

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/?tid=lk\\_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/?tid=lk_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,

James Edwards, Ph.D.  
Executive Director  
Conservatives for Property Rights

Seton Motley  
President  
Less Government

C. Preston Noell III  
President  
Tradition, Family, Property, Inc.

Saulius “Saul” Anuzis  
President  
60 Plus Association

Jeffrey Mazzella  
President  
Center for Individual Freedom

Ed Martin  
President  
Eagle Forum Education & Legal Defense Fund

Tom DeWeese  
President  
American Policy Center

Beverly McKittrick  
Director, Regulatory Action Center  
FreedomWorks Foundation

Ginevra Joyce-Myers  
Executive Director  
Center for Innovation and Free Enterprise

Charles Sauer  
President  
Market Institute

Kevin L. Kearns  
President  
U.S. Business & Industry Council

George Landrith  
President  
Frontiers of Freedom

Jim Martin  
Founder/Chairman  
60 Plus Association

Kent Kaiser, Ph.D.  
Executive Director  
Trade Alliance to Promote Prosperity

Ashley Baker  
Director of Public Policy  
The Committee for Justice

Gerard Scimeca  
Chairman  
Consumer Action for a Free Economy

Karen Kerrigan  
President & CEO  
Small Business & Entrepreneurship Council

Dee Stewart  
President  
Americans for a Balanced Budget

Tom Schatz  
President  
Council for Citizens Against Government Waste

Pete Sepp  
President  
National Taxpayers Union

Grover Norquist  
President  
Americans for Tax Reform

Ryan Ellis  
President  
Center for a Free Economy

Lisa B. Nelson  
President and CEO  
American Legislative Exchange Council

Daniel Schneider  
Executive Director  
American Conservative Union

Curt Levey  
President  
The Committee for Justice

Jessica Anderson  
Executive Director  
Heritage Action for America

David Williams  
President  
Taxpayers Protection Alliance

Joel M. Zinberg, M.D., J.D.  
Senior Fellow  
Competitive Enterprise Institute

Brent Wm. Gardner  
Chief Government Affairs Officer  
Americans for Prosperity

Michael Bowman  
President  
ALEC Action

Tom Giovanetti  
President  
Institute for Policy Innovation

\* Organization names appear for identification purposes only