Congress of the United States
Washington, DC 20510

February 17, 2022

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

Dear Secretary Becerra:

We write to urge you to move forward with the march-in petition submitted by Robert Sachs and Clare Love, and later joined by Eric Sawyer, for enzalutamide, also known by its brand name Xtandi. Exercising the government's march-in rights for enzalutamide will dramatically lower the price of this life-saving drug for millions of Americans.

March-in rights, established in the Bayh-Dole Act and codified at 35 U.S.C. § 203, allow the federal government, in certain cases, to grant licenses to "responsible applicants" for products developed with federal funds.[1] Specifically, the government may exercise its march-in rights 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.[2] 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.[3] "[T]he words 'reasonable terms' have uniformly been interpreted [by courts] to include price."[4] 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."[5]

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[1] 35 U.S.C. § 203.
[2] 35 U.S.C. §§ 203(a)(2) & 201(f).
[3] *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 and 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.
[4] Peter S. Arno & Michael H. Davis, *Why Don't We Enforce Existing Drug Price Controls?*, 75 Tulane L. Rev. 631, 650 (2001).
[5] 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.

On numerous occasions, HHS has committed to giving petitions for the use of march-in rights "due consideration," including in the agency's September 2021 "Comprehensive Plan for Addressing High Drug Prices."[6] You made the same commitment in the response you provided to our July 28, 2021 letter, and in your response to questions for the record following your June 10, 2021 appearance before the Senate Finance Committee.[7] The present petition on enzalutamide is a critical test case for HHS to follow through on these commitments.

Xtandi is used to treat prostate cancer and can cost Americans as much as six times what it costs individuals in other high-income countries to access the medicine. According to Knowledge Ecology International, the average wholesale price for Xtandi in the United States is $130, whereas the price of a 40mg capsule of the drug in Japan is just over $20.[8] The drug is intended for long-term use, and a typical course of treatment involves four pills taken daily: over the course of a year, the cost of Xtandi in the United States is nearly $160,000 higher than the drug's price in Japan.[9]

Xtandi is not the only case where Americans are paying exorbitantly high prices for prescription drugs – there are legions of examples. But the Xtandi costs are particularly galling because the drug's research and development were underwritten by American taxpayers. Grants from the U.S. Army and National Institutes of Health (NIH) to researchers at the University of California Los Angeles (UCLA) directly led to the invention of enzalutamide: all three FDA Orange Book patents for Xtandi credit state and federal grants with funding the patented technology's underlying research.[10]

As the administration continues to stress the importance of lowering drug prices, we urge you to use existing executive authority to deliver meaningful relief to consumers. HHS should hold a public hearing on the enzalutamide petition to allow petitioners and patent-holders to

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[6] U.S. Department of Health and Human Services, "Report to the White House Competition Council: Comprehensive Plan for Addressing High Drug Prices," September 9, 2021, https://aspe.hhs.gov/sites/default/files/2021-09/Competition%20EO%2045-Day%20Drug%20Pricing%20Report%209-8-2021.pdf.

[7] Letter from HHS Secretary Becerra to Senator Elizabeth Warren, November 15, 2021, https://www.warren.senate.gov/imo/media/doc/HHS%20Reply%20to%20July%2028%20Letter%20Regarding%20Prescription%20Drug%20Pricing.pdf; U.S. Senate Committee on Finance, "The President's FY 2022 HHS Budget," Questions for the Record for Secretary Xavier Becerra, June 10, 2021, [on file with the Office of Senator Elizabeth Warren].

[8] 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.

[9] Medical News Today, "Xtandi (enzalutamide)," Accessed on February 14, 2022, https://www.medicalnewstoday.com/articles/326429#What-is-Xtandi; 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.

[10] Knowledge Ecology International, "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," January 25, 2022, https://www.keionline.org/wp-content/uploads/KEI-Memo-HHS-Xtandi-Bayh-Dole-March-in-Paid-up-Royalty-25Jan2022.pdf.

present arguments and accompanying evidence on this case, and then move forward to exercise the government's march-in rights without delay.[11]

Sincerely,

Elizabeth Warren
United States Senator

Lloyd Doggett
Member of Congress

Angus S. King, Jr.
United States Senator

[11] Although this letter and the November 2021 petition primarily discuss march-in rights, we note that the federal government can also exercise its government-use rights to permit generic competition with Xtandi. 35 U.S.C. § 202(c)(4) grants a "nonexclusive, nontransferrable, irrevocable, paid-up license" to the federal government for inventions developed with federal funds, allowing the government to contract with a generic manufacturer to produce enzalutamide for use in government programs. HHS should strongly consider using this license – which does not require compensation to the patent owner – alongside its review of the Xtandi petition.