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The Honorable Xavier Becerra
Secretary, Department of Health & Human Services
Via Email: xavier.becerra@hhs.gov

Cc: Tara A. Schwetz, Ph.D.
Acting Principal Deputy Director, NIH
Via: NIHExecSec@nih.gov

January 19, 2022

Dear Secretary Becerra,

Public Citizen is a nonprofit organization with more than 500,000 members and supporters. Throughout its 50-year history, Public Citizen has advocated on behalf of consumers to advance public health through research, litigation, lobbying, and organizing. Our Access to Medicines program works to advance global access and lower drug prices in the United States to put an end to treatment rationing and prescription drug corporation price gouging.

We write you today to strongly encourage you to move forward with the march-in request on enzalutamide (brand name Xtandi) submitted on November 18, 2021, by Robert Sachs and Clare Love, later joined by Eric Sawyer. As a first step, without delay, the Administration should hold a hearing at which supporters of the petition as well as patentholders can present evidence. We also request that an impartial decision maker at HHS adjudicates this request.

Enzalutamide is a prostate cancer medicine invented at UCLA with U.S. government funding through grants provided by the National Institutes of Health and the U.S. Army. As a result of inventions embodied in enzalutamide having been discovered through these grants, the U.S. government has retained certain rights, including the right to march-in when these underlying inventions are not being made available on reasonable terms or to meet public health needs.

Astellas prices Xtandi in the United States three-to-five times higher as in other wealthy countries. The march-in statute and related definitions in the Bayh-Dole Act read very plainly that failure to make a subject invention available under reasonable terms is a ground for march-in, and authorizing price-cutting generic competition. It would strain credulity to suggest that charging triple price to consumers who paid for the invention of enzalutamide – namely U.S. taxpayers – is reasonable.

According to Knowledge Ecology International, in the United States, a required four-pill daily course of Xtandi would cost $427 per day and $156,000 per year, while a Canadian manufacturer has offered to sell a generic version of enzalutamide to the U.S. government for $3 per pill, less than 3% of the Astellas U.S. price. Exorbitant medicines prices can lead to extreme financial hardship and treatment rationing for patients and place an undue burden on public and private health program spending. As Universities Allied for Essential Medicines, which also supports the enzalutamide march-in petition, has noted, in the United States, Black men have twice the prostate cancer mortality as White men and 60% greater

incidence.[1,2] Consequently, failure of the Biden administration to accede to the petitioners' request would exacerbate racial disparities in health outcomes.

President Biden came into office promising to deliver on pocketbook issues that affect families across the country. Through marching-in and facilitating generic competition on enzalutamide, the Biden-Harris Administration has an opportunity to provide meaningful relief to Americans who are suffering as a result of Astellas' Xtandi pricing, but the implications would reach even further. Drug corporations considering abusing American taxpayers in similar fashion would be put on notice, chilling future price gouging on medicines invented under U.S. government grants, saving billions of dollars, and potentially many lives. Please move forward with this request with all due haste.

Sincerely,

Peter Maybarduk

Director, Access to Medicines Program, Public Citizen

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1 https://d3n8a8pro7vhmx.cloudfront.net/uaem/pages/1262/attachments/original/1642176700/Xtandi_Xavier_Becerra_Letter_2022_.pdf?1642176700

2 https://www.nature.com/articles/s41391-021-00451-z