



March 21, 2023

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Dear Mr. Sachs and Mr. Love:

On November 18, 2021, Health and Human Services (HHS) Secretary Xavier Becerra, received your petition requesting the exercise of the march-in authority under the Bayh-Dole Act (35 USC §203) to lower the price of Xtandi (enzalutamide). Additional requests to join the petition were received in November and December from Eric Sawyer, Knowledge Ecology International (KEI), and Universities Allied for Essential Medicines (UAEM). HHS referred this petition to the National Institutes of Health (NIH).

NIH shares your concern about the high price of drugs and the burden it places on patients and their families, particularly the uninsured and the underinsured. Nearly one in four Americans struggle to afford prescription drugs. Understandably, members of the public are concerned that the prices they pay are higher than those in other high-income countries. President Biden's Executive Order 14036 "Promoting Competition in the American Economy,"¹ Executive Order 14087 "Lowering Prescription Drug Costs for Americans,"² and the HHS "Comprehensive Plan for Addressing High Drug Prices" ("the Plan")³ provide approaches to address the high cost of prescription drugs through implementation of one of the three guiding principles for drug pricing reform laid out in the Plan. One of them—"to foster scientific innovation to promote better health care and improve health"—falls within the mission of NIH to uncover new knowledge that

¹ www.whitehouse.gov/briefing-room/presidential-actions/2021/07/09/executive-order-on-promoting-competition-in-the-american-economy/ (July 9, 2021).

² <https://www.whitehouse.gov/briefing-room/presidential-actions/2022/10/14/executive-order-on-lowering-prescription-drug-costs-for-americans/> (October 14, 2022).

³ https://aspe.hhs.gov/sites/default/files/2021-09/Drug_Pricing_Plan_9-9-2021.pdf (September 9, 2021).

will lead to better health for everyone. With the support of the President and Congress, NIH-funded research has and will continue to lead to improved health outcomes.

The purpose of the Bayh-Dole Act is to promote the commercialization and public availability of government-funded inventions, 35 U.S.C. § 200, et seq., and the overarching framework of the Act is to allow government funding recipients to own patent rights and to encourage them to seek and commit to partnering with the private sector for commercialization of these technologies. Section 203 of the Act, governing march-in, outlines residual rights retained by the government. In the last 18 years, much analysis has been published and discussed at public meetings concerning the application of the march-in authority. Diverse views on the use of march-in have been explored by the Congressional Research Service⁴ and presented at a National Academies' workshop.⁵ The National Academies' Consensus Study Report from 2018, "Making Medicines Affordable," recommends a variety of governmental actions.⁶

NIH's analyses in response to the petition request have 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 has determined that initiation of a march-in proceeding is not warranted in this case. This decision is consistent with NIH's determination in 2016, in which KEI and the Union for Affordable Cancer Treatment requested NIH and the Department of Defense march-in based on the price of Xtandi, but each declined.^{7,8} In responding to the march-in request for Xtandi in 2016, NIH explained that, consistent with march-in determinations for Cell Pro (1997), Norvir (2004, 2013) and Xalatan (2004),⁹ practical application is evidenced by the "manufacture, practice, and operation" of the invention and the invention's "availability to and use by the public...." Astellas, the maker of Xtandi, estimates that more than 200,000 patients were treated with Xtandi from 2012 to 2021.¹⁰ Therefore, the patent owner, the University of California, does not fail the requirement for bringing Xtandi to practical application, as the drug is manufactured and on the market in the manner of other prescription drugs. NIH has reviewed the information submitted by the current petitioners, which is substantially the same as that submitted in 2016, and reached the conclusion that Xtandi is still widely available as a prescription drug.

NIH and HHS will pursue a whole of government approach informed by public input to ensure the use of march-in authority is consistent with the policy and objective of the Bayh-Dole Act,

⁴ March-in rights under the Bayh-Dole Act (2016) <https://sgp.fas.org/crs/misc/R44597.pdf> (2016)

⁵ The role of NIH in drug development innovation and its impact on patient access (2020) <https://www.nap.edu/read/25591/chapter/2> ,

⁶ <https://www.nap.edu/catalog/24946/making-medicines-affordable-a-national-imperative>

⁷ See Army March-In Response at https://www.keionline.org/wp-content/uploads/USArmy_Response_Xtandi_Request_5Aug2016.pdf

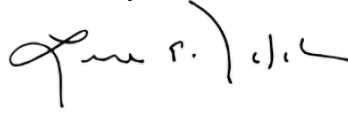
⁸ See NIH March-In Response at https://www.ott.nih.gov/sites/default/files/documents/policy/pdfs/Final_Response_Goldman_6.20.2016.pdf

⁹ See previous NIH March-In Responses at www.ott.nih.gov/policy/policies-reports

¹⁰ Estimate based on Astellas sales and use data September 2012 to June 2021. www.Xtandi.com

promotes commercialization of research results, maximizes the potential for HHS-funded technologies to become products, and serves the broader interest of the American public.

Sincerely,

A handwritten signature in black ink, appearing to read "Lawrence A. Tabak". The signature is fluid and cursive, with a large initial "L" and a distinct "A" and "T".

Lawrence A. Tabak, D.D.S., Ph.D.
Performing the Duties of the NIH Director

cc:

James Love, Director, Knowledge Ecology International
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Eric Sawyer, via his attorney Kathryn Ardizzone
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