Congress of the United States
Washington, DC 20515

March 20, 2024

The Honorable Christi Grimm
Inspector General
U.S. Department of Health and Human Services
200 Independence Avenue, SW
Washington, D.C. 20201

Dear Ms. Grimm:

We write today to express our concern for the actions recently undertaken by the current Administration to enable the exercise of march-in authority as a tool for government price controls across a broad range of technologies catalyzed from government funded early-stage research. We share the objective of improving access to cutting edge innovation, including prescription drugs and next generation cures, and believe that any efforts to achieve this must be done without stifling innovation and hindering future medical discoveries. The proposed actions fail to take this approach. We implore the administration to analyze the unintended consequences such actions could have, especially as they relate to patient access to life-saving health care products and services. We urge you to investigate these actions and to hold this administration accountable for misinterpreting established law and precedent for political gain.

Specifically, on December 8, 2023, the National Institute for Standards and Technology issued a request for information on a *Draft Interagency Guidance Framework for Considering the Exercise of March-in Rights* intended to provide guidance to federal agencies on the factors to assess when considering whether to exercise march-in authority as provided under the Patent and Trademark Law Amendments Act (Pub. L. 96-517), also known as the Bayh-Dole Act. The Draft Framework ignores the intent of the law and decades of historical precedent across Democratic and Republican administrations by suggesting that federal agencies should consider the price of a product when evaluating the statutory criteria for march-in. The use of march-in authority as described in the request for information would have sweeping negative consequences for American leadership and innovation across industries.

Congress passed the Bayh-Dole Act in 1980, with strong bipartisan support, to incentivize the private sector to transform discoveries resulting from government funded early-stage research into useful products, such as life-saving cures. By allowing grant recipients, such as universities, to retain the title to the patents covering their inventions and to license the patents and the right to use those inventions to private sector partners for commercialization, the Bayh-Dole Act facilitates the development of products to benefit the greater public good.

Bayh-Dole is widely regarded as a tremendous success and one of the greatest legislative achievements over the past 60 years.[1] Prior to enactment of the Bayh-Dole Act, the government retained patents on federally funded inventions – and only 5% of those patents were ever licensed for use in the private sector. Following enactment, U.S. patents exploded, increasing from 390 patents in 1980, to 3,088 in 2009, to 6,680 in 2015.[2] The growth in public and private sector collaboration that followed has allowed many universities to set up or expand technology transfer offices to facilitate the commercialization of federally funded research. As a result of the innovation engine the Act created, from 1996 to 2020, Bayh-

[1] The Economist, Technology Quarterly, December 2002. Available at: https://www.economist.com/technology-quarterly/2002/12/14/innovations-golden-goose

[2] https://itif.org/publications/2023/08/18/maximizing-return-to-federally-funded-research-technology-transfer/

Dole is estimated to have contributed $1.9 trillion to the U.S. economy, created 6.5 million jobs, and helped to form 17,000 startups.[3] This framework is now emulated around the world.[4]

Though the Bayh-Dole Act includes a right for the federal government to "march-in" under a narrow set of circumstances, "march-in" was never intended to serve as a mechanism for regulating the pricing of products. Provisions in the Bayh-Dole Act provide the right for the government to "march in" under an intentionally narrow set of circumstances and force patent holders to grant a license to a "responsible applicant" able to utilize the technology to address an unmet need. The two most commonly examined criteria are: 1) where effective steps have not been taken, or are not expected to be taken, within a reasonable period to achieve "practical application" of the invention; or 2) the action is necessary to alleviate "health or safety needs not reasonably satisfied" by the patent holder or licensee.[5]

The intent of march-in rights was affirmed by the law's authors, Senators Birch Bayh and Bob Dole. In an OpEd to the Washington Post in 2002, the Senators stated the law "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." In fact, this "omission was intentional; the primary purpose of the act was to entice the private sector to seek public-private collaboration rather than focusing on its own proprietary research." Rather, the Senators note "the ability of the government to revoke a license granted under the act is not contingent on the pricing of a resulting product or tied to the profitability of a company that has commercialized a product that results in part from government-funded research. The law instructs the government to revoke such licenses only when the private industry collaborator has not successfully commercialized the investment as a product."[6]

Across multiple administrations, the National Institutes of Health (NIH) has expressly stated and confirmed "the extraordinary remedy of march-in is not an appropriate means of controlling prices." [7,8] As recently as 2020, NIH Director Francis Collins echoed the goal of march-in rights, when he stated "if a product is simply not available because somebody has locked it up, then the government has the right to step in."[9] Further, NIH has consistently indicated the "practical application" requirement is satisfied if a drug is widely available for purchase and use by the public. Indeed, in the nearly four decades since the law has been in place, NIH has rejected each of the seven march-in petitions based on pricing that have been submitted to the agency—including as recently as March 2023 by the current administration. In rejecting the march-in petition for the cancer medicine Xtandi, NIH acknowledged the medicine is "widely available to the public" and concluded the patent owner "does not fail the requirement for bringing Xtandi to practical applications, as the drug is manufactured and on the market in the manner of other prescription drugs."[10]

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[3] https://autm.net/AUTM/media/Surveys-Tools/Documents/AUTM-Infographic-22-for-uploading.pdf
[4] *National Innovation Policies: What Countries Do Best And How They Can Improve* 5, GLOBAL TRADE & INNOVATION POLICY ALLIANCE (June 2019)
[5] Patent and Trademark Law Amendments Act of 1980, 35 U.S.C. § 203 (a) (1)-(2)
[6] Birch Bayh, Bob Dole, "Our Law Helps Patents Get Drugs Sooner," Washington Post (April 11, 2002). https://www.washingtonpost.com/archive/opinions/2002/04/11/our-law-helps-patients-get-new-drugs-sooner/d814d22a-6e63-4f06-8da3-d9698552fa24/
[7] NIH, Office of the Director, In the Case of Norvir, Available at: https://www.techtransfer.nih.gov/sites/default/files/documents/policy/March-In-Norvir.pdf
[8] NIH, Office of the Director, In the Case of Norvir, Available at: https://www.techtransfer.nih.gov/sites/default/files/documents/policy/March-in-xalatan.pdf
[9] Tuzman, Karen Tkach. "Francis Collins' 2020 Vision for NIH." BioCentury, 2020, https://www.biocentury.com/article/304227/francis-collins-2020-vision-for-nih
[10] Letter from Dr. Lawrence A. Tabak to Mr. Robert Sachs and Mr. Clare Love, ("*Xtandi II*"), NAT'L INSTS. OF HEALTH, 2 (Mar. 21, 2023)

Just one year later, and with an election now on the horizon, the Biden Administration has suddenly changed course, departing from decades of bipartisan policymaking and precedent. In press statements surrounding the release of the Draft Framework, the White House has made apparent these actions are a distinct piece of a political agenda. White House Domestic Policy Advisor Neera Tanden clearly stated that "fundamentally, we are establishing that price can now be a factor in determining when the federal government can march in to ensure that we have lower prices."[11] In another interview, Tanden touted, "it is a really big change. And we're the first administration to do this" … "We see this as a highly impactful tool to drive down prescription drug costs" … "When Americans and the federal government invest in a drug, that brand has to be accessible to the public. And I think it's a very common-sense assessment to say if you can't afford it, it's not accessible."[12]

These statements not only undermine the underlying intent of Bayh-Dole, which has successfully increased access to innovation for everyday Americans and supported millions of jobs, but they also stand in stark contrast to NIH's statements just last year in its decision on Xtandi. Specifically, NIH concluded it did not believe march-in authority "would be an effective means of lowering the price of the drug."[13] This notion is validated by research showing the actual impact of reinterpreting march-in authority would have very limited impact on drug pricing. A recent analysis found that 92% of medicines approved by the FDA between 2011 and 2020 have no mechanism of action or composition of matter patent connected to a government interest statement or federally funded co-development program. In total, only 5 of these 361 FDA approved pharmaceutical products, or just 1%, could be subject to march-in rights. [14] Reinterpreting Bayh-Dole for political gain would have far reaching negative consequences.

Using march-in as a tool for price-setting would deter investment in any technology resulting from federally funded research. History has demonstrated that imposing "reasonable pricing" requirements in licensing arrangements discourages private sector research partners from entering technology transfer and licensing agreements. A 1989 policy imposing such requirements on Collaborative Research and Development Agreements (CRADAs) between private research partners and the NIH was revoked in 1995 following a decrease in executed CRADAs and several public meetings held with companies, patient advocates, and researchers. The initial fallout was so pronounced that then-NIH Director Harold Varmus stated: "the pricing clause has driven industry away from potentially beneficial scientific collaborations with [NIH] scientists without providing an offsetting benefit to the public … Eliminating the clause will promote research that can enhance the health of the American people."[15] Soon after revoking the policy, the number of CRADAs experienced a striking rebound.[16]

We are concerned the administration's recent actions will evoke a similar response, yet with an even starker and more consequential impact on innovation and patient access. It is nearly impossible to measure the detrimental impact on patients who benefit from federally funded health research if the

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[11] CNN, Biden administration takes more steps aimed at lowering health care costs, Dec. 7, 2023 https://www.cnn.com/2023/12/07/politics/biden-health-care-costs/index.html

[12] Fortune Well, March-in rights are key to Biden's push to lower excessive drug prices, Dec. 2023, https://fortune.com/well/2023/12/21/march-in-rights-biden-lower-excessive-drug-prices/

[13] NIH. (2023). Determination in the Case of Xtandi Manufactured by Astellas. Available at: https://www.techtransfer.nih.gov/sites/default/files/documents/pdfs/NIH_Decision_Xtandi_March-In_Request(2023).

[14] https://vitaltransformation.com/2023/11/march-in-rights-under-the-bayh-dole-act-nih-contributions-to-pharmaceutical-patents/

[15] NIH News, April 11, 1995. The then-director of the NIH summarized the result of their review of the policy, finding that "the pricing clause has driven industry away from potentially beneficial scientific collaborations with [Public Health Service] scientists without providing an offsetting benefit to the public." https://www.techtransfer.nih.gov/sites/default/files/documents/pdfs/NIH-Notice-Rescinding-Reasonable-Pricing-Clause.pdf

[16] NIH. (2001). NIH Response to the Conference Report Request for a Plan to Ensure Taxpayers' Interests are Protected. Available at: http://www.ott.nih.gov/sites/default/files/documents/policy/wydenrpt.pdf.

administration chooses to exercise march-in rights on the basis of price – contrary to long-standing NIH precedent to explicitly reject doing so. NIH is the largest single public funder of biomedical research in the world, and patients continue to benefit from the innovative cures, therapies, and medical products that result from this research and the partnerships the agency facilitates.[17] Because of NIH-funded research, Americans live longer, healthier lives, and many conditions that previously led to serious illness and death are now able to be treated and mitigated. Jeopardizing this strong ecosystem of innovation and public-private partnerships would take products out of the pipeline and off the market, risking patients' access to life-saving care.

It would be both inappropriate and detrimental to patient care for the Administration to unilaterally reinterpret the Bayh-Dole statute that has spurred innovation for decades. We reject any effort by this Administration to seek to score political points at the expense of Americans who benefit every day from the innovation that our free market supports and encourages. We ask that your office promptly investigate the motives and factual basis of the administration's desire to redefine the terms of Bayh-Dole, using price as justification for exercising march-in authority.

We greatly appreciate your attention to this matter. Future access to products generated from discoveries derived from taxpayer funded research is at stake.

Sincerely,

Neal P. Dunn, M.D.

Brett Guthrie

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[17] NIH, Direct Economic Contributions, https://www.nih.gov/about-nih/what-we-do/impact-nih-research/serving-society/direct-economic-contributions, last reviewed December 8, 2023.