March 17, 2022

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

Dear Secretary Becerra:

We are writing to urge the Department of Health and Human Services to once again reject the petition asking the federal government to grant march-in rights for the patents on Xtandi, a prostate cancer drug, because of its price.

Similar petitions were appropriately rejected several times in the Obama-Biden Administration for a simple reason: the Bayh-Dole Act does not sanction marching in because critics don't like the price of a successfully commercialized product that partially arose from a federally funded invention.

The purpose of the Bayh-Dole Act was not to create a mechanism for the federal government to set prices on successfully commercialized products. Rather, its explicit and well-understood purpose is to incentivize the commercialization of technologies developed from federally funded inventions. To that end, the law has been tremendously successful.

The public-private sector collaboration bolstered by the Bayh-Dole Act has facilitated the creation of more than 480,000 inventions and 15,000 start-ups, while supporting nearly six million new jobs.[1] Before Bayh-Dole, not a single new drug had been developed from NIH-funded inventions when the government took patent rights away from their creators.[2] Since its enactment, approximately 300 new drugs and vaccines are now protecting public health world-wide.[3]

To ensure that discoveries and technologies supported by federal research funding are made available to the public, the law empowered government agencies to "march-in" forcing the patent owner to issue additional licenses – but only under very limited circumstances.

As Senator Birch Bayh explained, march-in rights were primarily a response to the concern that, "some companies might want to license university technologies to suppress them because they could threaten existing products."[4] The law specifies four conditions in which march-in may be appropriate.[5] Controlling prices is not among them.

Appropriately, the NIH has previously rejected all petitions to march-in based on concerns about the price of commercially available products.[6] As the agency correctly and consistently concluded, using march-in rights to involve the NIH in drug pricing is a clear misapplication of the law.

[1] https://autm.net/AUTM/media/Surveys-Tools/Documents/AUTM_FY2018_Infographic.pdf
[2] https://aspe.hhs.gov/sites/default/files/2021-09/Drug_Pricing_Plan_9-9-2021.pdf, 22.
[3] https://autm.net/AUTM/media/SurveyReportsPDF/FY20-US-Licensing-Survey-FNL.pdf, 3.
[4] https://www.ott.nih.gov/sites/default/files/documents/2004NorvirMtg/2004NorvirMtg.pdf, 2.
[5] https://www.law.cornell.edu/uscode/text/35/203.
[6] https://nvlpubs.nist.gov/nistpubs/SpecialPublications/NIST.SP.1234.pdf, 29.

As the Department of Defense succinctly stated to previous petitioners when it joined HHS in rejecting their similar efforts:

> *Your letter and supporting material show that Xtandi® has achieved practical application as the DHHS and DOD understand that term. Your request does not disclose information suggesting that supplies of Xtandi® are running low or that health or safety needs are not being met by the manufacturer. In view of the above information, we decline to exercise the government's march-in authorities or utilize the government's license to the enzalutamide patents.*[7]

The law has not changed, nor have the facts of this case. Thus, the current petition should be similarly rejected.

The Bayh-Dole Act laid the groundwork for the unprecedented partnerships between your department and the private sector, including those that helped lead to the development of life-saving vaccines and therapies to fight COVID-19. Misusing the law as the critics are now urging in the pending march-in petition threatens these relationships, as the government would appropriately no longer be viewed as a trustworthy partner.

The Bayh-Dole Act's purpose was to translate federally funded scientific research into real-world products that make lives better here and around the world. By that measure, it has been incredibly effective. It was never intended as a means for the government to impose arbitrary price controls on resulting products, as the NIH has concluded time and again. As then NIH Director Elias Zerhouni noted in 2004 while rejecting the first march in petition seeking to impose price controls on a successfully commercialized product: "... the extraordinary remedy of march-in rights is not an appropriate means of controlling prices."[8] That was correct then and remains so today.

Thank you for your consideration.

Sincerely,

- **Joseph P. Allen**, Executive Director, Bayh-Dole Coalition
- **Katherine Bayh**, wife of the late Senator Birch Bayh
- **John Hamre, Ph.D.,** former Deputy Secretary, U.S. Department of Defense
- **Paul Michel, J.D.,** (retired), former Chief Judge, U.S. Court of Appeals for the Federal Circuit
- **Brian Darmody, J.D.**, CEO, Association of University Research Parks (AURP); former Associate Vice President of Research and Economic Development, University of Maryland, College Park
- **AUTM**
- **Licensing Executives Society (USA and Canada), Inc.**
- **Council on Governmental Relations (COGR)**
- **Magee-Womens Research Institute & Foundation**
- **Purdue Research Foundation**
- **Wisconsin Alumni Research Foundation**
- **Small Business & Entrepreneurship Council**

[7] https://www.keionline.org/wp-content/uploads/USArmy_Response_Xtandi_Request_5Aug2016.pdf
[8] http://www.essentialinventions.org/docs/usa-ritonavir/zerhouni29jul04.pdf, 5.

Bayh-Dole COALITION

Celebrating the past. Protecting the future.

- **Niels Reimers**, Founder and former Executive Director of the Office of Technology Licensing, Stanford University
- **Joy Goswami**, Assistant Director of Technology Transfer & Corporate Partnerships, University of Delaware; Board Director, AUTM
- **Kelly Sexton, Ph.D.**, Associate Vice President for Research and Innovation Partnerships, University of Michigan
- **Fred Reinhart**, Sr. Advisor for Technology Transfer, UMass Amherst; Past President, AUTM
- **Jon Soderstrom, Ph.D.**, former Managing Director of University Technology Commercialization and Faculty Innovation, Yale University; Past President, AUTM
- **John Preston**, former Director of Technology Development, Massachusetts Institute of Technology (MIT)
- **Vinit Nijhawan**, former Managing Director of the Office of Technology Development, Boston University
- **John Fraser**, Past President, AUTM
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- **Jane Muir**, Past President, AUTM
- **Arundeep Pradhan**, President, APIO Innovation Transfer; Past President, AUTM
- **Lori Pressman**, 2017 AUTM Bayh-Dole Award Recipient
- **Lou Berneman, EdD**, Founding Partner, emeritus, Osage University Partners
- **Lawrence Udell**, Founder and Chairman, Licensing Executives Society – Silicon Valley Chapter
- **Adam Mossoff, J.D.**, Professor of Law Antonin Scalia Law School, George Mason University; Board Member Center for Intellectual Property Understanding
- **Christopher M. Holman, Ph.D.**, Professor of Law, University of Missouri-Kansas City School of Law; Senior Scholar, Center for Intellectual Property x Innovation at the Antonin Scalia Law School, George Mason University
- **Erika Lietzan, J.D.**, William H. Pittman Professor of Law & Timothy J. Heinsz Professor of Law at the University of Missouri School of Law

- **The Information Technology and Innovation Foundation (ITIF)**
- **Alliance of US Startups and Inventors for Jobs**
- **Arizona Bioindustry Association, Inc. (AZBio)**
- **Biocom California**
- **BioCT**
- **BioFlorida**
- **BioForward Wisconsin**
- **BioHealth Innovation**
- **BioKansas**
- **BioNJ**
- **Biotechnology Innovation Organization (BIO)**
- **BioUtah**
- **California Life Sciences**
- **Delaware Bio**
- **Georgia Bio**
- **Illinois Biotechnology Innovation Organization (iBIO)**
- **Indiana Health Industry Forum**
- **K2 Biotechnology Ventures**
- **Life Sciences Pennsylvania**
- **Maryland Technology Council**
- **MassBio**
- **MichBio**
- **Montana BioScience Association**
- **New Mexico Biotechnology & Biomedical Association**
- **NewYorkBIO**
- **North Carolina Biosciences Organization (NCBIO)**
- **Oklahoma Bioscience Association (OKBio)**
- **Oregon Bioscience Association**

- **Kevin Noonan, Ph.D.,** Adjunct Professor, University of Illinois Chicago Law School; Founding Author, Patent Docs
- **Mickie A. Piatt, J.D.**, Associate Professor of Law and Co-Director of the Program in Intellectual Property Law, Chicago-Kent College of Law; Board Member, Center for Intellectual Property Understanding
- **Kristen Osenga, J.D.,** Austin E. Owen Research Scholar & Professor of Law, University of Richmond School of Law
- **Russell Somma, Ph.D.**, President and Pharmacist, SommaTech; former Director, Novartis
- **Mary Somma, MS,** Manager and Pharmacist, Johnson & Johnson
- **Gene Quinn, J.D.**, President & CEO, IPWatchdog, Inc.
- **Richard T. Miner, J.D.,** (retired), former V.P. and General Counsel, Momentum Technologies, Inc.

- **Pharmaceutical Research and Manufacturers of America (PhRMA)**
- **SCBIO**
- **South Dakota Biotech**
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- **Virginia Bio**
- **Conservatives for Property Rights**
- **Eagle Forum Education & Legal Defense Fund**
- **Taxpayers Protection Alliance**
- **U.S. Chamber of Commerce**
- **Center for a Free Economy**
- **ELITE Strategic Services, LLC**
- **ExploraMed Development, LLC**
- **Incubate Coalition**

cc:
Secretary Lloyd J. Austin III, Department of Defense
Acting Director Lawrence A. Tabak, National Institutes of Health