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 14th, 2022

Dear Secretary Becerra,

Universities Allied for Essential Medicines (UAEM) is a global network of university students who believe that our universities have a responsibility to improve global access to public health and life-saving medicines. We write with the intention of joining the petitions before the Department of Health and Human Services (HHS) to grant march-in rights on patents on the prostate cancer drug Xtandi (enzalutamide). We also ask that HHS urgently hold a public hearing to provide the supporters and the opponents of using the march-in authority an opportunity to present evidence in support of their positions.

In 2016, UAEM was among the organizations that petitioned the National Institutes of Health (NIH) to grant a march-in request for Xtandi on the grounds that the price in the United States was excessive and discriminatory. U.S. residents were being charged the highest prices in the world, by far, for a prostate cancer drug invented at the University of California, Los Angeles (UCLA) on grants from the United States Army and the NIH. The NIH rejected the 2016 case, on the grounds that Astellas only had to make the product “available to the public,” and the NIH would not enforce the requirement that the benefits of the inventions be made available “to the public on reasonable terms.”

When UCLA students learned that their own public institution was also complicit in preventing access to this life-saving medicine, they organized. Outraged that the exorbitant price of Xtandi, developed on their campus, would not be accessible domestically or globally to some of those who would need it most, they pressured the university to introduce new socially responsible licensing and won. The university introduced new guidelines for ensuring access to all new medicines, but these guidelines were not applied retrospectively to Xtandi, the drug that mobilized UCLA students in the first place.

Prostate cancer has the widest racial disparities of any cancer. In the U.S., Black men have twice the prostate cancer mortality and 60% greater incidence than White men1. If the HHS were to decide not to grant march-in rights on Xtandi, this decision would disproportionately impact the health of Black men in the U.S., further exacerbating disparities in health outcomes. Some reforms to control drug pricing will require hard legislative action. This is not necessary in this

1 https://www.nature.com/articles/s41391-021-00451-z
The government must act now for a case in which the pricing abuses are obvious. It is not reasonable to charge a prostate cancer patient $157,000 per year to treat a common form of cancer, when no other high-income country pays anything remotely as high. The public clearly wants the government to act now to deal with the problem of high drug prices. -The May 2021 KFF Health Tracking Poll found about two-thirds of adults say there is “not as much regulation as there should be” when it comes to limiting the price of prescription drugs.

Now is the time to take action. Due consideration in this case means publicly acknowledging whether a company, located in Japan, can charge U.S. residents 3 to 5 times more for a cancer drug invented at UCLA with federal grants. It is also the case that a rejection of this petition will encourage corporations to steeply raise prices even more at the expense of people’s lives. After the NIH denied the 2016 March-In Rights request for Xtandi put forward by our organization and others, Pfizer and Astellas did just this. From 2015 to 2019, the average price of a 40 mg capsule of Xtandi to the U.S. Medicare program increased from $73.94 to $97.81, an increase of more than 32 percent.

Request to join outstanding petitions

On November 18, 2021, Robert Sachs and Clare Love petitioned the Secretary of Health and Human Services (HHS), Xavier Becerra, requesting that HHS grant march-in rights for the patents on Xtandi. Eric Sawyer requested to join the petition on December 13, 2021. UAEM requests to join the outstanding petitions of Robert Sachs, Clare Love, and Eric Sawyer that are currently before HHS. UAEM is aware of their requests for an administrative hearing on the Xtandi petition, and we urgently support that request as well.

If UAEM students, as America’s future doctors, lawyers, and leaders, have been advocating that their own institution UCLA must be a better stewards of public funds, so must HHS. This is not only a matter of equity but a pressing concern of racial justice.

Sincerely,

Merith Basey
Executive Director, MSc
Universities Allied for Essential Medicines, North America

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3 [Data from the HHS/CMS/ Medicare Part B dashboard]