U.S. PIRG

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November 18, 2022

The Honorable Xavier Becerra
Secretary
U.S. Department of Health and Human Services
200 Independence Ave SW,
Washington, DC 20201

Via Email: xavier.becerra@hhs.gov

Dear Secretary Becerra:

On behalf of U.S. PIRG and our state affiliates, we are writing to urge action on the request that HHS use the federal government rights in patents on the prostate drug enzalutamide, marketed by Astellas under the brand name Xtandi. It has been one year since four prostate cancer patients requested HHS to hold a hearing (November 18, 2021). We joined a letter in February (copied below) urging HHS to take action to bring this treatment to patients through "march-in" rights. Your department has yet to decide the case.

This delay has resulted in one more year of federal government programs, health plans and patients living with prostate cancer paying higher prices for this treatment than the rest of the world. We urge you to swiftly make a decision in favor of patients and utilize the power of the federal government under the Bayh-Dole Act to protect the public against "unreasonable use of inventions."

Thank you for your attention to the impact of high drug prices and your commitment to solve this issue.

Sincerely,

Patricia Kelmar
Health Care Campaigns Director

Attachment: February 23, 2022 Coalition Sign-on Letter

February 23, 2022

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

Dear Secretary Xavier Becerra:

We are writing to urge you to exercise the government's rights in patents on the prostate drug Xtandi, to authorize generic competition. The current price discrimination against U.S. residents and the exorbitant price of almost $190,000 per patient per year violates the obligation to make the benefits of Xtandi's patents "available to the public on reasonable terms."

Xtandi (generic name enzalutamide) was invented at UCLA on grants from the U.S. Army and the National Institutes of Health (NIH). Astellas, which markets Xtandi in the U.S. along with Pfizer, holds an exclusive license to use those patents worldwide. U.S. prostate cancer patients and private and government payers face staggering costs for the drug. In the first quarter of 2021, Xtandi cost Medicaid $149,460 per patient per year. In January of 2022, the U.S. average wholesale price per patient was $189,800 per year. In Japan, where Astellas is headquartered, the price is $30 thousand. For all high income countries besides the U.S. prices range from $30-$57 thousand. This is an extreme and unjustified price discrimination against U.S. residents, particularly when the drug was invented with U.S. taxpayers' dollars.

HHS has the authority to eliminate this price discrimination by telling Astellas that the U.S. government will use its march-in or government use rights in the Xtandi patents, unless the company agrees to sell the drug at prices that are reasonable. The petitioners in this case have proposed that the price ceiling be no higher than the median price charged in the seven countries with the largest GDP and at least half the per capita income of the United States. This is a very modest request considering the U.S. taxpayers have paid for the invention of the drug, which is the most risky element of drug development. We also note that cumulative Xtandi sales worldwide already exceed $20 billion, eliminating any possible concerns over the company making a sufficient profit.

It is our understanding that the persons living with prostate cancer who have petitioned the government to exercise its rights in Xtandi to authorize generic competition have requested a public hearing on their request, in order to facilitate a transparent debate between supporters and opponents of the requested use of the government's patent rights. The hearing that petitioners have requested would give Astellas and its partner Pfizer the opportunity to defend the decision to ask U.S. residents to pay $189,800 per year for this drug. The public should have the right to scrutinize any justification for the price discrimination against U.S. patients.
For 42 years, the United States has failed to use the Bayh-Dole Act march-in or government use rights to address abusive pricing of taxpayer-funded inventions. It is impossible to claim that in 42 years there have been no pricing abuses on federally-funded pharmaceutical inventions. Instead, it seems as though government officials have abused their responsibility to protect the public against "unreasonable use of inventions", contrary to the Policy and Objective of the Bayh-Dole Act. *See* 35 U.S.C. § 200.

Please advise us of the measures that HHS will take to protect the public from the outrageous and correctible

price discrimination against U.S. residents.

Sincerely,

The Undersigned

Organizations (alphabetically):

- The American Medical Student Association (AMSA)
- Center for Popular Democracy
- Consumer Action
- Democracy Collaborative
- Doctors for America
- Health Care Voices
- Health Care Voter
- I-MAK
- Indivisible
- Knowledge Ecology International (KEI)
- NETWORK Lobby for Catholic Social Justice
- Public Citizen
- R2H Action [Right to Health], USA
- Social Security Works
- UMMA Volunteer Project at UCLA
- U.S. PIRG (Public Interest Research Group)
- Universities Allied for Essentials Medicines (UAEM)

Individuals (alphabetically):

- Allen Black, Ph.D., J.D. Counsel, Petitioners for the March-In petition "In the case of Fabrazyme" ● Brook K. Baker, Professor, Northeastern U. School of Law; Honorary Research Fellow, University of KwaZulu Natal; Health GAP (Global Access Project) Senior Policy Analyst
- Cathy Hurwit
- Christopher J. Morten, PhD, JD, Associate Clinical Professor Law, Columbia Law School ● Dana Neascu, Lecturer, Columbia Law School
- Deborah S. Socolar, MPH
- Liza Vertinsky, Associate Professor, Emory University Law School
- Peter Arno, Economist, Senior Fellow and Director of Health Policy Research at the Political Economy Research Institute at the University of Massachusetts-Amherst
- Reshma Ramachandran, MD, MPP - Physician-Fellow, Yale National Clinician Scholars Program)

CC: Lawrence A. Tabak, DDS, PhD
Acting Director
National Institutes of Health