THE SECRETARY OF HEALTH AND HUMAN SERVICES
WASHINGTON, D.C. 20201

February 5, 2024

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Dear Mr. Sachs, Mr. Love, and Mr. Sawyer:

I received your request to the Department of Health and Human Services (HHS) appealing the National Institutes of Health (NIH) decision on the November 2021 petition regarding the use of march-in authority for Xtandi® (enzalutamide).

I assure you that HHS and the Biden-Harris Administration remain steadfastly committed to increasing all Americans' access to health care and lowering costs for lifesaving treatments and cures. In support of President Biden's Executive Order on Lowering Prescription Drug Costs for Americans, HHS is pursuing a whole-of-government approach to build on this Administration's priorities.

We know more must be done as too many Americans, particularly the uninsured, find these therapies to be out of reach. March-in authority is indeed a powerful tool designed to ensure that the benefits of the American taxpayer's investment in research and development are reasonably accessible to the public. In March 2023, NIH declined your petition to initiate a march-in proceeding for the prostate cancer drug Xtandi. In the case of Xtandi, NIH thoroughly reviewed your petition in a manner consistent with the policy and objectives of the Bayh-Dole Act, including an assessment of the relevant intellectual property and applicability of the four

statutory criteria.[1] NIH's analyses found Xtandi to be widely available to the public on the market. In addition, given the remaining patent life and the lengthy administrative process involved for a march-in proceeding, NIH does not believe that use of the march-in authority would be an effective means of lowering the price of the drug. For these reasons, NIH determined[2] that initiation of a march-in proceeding is not warranted in this case and HHS concurs with this decision. This decision is consistent with NIH's determination in 2016 in which Knowledge Ecology International and the Union for Affordable Cancer Treatment requested NIH and the Department of Defense initiate march-in proceedings based on the price of Xtandi, but both declined.

We recognize, however, that there is a need to evaluate how pricing may be a contributing factor when weighing the use of the march-in authority and have committed to working with the Department of Commerce to review the use of march-in authority as laid out in the Bayh-Dole Act. Through this partnership, the National Institute of Standards and Technology (NIST) recently released a Request for Information (RFI) on the *Draft Interagency Guidance Framework for Considering the Exercise of March-In Rights*.[3] The information received in response to this RFI will inform NIST and the Interagency Working Group for Bayh-Dole (IAWGBD) in developing a final framework document that may be used by an agency when making a march-in decision.

Sincerely,

Xavier Becerra

[1] See statutory criteria in 35 U.S.C. §203 at https://www.govinfo.gov/content/pkg/USCODE-2011-title35/html/USCODE-2011-title35-partII-chap18-sec203.htm

[2] See NIH decision letter at: https://www.techtransfer.nih.gov/sites/default/files/documents/pdfs/NIH_Decision_Xtandi_March-In_Request(2023)

[3] See RFI at: https://www.federalregister.gov/documents/2023/12/08/2023-26930/request-for-information-regarding-the-draft-interagency-guidance-framework-for-considering-the