Congress of the United States
Washington, DC 20515

January 10, 2023

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

Dear Secretary Becerra:

We write to urge you to use your administrative authority under the Bayh-Dole Act to lower the price of enzalutamide, also known by its brand name Xtandi, by exercising the federal government's taxpayer protection rights under the Bayh-Dole Act. This action would allow the government to grant patent licenses so generic manufacturers can produce the drug and bring down costs, without delay. In November 2021, two prostate cancer patients, later joined by a third, submitted a petition to initiate march-in proceedings for Xtandi.[1] However, the Department of Health and Human Services (HHS or the Department) has yet to act on this petition. The Inflation Reduction Act (IRA) has been signed into law[2] and will provide critical relief for Medicare beneficiaries,[3] but there are additional actions – including granting march-in rights for Xtandi – that the administration can take to follow through on its commitment to reduce drug prices for all Americans.

Recent legislation allows the federal government to negotiate some drug prices, requires pharmaceutical companies to pay rebates if they increase prices more than inflation, and caps out-of-pocket spending for Medicare drug plan enrollees at $2,000 annually.[4] However, many of these provisions will not take effect immediately, with some not starting until 2026.[5] The Administration has the tools to bring relief to Americans now, including by using its existing authority to lower the cost of Xtandi.

Provisions in the Bayh-Dole Act, codified at 35 U.S.C. § 203, allows federal agencies to protect taxpayer investments by permitting agencies to grant licenses to "responsible

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[1] Knowledge Ecology International, "HHS Asked to Take Up March-in Request of Prostate Cancer Drug Xtandi," Claire Cassedy, December 15, 2021, https://www.keionline.org/37142;Knowledge Ecology International, "Xtandi: 2021-2022 Request to US Department of Health and Human Services to Use the US Government's Rights in Patents," https://www.keionline.org/xtandi2021.
[2] Inflation Reduction Act of 2022, Public Law 117-169.
[3] New York Times, "Biden Signs Expansive Health, Climate and Tax Law," Jim Tankersley, August 16, 2022, https://www.nytimes.com/2022/08/16/business/biden-climate-tax-inflation-reduction.html.
[4] Kaiser Family Foundation, "Explaining the Prescription Drug Provisions in the Inflation Reduction Act," Juliette Cubanski, Tricia Neuman, Meredith Freed, September 22, 2022, https://www.kff.org/medicare/issue-brief/explaining-the-prescription-drug-provisions-in-the-inflation-reduction-act/.
[5] *Id.*

applicant[s]" for patented inventions developed with federal funds.[6] Specifically, the government may exercise its march-in rights on behalf of taxpayers 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."[7] Legal experts have repeatedly concluded that a product's price plays a critical role in determining whether it is reasonably available to the public,[8] stating, "the words 'reasonable terms' have uniformly been interpreted [by courts] to include price."[9] It is clear that "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."[10]

Xtandi, which is a drug used to treat prostate cancer, can cost Americans as much as six times what it costs individuals in other high-income countries to access the medicine, even though American taxpayers contributed to its research and development.[11] According to the latest data from Centers for Medicare and Medicaid Services, Medicare spent nearly $2 billion for Xtandi in 2020.[12] Researchers at the University of California Los Angeles (UCLA) developed Xtandi in part with funding from grants from the U.S. Army and National Institutes of Health (NIH),[13] and all three FDA Orange Book patents for the drug state that federal grants supported the research underlying the patented technology.[14] Therefore, the federal government is clearly eligible to use march-in rights to lower the costs of Xtandi for all Americans.

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[6] 35 U.S.C. § 203.
[7] 35 U.S.C. §§ 203(a)(2) & 201(f).
[8] *See, e.g.*, Peter S. Arno & Michael H. Davis, *Why Don't We Enforce Existing Drug Price Controls? The Unrecognized and Unenforced Reasonable Pricing Requirements Imposed upon Patents Deriving in Whole or in Part from Federally-Funded Research*, 75 Tulane L. Rev. 631 (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 & 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.
[9] Peter S. Arno & Michael H. Davis, *Why Don't We Enforce Existing Drug Price Controls? The Unrecognized and Unenforced Reasonable Pricing Requirements Imposed upon Patents Deriving in Whole or in Part from Federally-Funded Research*, 75 Tulane L. Rev. 631, 650 (2001).
[10] 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, p. 27, https://cdn.americanprogress.org/wp-content/uploads/2015/09/15131852/DrugPricingReforms-report1.pdf.
[11] Letter to Secretary Becerra and Acting Director Tabak on Xtandi March-in Petition and Most Favored Nation Clause in Pfizer Contract, Clare M. Love, Eric L. Sawyer, Robert Sachs, 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.
[12] Center for Medicare and Medicaid Services, "Medicare Part D Spending by Drug," https://data.cms.gov/summary-statistics-on-use-and-payments/medicare-medicaid-spending-by-drug/medicare-part-d-spending-by-drug/data.
[13] Memorandum in support of the petition to HHS to exercise the march-in or paid up royalty right in patents on the prostate drug Xtandi, Knowledge Ecology International, January 25, 2022, pp. 3-4, https://www.keionline.org/wp-content/uploads/KEI-Memo-HHS-Xtandi-Bayh-Dole-March-in-Paid-up-Royalty-25Jan2022.pdf.
[14] *Id*.

You have repeatedly committed to considering petitions urging the use of march-in rights: in the response you provided to a letter we sent in July 2021, in your response to questions for the record (QFRs) following your June appearance before the Senate Finance Committee, and in the September 2021 "Comprehensive Plan for Addressing High Drug Prices."[15] Over a year has passed since the petition to exercise march-in rights for Xtandi was first submitted to HHS, and despite numerous commitments from HHS that the Department would give such petitions "due consideration,"[16] the petition has not been fully reviewed. In January 2022, the NIH told petitioners that the review would likely take a month.[17] In April 2022, the NIH was "carefully reviewing the Xtandi march-in petition to determine whether the information received might warrant the exercise of march-in rights."[18] And earlier this month, nearly eight months later, the NIH finally sent its first formal response to the petitioners, again providing no information on any progress, but instead restating that it is "currently coordinating with HHS to review and assess the information submitted in the 2021 petition requesting the government to use its march-in authority for Xtandi® (enzalutamide) to determine whether the initiation of the march-in procedures outlined in 37 CFR §401.6 may be warranted."[19]

You have the power to take on the monopoly abuses of the pharmaceutical industry and the responsibility to ensure Americans have affordable access to the medicines they need. We urge you to send a clear message to companies trying to price gouge products that have been funded with taxpayer money by holding a long overdue public hearing on the Xtandi petition and determining whether to exercise the government's rights. HHS can and should use these existing authorities to deliver on the administration's promises to lower prescription drug prices. You can provide immediate relief for patients from Big Pharma's price gouging and show millions more Americans that you, President Biden, and his administration are on their side. We urge you to move forward with the march-in petition for Xtandi without delay and ask that you provide answers to the following questions by January 31, 2023:

1. Does HHS currently have procedures governing how officials respond to march-in petitions, including an internal review process and associated review and response deadlines? If so, please describe them.

2. Does HHS currently have an internal deadline in place to respond to the Xtandi march-in petition? What is that deadline?

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[15] Letter from HHS Secretary Becerra to Senator Elizabeth Warren, November 15, 2021; See also: U.S. Senate Committee on Finance, "The President's FY 2022 HHS Budget," Questions for the Record for Secretary Xavier Becerra, June 10, 2021; Department of Health and Human Services, "Comprehensive Plan for Addressing High Drug Prices," September 9, 2021, p.22, https://aspe.hhs.gov/sites/default/files/2021-09/Drug_Pricing_Plan_9-9-2021.pdf.

[16] Department of Health and Human Services, "Comprehensive Plan for Addressing High Drug Prices," September 9, 2021, p.22, https://aspe.hhs.gov/sites/default/files/2021-09/Drug_Pricing_Plan_9-9-2021.pdf.

[17] Endpoint News, "Scoop: NIH resets the clock on Xtandi 'march-in' petition request from patients with prostate cancer," Zachary Brennan, April 25, 2022, https://endpts.com/nih-resets-the-clock-on-xtandi-march-in-petition-request-from-patients-with-prostate-cancer/.

[18] *Id*.

[19] Letter from Acting Acting Principal Deputy Director, NIH Tara. A. Schwetz, Ph.D. to Robert Sachs and Clare Love, December 1, 2022, https://www.keionline.org/wp-content/uploads/NIH-Response2Sachs-Love1dec2022.pdf.

3. What standards of evidence are used to judge whether HHS will initiate march-in proceedings?

4. Which HHS officials are involved in reviewing this evidence? Would NIH officials be involved in the review process if the funding agreement in question was issued by the agency?

5. What steps must be taken before HHS reaches a final decision?

6. Does HHS plan on notifying the individuals who submitted the petition of the decision?

Sincerely,

Elizabeth Warren
United States Senator

Lloyd Doggett
Member of Congress

Angus S. King, Jr.
United States Senator

Katie Porter
Member of Congress

Bernard Sanders
United States Senator

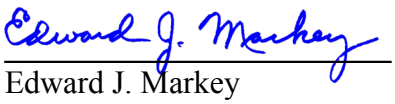
Raúl M. Grijalva
Member of Congress

Jeffrey A. Merkley
United States Senator

Barbara Lee
Member of Congress

Cory A. Booker
United States Senator

Jesús G. "Chuy" García
Member of Congress

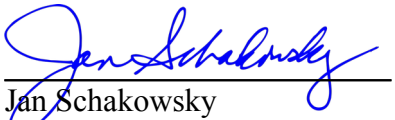


Edward J. Markey
United States Senator

André Carson
Member of Congress

Chris Van Hollen
United States Senator

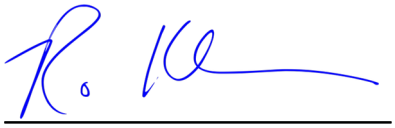
Pramila Jayapal
Member of Congress



Jan Schakowsky
Member of Congress

Cori Bush
Member of Congress

Mark Pocan
Member of Congress

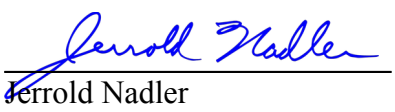


Ro Khanna
Member of Congress

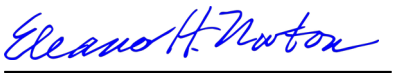
Rosa L. DeLauro
Member of Congress

Sheila Jackson Lee
Member of Congress

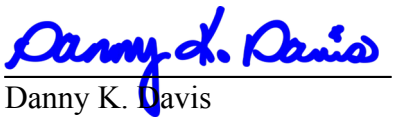
Jill Tokuda
Member of Congress



Jerrold Nadler
Member of Congress



Eleanor Holmes Norton
Member of Congress



Danny K. Davis
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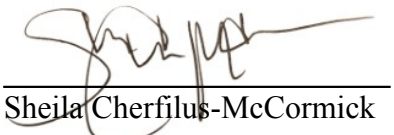

Sheila Cherfilus-McCormick
Member of Congress