

# Congress of the United States

## Washington, DC 20515

February 8, 2022

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

Dear Secretary Becerra,

We are writing to urge the Department of Health and Human Services (HHS) to move forward with the November 2021 petition<sup>1</sup> to use either march-in or government use rights to remedy the unjustified pricing discrimination against United States residents for Xtandi, a drug to treat prostate cancer that was invented using grant funding from the U.S. Army and the National Institutes of Health (NIH).

Xtandi is marketed by Astellas, a large drug company headquartered in Japan. The drug is used to prevent the progression of prostate cancer, and treatment can last several years for some patients. Astellas charges high prices for the treatment everywhere, but the price in the U.S. is three to five times more expensive than in any other high-income country. In January 2022, the average wholesale price in the U.S. was \$189,800 for a year of treatment, whereas in Japan – where Astellas is headquartered – the price is less than \$30,000 per year.<sup>2</sup>

President Biden’s 2021 Executive Order on Competition<sup>3</sup> and HHS’s September 2021 report<sup>4</sup> to the White House on high drug prices both indicated that the federal government would take the pricing of products into account when considering march-in petitions, and they signaled the administration’s commitment to addressing the increasingly exorbitant cost of life-saving prescription drugs in the United States. Under the Bayh-Dole Act, federal agencies are well within their authority to march in when patent holders and their exclusive licensees fail to make the benefits of inventions “available to the public on reasonable terms.”<sup>5</sup>

It is our strongly held view that it is not reasonable to charge U.S. residents as much as five times the cost for a drug invented using American taxpayer dollars than the price offered to residents of other high-income countries.

If HHS rejects the pending petition to use the federal government’s rights in the Xtandi patents, it will send a dangerous signal to drug manufacturers that there are no practical limits on the degree to which a company can price-gouge U.S. patients. Choosing not to act on this textbook example of price-gouging prescription drugs will likely encourage further abuses.

Astellas has increased the average wholesale price of Xtandi by 76 percent since the drug was first introduced in the market in 2012, including an increase of 5.9 percent in January of this year. Global sales for Xtandi are more than \$20

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<sup>1</sup> Love, Clare Melvin, and David P Reed. Letter to Secretary Xavier Becerra “Request to the Department of Health and Human Services (HHS) to grant march-in rights for the patents on the prostate cancer drug enzalutamide,” November 18, 2021.

<https://www.keionline.org/wp-content/uploads/Love-Sachs-HHS-Xtandi-Request-18Nov2021.pdf>

<sup>2</sup> The normal dose is 160 mg per day. The Redbook AWP was \$130 per 40 mg capsule in January 2022. A 2021 published price in Japan was 2,354 yen. At the current exchange rate of 115.22 Japanese Yen to the dollar, his would be \$20.41 per 40 mg capsule)

<sup>3</sup> “Executive Order on Promoting Competition in the American Economy,” The White House, July 9, 2021,

<https://www.whitehouse.gov/briefing-room/presidential-actions/2021/07/09/executive-order-on-promoting-competition-in-the-american-economy/>.

<sup>4</sup> “Comprehensive Plan for Addressing High Drug Prices: A Report in Response to the Executive Order on Competition in the American Economy,” ASPE, September 9, 2021, <https://aspe.hhs.gov/reports/comprehensive-plan-addressing-high-drug-prices>.

<sup>5</sup> “35 U.S. Code § 203 - March-in Rights,” LII / Legal Information Institute, n.d., <https://www.law.cornell.edu/uscode/text/35/203>.

billion so far. It is unacceptable that the U.S. government continues to stand by while Astellas price-gouges Americans on a drug that was funded by their own taxpayer dollars.

The petitioners have asked HHS to hold a public hearing on their request, where arguments for or against the use of the march-in or government use right can be aired. This is an extremely important case, dealing with a long-neglected public interest safeguard in the Bayh-Dole Act, and such a hearing would help clarify the issues and ensure procedural fairness to the petitioners, not to mention those who will be or are already receiving this expensive treatment.

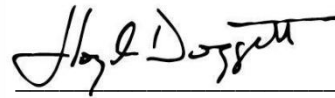
Prostate cancer is the most common cancer among American men. This year, nearly 250,000 American men will be diagnosed with prostate cancer.<sup>6</sup>

We urge HHS to use march-in or government use rights to curtail the unreasonable price of the prostate cancer drug Xtandi, and to ensure the public hearing requested by petitioners is held in a timely manner as it is essential to fully understanding the need to rein in the cost of this medication.

Sincerely,



Peter A. DeFazio  
Member of Congress



Lloyd Doggett  
Member of Congress



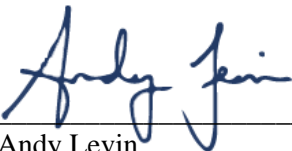
Mark Takano  
Member of Congress



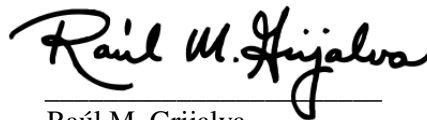
Katie Porter  
Member of Congress



Rosa DeLauro  
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Andy Levin  
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Raúl M. Grijalva  
Member of Congress



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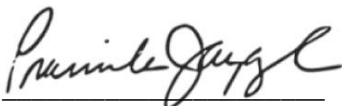
Marcy Kaptur  
Member of Congress



Mark DeSaulnier  
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Al Green  
Member of Congress



Pramila Jayapal  
Member of Congress

<sup>6</sup> Siegel, RL, Miller, KD, Fuchs, H, Jemal, A. Cancer Statistics, 2021. *CA Cancer J Clin.* 2021; 71: 7- 33. <https://doi.org/10.3322/caac.21654>