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. 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.

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. Charging U.S.

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3Note: 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