

President Joseph R. Biden
United States of America
%: Jeffery Zients
Assistant to the President and Chief of Staff
jeffrey.d.zients2@who.eop.gov

Cc:
Xavier Becerra
Secretary
Department of Health & Human Services
United States of America
Via: xavier.becerra@hhs.gov

Gina M. Raimondo
Secretary
Department of Commerce
United States of America
Via: thesec@doc.gov

May 2, 2023

Dear President Biden,

We are writing to express our support for the administrative appeal of a request for the Department of Health and Human Services (HHS) to use its rights in the federally-funded patented inventions for the prostate cancer drug enzalutamide (brand name Xtandi), in order to address a failure by the current licensed patent holders. Astellas and Pfizer have failed to make the drug “available to the public on reasonable terms.”

HHS received the petition from prostate cancer patients on November 18, 2021. The petition was filed with HHS following two years of inaction by the Department of Defense (DOD) on a similar petition. That DOD petition was originally filed during the Trump Administration, and subsequent to a Directive by the Senate Armed Services Committee that had instructed the DOD to approve such petitions when the price for a drug using a DOD-funded patented invention was more expensive in the U.S. than in the seven countries with the largest GDP and at least half the per capita income of the US.

The petition to HHS in 2021 focused on a single issue, the fact that Xtandi was far more expensive in the US than in any other high income country, despite the inventions being funded by the US Army and the National Institutes of Health (NIH). The petition was based on the requirement that licensees bring products to “practical application,” a term defined by the Bayh-Dole Act to include an obligation to make the benefits of inventions “available to the public on reasonable terms.” The cancer patients stated in their petition that a price 3 to 6 times higher in the US than in any other high income country did not satisfy the requirement of “available to the public on reasonable terms.” We agree with the cancer patients.

There are no compelling reasons to ignore the abusive pricing identified by the cancer patients' petition. Xtandi is a blockbuster drug for a common form of cancer. There is a simple regulatory pathway for generics, and there are already two generic products with tentative FDA approval. In January 2023, the Redbook AWP for Xtandi was \$136.50 per 40 mg capsule, which would cost \$199,270 for a full year of treatment. The April 2023 USA (Drugs.com) coupon price was \$119.86 per capsule, or \$174,992 per year. The 2021 average Medicare Part D price was \$112.28 per capsule or \$163,922 per year. The cancer patients provide extensive price comparisons from other high income countries, for example, they noted the price of Xtandi was \$21.64 per capsule in Japan, where Astellas is headquartered, or less than one fifth the Medicare Part D price and one sixth the Redbook AWP. The price in Australia was \$21.16 per capsule, and in Canada, \$21.13. US residents, including both cancer patients and everyone else who pays for drug reimbursements, are subject to highly objectionable discriminatory price gouging on a government-funded invention.

The NIH has in part justified their rejection of the Xtandi petition on the grounds that the Bayh-Dole march-in process will take too long to provide relief from the high prices. However, as noted both by the petitioners and in this March 28, 2023 *Harvard Bill of Health* blog, "How Soon Could President Biden Enable Generic Competition to Xtandi? Very Quickly, If There Is the Will," the federal government has sufficient rights in the Xtandi patents under 35 USC § 202(c)(4) and 28 USC § 1498(a) to enable generic competition right now. This gives the federal government enormous and unused leverage in this dispute, if the Biden Administration is willing to remedy the outrageous price discrimination against US residents by Astellas.

We note that HHS has also announced it will hold a government-wide review of Bayh-Dole march-in rights, with input from "stakeholders." We also ask that our groups be briefed on the plans for such a review as soon as possible, but urge that such a review must not delay any longer the resolution of the outstanding petition before HHS to address the unreasonable price discrimination described in the Xtandi petition, and that HHS reject the NIH practice of misquoting by omission the relevant parts of the Bayh-Dole Act that the petition relies upon, namely that "available to the public on reasonable terms" is the actual standard for practical application, and not merely "available to the public." The Administration has to decide the case on what the actual statutory obligation is for practical application of the invention, and in a way consistent with the policy and objective of the Bayh-Dole Act to "protect the public against nonuse or unreasonable use of invention," which in this case, involves "unreasonable use."

Sincerely,

Center for Medicare Advocacy
Center for Popular Democracy
Knowledge Ecology International
Public Citizen
U.S. PIRG
Union for Affordable Cancer Treatment
Universities Allied for Essential Medicines
West Virginia Citizen Action