November 18, 2022

Xavier Becerra
Secretary
Department of Health & Human Services
Washington, DC

Via Email: xavier.becerra@hhs.gov

Dear Secretary Becerra:

Today marks the one-year anniversary since the undersigned prostate cancer patients petitioned the Department of Health & Human Services (HHS) to grant march-in rights or exercise its royalty-free rights for patents on the prostate cancer drug enzalutamide (marketed as “Xtandi”).

More than 250,000 new cases of prostate cancer will have been diagnosed in the U.S. and more than 33,000 men will have died from the disease during these 12 months. And during this period, Medicare will have spent more than an estimated $2 billion to purchase Xtandi from Japanese drug maker Astellas.

Meanwhile, HHS has not taken any action on our petition despite assurances from the NIH on January 10, 2022 that the petition would be reviewed by the NIH Office of the Director, and “the review will likely require approximately a month.” It has been more than 10 months since Tara A. Schwetz, Ph.D., Acting Principal Deputy Director, NIH, provided these assurances. NIH has apparently not even decided whether to grant the evidentiary hearing petitioners sought based upon prima facie evidence showing that Astellas has discriminated against American prostate cancer patients and U.S. taxpayers.

As documented in our petition and supporting legal memorandum, the core issue that we seek to address is the fact that the Astellas prices for the federally funded Xtandi are three to six times more in the U.S. than in other high-income countries. Astellas has not offered any evidence that this is not true. This price discrimination against U.S. residents constitutes an appalling abuse.

Were Astellas to price Xtandi comparably in the U.S. to these other markets, Medicare would save at least $1.2 billion annually. The HHS’ failure to act also flies in the face of HHS’ September 2021 “Comprehensive Plan for Addressing High Drug Prices.” This states that HHS would give “due consideration” to march-in petitions, explaining that “the government may grant a license to use the intellectual property arising from government funding without the permission of the rights-holder” when the benefits of the patented product “are not available to the public on reasonable terms.” With Xtandi being sold to U.S. cancer patients at three to six times the price available in other wealthy countries, our petition presents clear and convincing evidence of a drug NOT being “made available to the public on reasonable terms.”

We applaud other efforts the Biden Administration has taken to reduce excessive drug prices, most notably the price-lowering provisions contained in the Inflation Reduction Act of 2022 (IRA). Unfortunately, these measures will not reduce the excessive and unreasonable Astellas prices for Xtandi in the U.S. market.

We note that in January 2022, the Redbook Average Wholesale Price (AWP) price of Xtandi was $130 per 40 mg capsule/tab. For a standard dose of 160 mg/day, this comes to $520 per day, or $189,800 for a 365-day year, for a government funded invention that treats one of the three most common types of cancer.

Beginning in 2026, the IRA requires the government to negotiate prices for a handful of drugs with the highest federal spending covered by Medicare Part D. Because Xtandi patents will expire in 2027, HHS is unlikely to select Xtandi, even if it otherwise qualified. Meanwhile, U.S. residents, as patients, employers, and taxpayers, will pay the exorbitant and discriminatory price for Xtandi, until at least 2027.

The IRA requires drug makers to pay a rebate to the federal government if the price for a drug covered by Part D exceeds the rate of inflation (CPI-U). Astellas will still be able to raise the cost of Xtandi by more than $14,000 in 2023 alone, creating an even further disparity between the U.S. and other countries. To put this into perspective, a 7.7 percent increase in the price of AWP price for Xtandi in the U.S. would be an increase of $10.01, per capsule in just one year. The current price of the same capsule in Australia (in U.S. dollars at current exchange rates) is $21.16. If Astellas takes advantage of the 7.7 increase, the new AWP in the U.S. would be $140.01 per capsule, or more than 6.6 times the Australian price. The discrimination against U.S. residents is getting worse over time, and HHS, by refusing to act on our petition, just exacerbates the problem.

We have asked HHS to set a modest standard for a federally funded drug. The standard we have suggested is that the price should be no higher than the median price charged in other large high income countries.

As noted in our February 3 letter, Pfizer, a partner with Astellas in the U.S. market, recently entered a contract with the U.S. government to provide Paxlovid, a treatment for COVID-19, at the lowest price for a group of eight high-income countries (G7+Switzerland). In other words, Pfizer negotiated an even tougher most favored nations pricing clause, for a drug where the U.S. government did not fund the patented inventions.

HHS can clearly insist on limiting the U.S. price of Xtandi to the median price for other large high-income countries, particularly since the drug has already generated more than $10 billion in sales from Medicare alone based upon these unconscionable pricing disparities.

Some cancer patients and other consumers will benefit directly from the IRA's cap on out-of-pocket costs for Part D drug benefits. Beginning in 2024, the IRA effectively caps those costs at approximately $3,250 and in 2025 adds a hard cap on out-of-pocket spending of $2,000/year, indexed in future years. Although this will provide a lower cap on out-of-pocket costs for Medicare

Part D subscribers, it does nothing to address the fundamental issue of extreme price discrimination by Astellas. Regrettably, because of the HHS' inaction to enforce the safeguards in the Bayh Dole Act, the cost of this practice will continue to be borne by U.S. taxpayers who already paid for the inventions and early development of Xtandi.

Unable to negotiate the price of Xtandi, Medicare will still face charges that are three to six times what Xtandi is sold for in other wealthy countries. Private insurers will be forced to pay whatever price Astellas chooses. As a consequence of the price discrimination, patients will face barriers to access when insurance companies use restrictive formularies and other measures to discourage the use of this extremely expensive drug, in favor of less effective alternatives.

The HHS' failure to grant a hearing, much less even consider the Xtandi petition, flies in the face of the Administration's laudable efforts to lower excessive drug prices and does a disservice to cancer patients like ourselves and other American taxpayers who must bear the cost of the HHS failure to ensure that government-funded drugs are made "available to the public on reasonable terms." After waiting a full year for HHS to even consider our petition, we respectfully ask you as Secretary of HHS, and one who has in the past advocated the use of march-in rights, to act on our petition without any further delay, or exercise HHS's royalty rights in the relevant patents, providing even more immediate relief.

Cancer does not wait, nor should cancer patients have to wait for years for their government to act.

Thank you.

Sincerely,

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cc: Lawrence Tabak, Acting Director, NIH
Tara A. Schwetz, Acting Principal Deputy Director, NIH