

The Honorable Joseph R. Biden  
The White House  
1600 Pennsylvania Ave.  
Washington, DC 20500

October 6, 2022

Dear President Biden,

We write to strongly encourage you to use your executive authority to lower the price of the prostate cancer medicine enzalutamide (brand-name Xtandi) by directing your administration to initiate march-in proceedings, as requested in the petition filed by prostate cancer patients Robert Sachs and Clare Love on November 18, 2021, and later joined by Eric Sawyer. The Xtandi march-in petition has now been pending before the Department of Health and Human Services (HHS) for 10 months, even though the National Institutes of Health (NIH) informed petitioners its review would be concluded by early February.

Enzalutamide is a prostate cancer medicine invented at UCLA with U.S. government funding through grants provided by the NIH and the U.S. Army. Because enzalutamide was invented under a U.S. taxpayer-funded grant, the U.S. government has the right to march-in when it is not being made available on reasonable terms or when the patentholder is not reasonably satisfying public health and safety needs.

According to Knowledge Ecology International, the Average Wholesale Price of Xtandi in the United States is six times the price of Xtandi in Japan.<sup>1</sup> Over the course of a year of receiving treatment, this pricing differential amounts to more than \$150,000. This price gouging is disproportionately borne by Black men and their families; prostate cancer has the widest racial disparity of any cancer, with Black men in the United States having two times the prostate cancer mortality and 60% greater incidence than White men.<sup>2</sup>

The Bayh-Dole Act plainly states that failure to make a subject invention available under reasonable terms is a ground for march-in, and authorizing price-cutting generic competition.<sup>3</sup> Charging U.S.

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<sup>1</sup> 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-PfizerContract-3Feb2022.pdf>

<sup>2</sup> Chowdhury-Paulino, I.M., Ericsson, C., Vince Jr., R. et al. Racial disparities in prostate cancer among black men: epidemiology and outcomes. *Prostate Cancer Prostatic Dis* 25, 397–402 (2022). <https://doi.org/10.1038/s41391-021-00451-z>

<sup>3</sup> Note: As dozens of academic experts on intellectual property, drug pricing and public health noted in a letter earlier this year, “Based on the plain text of the statute, excessive pricing alone should provide sufficient grounds for exercising march-in rights. [...] Price is a crucially important element of the terms of a transaction, and providing goods or services only at excessive prices *is* offering only unreasonable terms.” See <https://www.warren.senate.gov/imo/media/doc/2022.4.20%20Letter%20to%20Warren%20on%20Drug%20Pricing%20Executive%20Authorities.pdf>

taxpayers who paid for the invention of enzalutamide multiples more than people in other high-income countries is far from reasonable.

Your administration will set a precedent regardless of how this case is resolved. If your administration rejects the petition, the practice of charging U.S. residents far more for drugs invented on a government grant will be condoned, and effectively encouraged. To the extent that your administration is still evaluating its position relative to reasonable pricing standards, it is possible to issue a decision in this case that makes the following distinctions: (1) that the decision is based upon the drug having been on the market for several years and having realized enormous revenue, (2) that the price disparities are particularly aggressive, (3) that the drug has a large fiscal impact on federal programs including but not limited to Medicare and Medicaid, and (4) that there is evidence that the high price has led to restrictive formularies for the drug.

To the extent that Astellas has made what appear to be unsupportable assertions regarding their investments in the development of Xtandi, your Administration has the option of granting the petitioners their requested hearing to evaluate these claims and consider other factors that the cancer patients and the drug corporation present.

Our organizations are grateful for the historic progress your administration has achieved in reforming our broken drug pricing system. We look forward to supporting the successful implementation of the Inflation Reduction Act, which will provide Medicare beneficiaries access to some negotiated prices beginning in 2026. This legislation is only the beginning. Through using your existing congressionally authorized power to license generic competition with Xtandi, your administration can provide urgent relief to patients and send an unequivocal signal to pharmaceutical corporations that unfettered profiteering on drugs that American families paid to invent will no longer be tolerated.

Sincerely,

Action Center on Race and the Economy  
Arkansas Community Organizations  
Asian Pacific American Labor Alliance, AFL-CIO  
Center for Common Ground  
Center for Popular Democracy  
Citizen Action of NY  
Citizen Action of Wisconsin  
Doctors for America  
Down Home NC  
Empowering Pacific Islander Communities  
Families USA  
Health Care for All WV  
Health Care Is a Human Right WA  
Health Care Voices  
Health GAP (Global Access Project)  
Hometown Action  
Hoosier Action  
Indivisible  
Iowa Citizens for Community Improvement

Jane Addams Senior Caucus  
Keystone Progress  
Maine People's Alliance (MPA)  
Maine Service Employees Association of the  
Service Employees International Union Local  
1989  
Mainers for Accountable Leadership  
Metro New York Health Care for All  
Metropolitan Community Church of New York  
Michigan United  
Missouri Jobs with Justice Voter Action  
National Committee to Preserve Social Security  
and Medicare  
National Health Care for the Homeless Council  
New York Doctors Coalition  
North Carolina Justice Center  
North Carolina Medicare For All Coalition  
ONE Northside  
Oregonizers

Our Revolution  
People's Action  
Physicians for a National Health Program  
PrEP4ALL  
Progressive Maryland  
Public Citizen  
R2H Action [Right to Health]  
Revolving Door Project (RDP)  
Right Care Alliance  
Rights & Democracy  
Salud y Farmacos  
Social Security Works

T1International USA  
TakeAction Minnesota  
Taller Salud  
U.S. PIRG  
United Vision for Idaho  
Unity Fellowship of Christ Church-NYC  
Universities Allied for Essential Medicines  
VOCAL-NY  
Washington CAN  
West Virginia Citizen Action Group  
WV Citizen Action Group  
Yale Global Health Justice Partnership

Cc: The Honorable Xavier Becerra  
Secretary, Department of Health & Human Services

Lawrence A. Tabak, D.D.S., Ph.D  
Acting Director, NIH

Tara A. Schwetz, Ph.D.  
Acting Principal Deputy Director, NIH

The Honorable Gina Raimondo  
Secretary, Department of Commerce