

December 19, 2023  
Xavier Becerra  
Secretary  
Department of Health & Human Services  
Washington, D.C.  
Via email: [xavier.becerra@hhs.gov](mailto:xavier.becerra@hhs.gov)

Re: Appeal of NIH decision rejecting petition for HHS to exercise Federal rights in patents on Xtandi in order to address price discrimination against US cancer patients

Dear Secretary Becerra:

This letter is to renew the [March 23, 2021 appeal](#) to HHS of NIH's March 21, 2023 decision rejecting the November 18, 2021 petition submitted by the undersigned prostate cancer patients, Clare Love and Robert Sachs, later joined by prostate cancer patient Eric Sawyer (collectively, "cancer patients") and Universities Allied for Essential Medicines (UAEM). In renewing our appeal to HHS to review and reverse NIH's decision, we take note of the White House's recent announcement that the high price of taxpayer funded drugs is a factor to be considered in determining cases involving the exercise of Federal patent rights. A copy of our appeal is attached.

In it we point out that NIH took 16 months to issue a perfunctory decision ignoring the provision of the Bayh-Dole Act requiring US taxpayer funded inventions be made available to the public "on reasonable terms." (See [35 USC Sec. 203, and 35 USC Sec. 201\(f\)](#)), defining "practical application.") It's been an additional nine months since we filed our appeal and based upon Medicare's 2021 total spending for Xtandi, it has paid almost \$5 billion for the drug just since our petition was submitted in November 2021.

Since then, HHS has taken no action to address the excessive and discriminatory price at which Xtandi is sold in the US. In fact, NIH review and the current appeal process have now consumed more than two years—even though HHS had recognized in a report issued two months before we submitted our petition that "march-in" rights were a tool that could be used to address excessively priced taxpayer funded drugs. The September 9, 2021 [report](#), titled "Comprehensive Plan for Addressing High Drug Prices," states, "The federal government may grant a license to use the intellectual property arising from government funding without the permission of the rights-holder including when 'action is necessary to alleviate health and safety needs which are not reasonably satisfied' or when the benefits of the patented product are not 'available to the public on reasonable terms.'"

NIH justified its rejection of our petition on the grounds that Xtandi is "widely available as a prescription drug." This was never at issue but, more importantly, the Bayh-Dole Act does not set "availability" alone as a standard. Despite HHS's September 2021 guidance, then Acting NIH Director Lawrence Tabak refused to acknowledge that government-funded drug discoveries need to be made publicly available "on reasonable terms." Indeed, the last three words of the requirement— "on reasonable terms"—were totally ignored in NIH's March 21 decision, as if they had been excised from the Bayh-Dole Act. As we state in our appeal, "NIH's decision effectively declares that drug prices are irrelevant, and more specifically that price discrimination against US cancer patients is irrelevant."

A second reason NIH cited for rejecting our petition was that a march-in proceeding would be "lengthy" in view of the remaining patent life and therefore not be "an effective means of lowering the price of the drug." But as we explain in our appeal, "the 'clock has run' argument might have some weight if NIH had not totally ignored the government's parallel authority, cited by petitioners, to use its royalty-free rights in the patents under [35 USC Sec. 202\(c\)\(4\)](#), which gives the US government a "paid-up license to practice or have practiced for or on behalf of the United States any subject invention throughout the world."

If this acquisition authority is extended to Medicare and Medicaid, and a generic form of Xtandi is put on the Federal Supply Schedule (FSS), it would have a rapid impact on Xtandi's US price, saving the Federal government and American taxpayers billions of dollars during each of the next several years. Clearly, the potential exercise of the government's royalty-free rights gives HHS another powerful tool to address the excessive and discriminatory price of Xtandi paid by US prostate cancer patients.

Against this backdrop, the [White House](#) announced on December 7, 2023 "new actions to promote competition in health care and support lowering prescription drug costs for American families, including the release of a proposed framework for agencies on the exercise of march-in rights on taxpayer funded drugs and other inventions, which specifies that price can be a factor in considering whether a drug is accessible to the public."

In a short [video](#) released to You Tube the night before the announcement, President Biden declared, "Today we're taking a very important step toward ending price gouging so you don't have to pay more for the medicine you need."

During a press call before the announcement, National Economic Advisor Lael Brainard stated, "When drug companies won't sell taxpayer funded drugs at reasonable prices, we will be prepared to let other companies provide those drugs for less." Emphasizing this point she went on to say, "If American taxpayers paid to help invent a prescription drug, the drug companies should sell it to the American public for a reasonable price."

And domestic Policy Adviser Neera Tanden said, "For the first time, ever, the high price of that taxpayer-funded drug is a factor in determining that the drug is not accessible to the public on reasonable terms."

Cancer patients fully agree with these statements and fervently hope the White House's announced drug price control efforts do not result in dashed hopes about lowering excessive costs for potentially life-saving drugs. To this end, petitioners urge HHS to consider our appeal directly, and not assign NIH to review its own decision. (This is consistent with guidance contained in the proposed framework.) As explained in our appeal, NIH has a long track record "of dismissing requests to use the government's Bayh-Dole safeguard to address pricing abuses and access restrictions including the federal government's march-in rights under [35 USC Sec. 203](#), and the federal government's global royalty-free license under [35 USC Sec. 202\(c\)\(4\)](#)."

In contrast to the White House's and HHS' recognition that drug prices are a factor to be considered in reviewing such requests, NIH has totally ignored the Bayh-Dole Act requirement that taxpayer funded drugs be "made available to the public on reasonable terms." In the case of Xtandi, which has a Redbook average US wholesale price of \$189,900/year as of January 12, 2022, the excessive price of the drug should be a major factor in determining whether the Bayh-Dole "on reasonable terms" mandate has been met. To appreciate the arbitrariness of the US price for Xtandi, compare it with the situation in other highly developed markets, where Astellas sells Xtandi for one-sixth to one-third its US price. Had Astellas sold Xtandi in the US for even one third its price, Medicare alone would have saved more than \$3.3 billion over the two years since we filed our petition.

As President Biden declared, the "price gouging" of American consumers has to stop. In keeping with the President's and his top advisors' embrace of exercising government patent rights to control excessive drug prices, we respectfully ask you to rule expeditiously on our appeal and exercise HHS's authority to ensure Xtandi is made available to the public "on reasonable terms."

Sincerely,

Robert J Sachs

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[Petitioners March 23,2023 Appeal to HHS of NIH's March 21, 2023 Xtandi Decision](#)

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