November 29, 2022

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

Via Email: xavier.becerra@hhs.gov

Dear Secretary Becerra:

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. The request to HHS, by four prostate cancer patients, was made on November 18, 2021. More than one year has passed, and HHS has yet to decide the case.

The central issue in the case is the fact that Astellas charges U.S. residents three to six times more for this drug than the company charges in any other high income country.

If there are members of the administration who are reluctant to set a standard for the pricing of drugs that use federally funded patented inventions, this case involves facts that should make this decision easy.

The drug, Xtandi, is for a common rather than a rare disease. Xtandi has already generated massive revenues, including more than $10 billion from the Medicare program alone. The US government funded each of the three patented inventions in the FDA Orange Book. The pricing disparities are enormous.

If a product meets each of these standards, (1) the product is for a non rare disease (2) the product has already generated very large revenues (3) the government funded all of the patented inventions and (4) the pricing disparities are enormous, then the federal government should state it will use its rights to remedy the pricing abuse. This is a modest but important step toward addressing the excessive pricing of drugs that can be taken now.

In Australia, Xtandi costs less than $31 thousand per year. The 2021 price in Japan, where Astellas is headquartered, is less than $25 thousand a year at current exchange rates. The January 2022 Redbook Average Wholesale Price (AWP) for the U.S. was $189,800 per year.

If the Administration rejects the Xtandi petition, it sets a precedent on pricing, that the Biden Administration will permit a company to charge exorbitant prices, even when the drug is invented on a government grant, and is subject to a statute that requires products to be made “available to the public on reasonable terms.” (35 USC 201.f)

A rejection of the petition will encourage more aggressive pricing of drugs.

HHS needs to bring this case to a conclusion, either by deciding now, based upon the evidence before it, that the use of federal government's rights in the patent are warranted, or at the very least, granting a public hearing on the petition.

signed

(in alphabetical order).

1. ACA Consumer Advocacy
2. Arkansas Community Organizations
3. Beta Cell Foundation
4. Church World Service,
5. Health Care Voices
6. Just Care USA
7. Knowledge Ecology International
8. People's Action
9. Physicians for a National Health Program
10. Progressive Maryland
11. Public Citizen
12. R2H Action [Right to Health], USA
13. Salud y Farmacos
14. Social Security Works
15. T1International USA
16. Tennessee Health Care Campaign
17. The Diabetes Link at Yale
18. Union for Affordable Cancer Treatment
19. Unity Fellowship of Christ Church- NYC VOCAL-NY