-report1.pdf; Essential Inventions, "The Bayh-Dole Act and March-In Rights," David Halperin, May 2001, https://www.essentialinventions.org/legal/norvir/halperinmarchin2001.pdf; Health Affairs, "March-In Rights Could Ensure Patient Access By Keeping Drug Prices In Check. They're Under Attack.," Peter S. Arno, Dana Neacsu, and Kathryn Ardizzone, April 30, 2021, https://www.healthaffairs.org/do/10.1377/hblog20210428.519540/full; 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*, 54 Willamette L. Rev. 171 (2017); The Incidental Economist, "Pushing Back on Exorbitant Drug Prices," Nicholas Bagley, September 21, 2015, https://theincidentaleconomist.com/wordpress/pushing-back-on-exorbitant-drug-prices.

[12] Peter S. Arno & Michael H. Davis, *Why Don't We Enforce Existing Drug Price Controls?*, 75 Tulane Law Review 631, 650 (2001).

[13] Center for American Progress, "Enough Is Enough: The Time Has Come to Address Sky-High Drug Prices," Topher Spiro, Maura Calsyn, and Thomas Huelskoetter, September 2015, p. 27, https://cdn.americanprogress.org/wp-content/uploads/2015/09/15131852/DrugPricingReforms-report1.pdf.

[14] Letter from legal and public health experts to Senator Elizabeth Warren, April 20, 2022, https://www.warren.senate.gov/imo/media/doc/2022.4.20%20Letter%20to%20Warren%20on%20Drug%20Pricing%20Executive%20Authorities.pdf.

invention is not the lowest available in any of the 15 countries with the largest gross domestic products and per capita incomes at least half that of the United States. This would be consistent with "Most Favored Nation (MFN)" policies adopted in some COVID-19-related contracts, including regarding nirmatrelvir/ritonavir, also known as Paxlovid.[15] The Working Group may wish to consider additional standards, but a clear definition and way to evaluate price is essential to ensure predictability for all parties on when taxpayer protection authorities will be exercised.

Expand the scope of the Working Group to include a review of other public interest licensing provisions in the *Bayh-Dole Act*, such as paid-up licenses. It should be uncontroversial to expect U.S. taxpayers to pay no more than peer nations for medicines they paid to invent. In the case of government health programs like Medicare and Medicaid, this expectation should be indisputable. The Working Group should identify achieving fair drug prices in federal programs as a reason to exercise the agency's paid-up license. Under 35 U.S.C. 202, the federal government holds an irrevocable, non-transferable, paid-up license to practice or have practiced on its behalf inventions developed with its funding.[16] Unlike march-in rights, the government using its paid-up license is not contingent on the contractor or assignee failing to make the invention available on reasonable terms or action being necessary to alleviate health or safety needs. Legal experts contend that the plain reading of the statute suggests the Section 202 license includes production of drugs for Medicare and Medicaid.[17]

Ensure the framework contemplated by the Working Group includes a robust appeals process for petitioners. The Working Group is charged with developing a framework that "clearly articulates guiding criteria and processes" for making march-in determinations.[18] It is critical to ensure that an appeals process does not permit the same individuals to consider the appeal as those who rendered the initial decision. Following the NIH's denial of the march-in request for Xtandi, petitioners wrote in their request for an appeal that a decision to delegate the appeal to the same office that reviewed the original petition "would be tantamount to no review at all."[19] This would also ensure that the individuals considering an appeal have a fresh perspective on the subject.

Provide a list of drugs developed with taxpayer funds and related patents. The public deserves greater transparency related to taxpayer developed drugs. The Working Group should disclose patents that benefited from government resources, which could be subject to authorities under Bayh-Dole. Any eligible drug product should also include information about research and development costs incurred by the manufacturer and the amount of government funding provided, including through tax credits and direct funding.

Clarify guidelines for disclosing government support on patent applications. A recent Government Accountability Office report highlighted that NIH grant awardees are not always disclosing government support on patent applications.[20] The NIH "is the largest public funder of biomedical research and

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[15] See discussion of the MFN provision at: Knowledge Ecology International, "Pfizer Agrees to International Reference Pricing in Government Contract for Covid-19 Therapeutic," Claire Cassedy, February 2, 2022, https://www.keionline.org/37294.

[16] 35 U.S.C. 202(c)(4).

[17] Letter from legal and public health experts to Senator Elizabeth Warren, April 20, 2022, https://www.warren.senate.gov/imo/media/doc/2022.4.20%20Letter%20to%20Warren%20on%20Drug%20Pricing%20Executive%20Authorities.pdf.

[18] U.S. Department of Health and Human Services, "HHS and DOC Announce Plan to Review March-In Authority," press release, March 21, 2023, https://www.hhs.gov/about/news/2023/03/21/hhs-doc-announce-plan-review-march-in-authority.html.

[19] Letter from Robert J. Sachs, Clare M. Love, and Eric Sawyer to Secretary Becerra, March 23, 2023, https://www.keionline.org/xtandidocs/xtandi-appeal-23march2023.pdf.

[20] U.S. Government Accountability Office, "National Institutes of Health:

development," which supports critical drug development and may lead to the identification of new uses for existing drugs.[21] Yet, NIH awardees did not disclose NIH support on almost 15 percent of patents submitted between 2012 and 2021.[22] Proper identification of the NIH's contributions is necessary to understand taxpayers' rights as to enjoying the benefits of these discoveries.

Ensure officials involved with the Working Group are free from conflicts of interest. Public officials are required to follow federal ethics laws,[23] and appointees are subject to additional requirements as outlined in President Biden's Executive Order on Ethics Commitments by Executive Branch Personnel.[24] However, recent reporting has exposed troubling gaps in existing ethics requirements. For example, a Wall Street Journal investigation revealed that thousands of senior government employees held stock in companies that their agencies regulated.[25] For the public to have confidence in this process, individuals charged with representing, supporting, or serving on the Working Group should adhere to high standards for preventing conflicts of interest. People should know that the government is working on their side, not on behalf of the companies whose profits could be affected by Working Group decisions.

Ensure the Working Group involves a wide range of government offices, including representatives from the Federal Trade Commission (FTC), National Economic Council (NEC), and Domestic Policy Council (DPC). Consistent with the "whole-of-government approach" announced by your agencies,[26] we urge you to involve representatives from the FTC, NEC, and DPC in the Working Group. We also recommend you consider including representatives from government agencies responsible for prescription drug purchasing and/or reimbursement, such as the Department of Veterans Affairs.

Ensure balance and transparency of Working Group proceedings. HHS has announced its intention to convene a workshop in 2023; however, no other information has been provided about the Working Group's meetings or consultation process. Corporate interests will undoubtedly seek to influence the Working Group's framework to protect their profits. In designing and running this process, HHS and the Department of Commerce (DOC) should ensure that consumer advocates, academics, and other public interest stakeholders have equal opportunities to inform the Working Group's products as other parties. The Working Group should not hold invitation-only meetings or stakeholder calls. All consultation and briefings on the framework should be public and open to all interested participants. The Working Group's proposed framework should follow a standard notice and comment process that invites written comments from the broader public as well as public hearings. This public engagement process should not be contracted out to a third party, and if agencies other than HHS and DOC choose to run parallel processes to gather feedback on Working Group products, they should abide by these same standards.

Better Data Will Improve Understanding of Federal Contributions to Drug Development," April 4, 2023, https://www.gao.gov/products/gao-23-105656.

[21] *Id.*

[22] *Id*.

[23] 5 C.F.R. 2635.101(b); 18 U.S.C. 208; 5 C.F.R. 2635.802.

[24] The White House, "Executive Order on Ethics Commitments by Executive Branch Personnel," January 20, 2021, https://www.whitehouse.gov/briefing-room/presidential-actions/2021/01/20/executive-order-ethics-commitments-by-executive-branch-personnel/.

[25] The Wall Street Journal, "Federal Officials Trade Stock in Companies Their Agencies Oversee," Rebecca Ballhause, Brody Mullins, Chad Day, John West, Joe Palazzolo, and James V. Grimaldi, October 11, 2022, https://www.wsj.com/articles/government-officials-invest-in-companies-their-agencies-oversee-11665489653-.

[26] U.S. Department of Health and Human Services, "HHS and DOC Announce Plan to Review March-In Authority," press release, March 21, 2023, https://www.hhs.gov/about/news/2023/03/21/hhs-doc-announce-plan-review-march-in-authority.html.

Publish the final "framework for implementation of the march-in provision" by December 31, 2023.[27] HHS has stated that it will "convene a workshop in 2023 to further refine the cases for which HHS could consider exercising march-in authority" and "to assess when the use of march-in is consistent with the policy and objectives of the Bayh-Dole Act."[28] To ensure timely relief for consumers who face high drug prices, we urge you to convene this workshop no later than September 1, 2023 and to publish a final framework no later than December 31, 2023.

We support President Biden's goal of lowering drug prices for Americans, and if adopted, we believe these principles will allow the Working Group to fully and independently study these authorities. In an effort to learn more about this effort, we also request answers to the following questions by June 23, 2023.

1. Will you ensure that the Working Group's discussion of price includes whether a drug's price is higher in the United States than in other high-income countries?

2. Will the Working Group consider reasonable pricing as it relates to the use of paid-up licenses?

3. Will you ensure that the framework contemplated by the Working Group guarantees a robust appeals process for petitioners?

4. Will you ensure the Working Group publishes a list of drugs developed with taxpayer funds and related patents to increase transparency?

5. Will you ensure the Working Group clarifies guidelines for disclosing government support on patent applications?

6. Will you ensure members involved with the Working Group are free from conflicts of interest?

7. Which other agencies or offices will be represented on the Working Group?

    a. Will you include representatives from the FTC?

    b. Will you include representatives from NEC?

    c. Will you include representatives from DPC?

    d. Will you include representatives from agencies responsible for prescription drug purchasing and/or reimbursement, such as the Department of Veterans Affairs?

8. Will you ensure that consumer advocates, academics, and other public interest stakeholders have equal opportunities to inform the Working Group's products as other parties?

9. Will you commit to making meetings of the Working Group public?

[27] *Id.*
[28] *Id.*

10. Will you commit to managing the public engagement process in-house, rather than hire a third-party consultant?

11. Will you commit to publishing a proposed "framework for implementation of the march-in provision" for public comment no later than September 1, 2023?[29]

12. Will you commit to publishing the Working Group's final "framework" no later than December 31, 2023?[30]

Thank you for your attention to this important matter.

Sincerely,

Elizabeth Warren
United States Senator

Angus S. King, Jr.
United States Senator

Lloyd Doggett
Member of Congress

[29] *Id.*
[30] *Id.*