

March 8, 2022

The Honorable Xavier Becerra  
Secretary  
U.S. Department of Health & Human Services  
200 Independence Avenue, S.W.  
Washington, D.C. 20201

Dear Secretary Becerra,

On behalf of millions of Americans across the country, we urge you to ignore calls and petitions asking you to deliberately twist the plain meaning of the bipartisan Bayh-Dole Act in ways that would decimate technological and medical progress.

As you know, Knowledge Ecology International has petitioned the federal government to invoke its "march-in" rights under the Bayh-Dole Act and relicense the patent rights on Xtandi, a prostate cancer drug developed and manufactured by Astellas, to generic drug companies on the theory they could produce cheaper knockoffs. Twelve members of Congress, led by Representatives Peter DeFazio (D-OR) and Lloyd Doggett (D-TX),<sup>1</sup> as well as Senators Elizabeth Warren (D-MA) and Angus King (I-ME),<sup>2</sup> have echoed that request.

The bipartisan Bayh-Dole Act was created to empower universities, small businesses, and non-profit institutions to license to the private sector for further development and potential commercialization the technologies and discoveries emanating from federal research grants. By spurring investment due to secure intellectual property rights to these inventions, the Act has been a catalyst for incredible innovation.<sup>3</sup>

One provision of the law allows the government to "march-in" and relicense patents that stemmed from federally funded research -- but only under certain very limited circumstances, such as when the licensed invention in question is not being commercialized or during national emergencies.<sup>4</sup>

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<sup>1</sup> <https://defazio.house.gov/sites/defazio.house.gov/files/DeFazio%20Letter%20to%20HHS%20Re%20Xtandi%20Petition.pdf>

<sup>2</sup> [https://www.warren.senate.gov/imo/media/doc/2022.02.17%20Letter%20to%20Sec.%20Becerra%20on%20Xtandi%20March-in%20Petition%20\(2\).pdf](https://www.warren.senate.gov/imo/media/doc/2022.02.17%20Letter%20to%20Sec.%20Becerra%20on%20Xtandi%20March-in%20Petition%20(2).pdf)

<sup>3</sup> <https://itif.org/publications/2019/03/04/bayh-dole-acts-vital-importance-us-life-sciences-innovation-system>

<sup>4</sup> <https://bayhdolecoalition.org/wp-content/uploads/2020/01/bayh-dole.pdf>

However, Representatives DeFazio and Doggett hinge the proposed march-in entirely on the cost of Xtandi.<sup>5</sup> Yet, the Bayh-Dole Act purposely omitted any mention of product price when it came to march-in rights.

Of the four statutory grounds that permit the use of march-in rights, not one establishes pricing as a legal application.<sup>6</sup> In fact, the coauthors of the Bayh-Dole Act, Senator Birch Bayh (D-IN) and Senator Robert Dole (R-KS), explicitly noted that they "did not intend that government set prices on resulting products. The law makes no reference to a reasonable price that should be dictated by the government. This omission was intentional."<sup>7</sup>

Further, both Democratic and Republican administrations for over 40 years have consistently declined to invoke Bayh-Dole's march-in to control prices. Representatives DeFazio and Doggett's proposal is just one of many deliberate misinterpretations seeking to control the cost of a drug. Not once has a federal agency found these proposals to be legally permissible.<sup>8</sup>

Beyond the dubious legality of KEI's and Representative DeFazio and Doggett's request, it is patently misguided. Using march-in rights to regulate prices would have a chilling effect on drug development and on other innovative sectors.

The private investments needed to commercialize inventive discoveries arising from federally funded research are massive -- far exceeding initial federal investments. In the case of Xtandi, the federal government funded about \$500,000 of initial, basic research. Astellas, by contrast, spent \$1.4 billion commercializing the drug.<sup>9</sup>

If the government can revoke firms' intellectual property rights outside of what the statute allows, private companies will never be able to raise the funding for the extensive research required to create new drugs and other technologies. Significant lines of scientific and technological innovation would grind to a halt. Far from getting a better price on products, American taxpayers would instead see their grant dollars wasted, as initial promising insights languish in labs without any private-sector partners willing to commercialize them—as was the case prior to Bayh-Dole.

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<sup>5</sup> <https://defazio.house.gov/sites/defazio.house.gov/files/DeFazio%20Letter%20to%20HHS%20Re%20Xtandi%20Petition.pdf>

<sup>6</sup> <https://www.law.cornell.edu/uscode/text/35/203>

<sup>7</sup> [https://www.washingtonpost.com/archive/opinions/2002/04/11/our-law-helps-patients-get-new-drugs-sooner/d814d22a-6e63-4f06-8da3-d9698552fa24/?itid=ik\\_inline\\_manual\\_11](https://www.washingtonpost.com/archive/opinions/2002/04/11/our-law-helps-patients-get-new-drugs-sooner/d814d22a-6e63-4f06-8da3-d9698552fa24/?itid=ik_inline_manual_11)

<sup>8</sup> <https://www.jdsupra.com/legalnews/changes-to-march-in-rights-under-bayh-1121759/>

<sup>9</sup> <https://newsroom.astellas.us/Astellas-Quote-and-Statement-on-the-Bayh-Dole-Act-and-XTANDI-February-9,-2022>

We encourage you to uphold the plain meaning and legal framework of the Bayh-Dole Act and turn aside this latest vain petition. Failure to do so would prove disastrous for American workers and consumers.

Respectfully,

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Market Institute

Seton Motley  
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\* Organization names appear for identification purposes only