AMERICANS for TAX REFORM

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February 6, 2024

The Honorable Gina Marie Raimondo
U.S. Secretary of Commerce
Washington, DC 20230

The Honorable Laurie E. Locascio
National Institute of Standards and Technology Director and Undersecretary of Commerce for Standards and Technology
Washington, DC 20230

Re: Request for Information Regarding the Draft Interagency Guidance Framework for Considering the Exercise of March-In Rights (NIST-2023-0008)

Dear Secretary Raimondo and Undersecretary Locascio,

On behalf of Americans for Tax Reform, we appreciate the opportunity to provide input regarding the draft interagency guidance framework for considering the exercises of march-in rights. **We urge you to withdraw this Draft Framework, as it violates the original intent of the Bayh-Dole Act and would threaten medical innovation.**

The *Patent and Trademark Law Amendments Act*[1], more commonly known as the Bayh-Dole Act, passed with bipartisan support in 1980.

Bayh-Dole allowed academic institutions and businesses to keep ownership of their IP to encourage medical innovation.

The law also included a provision allowing the federal government, if it funded the research, to "march-in" and relicense the institution's IP in very narrow circumstances. Ultimately, the law helped create the American pharmaceutical sector we know today, which dominates the world in innovation and has provided countless, life-saving and life-preserving cures and treatments.

The Bayh-Dole Act created narrow circumstances in which the government could exercise its march-in rights. The NIST's Draft Framework would violate these parameters.

Under 35 U.S. Code § 203[2], federal agencies have the right to "march in" under specific circumstances:

- action is necessary because the contractor/assignee "has not taken, or is not expected to take within a reasonable time, effective steps to achieve practical application" of the invention;
- action is necessary "to alleviate health or safety needs which are not reasonably satisfied by the contractor, assignee, or their licensees";
- "action is necessary to meet requirements for public use specified by Federal regulations and such requirements are not reasonably satisfied by the contractor, assignee, or licensees"; or

[1] **"35 U.S. Code Chapter 18 – PATENT RIGHTS IN INVENTIONS MADE WITH FEDERAL ASSISTANCE https://www.law.cornell.edu/uscode/text/35/part-II/chapter-18**
[2] **35 U.S. Code § 203 - March-in rights https://www.law.cornell.edu/uscode/text/35/203**

- action is necessary because the requirement that the invention be manufactured substantially in the United States was not obtained or waived.

Not only has the government never had to use march-in, but pricing has not, precedence-wise, been considered a factor that was covered under these listed circumstances.

Further, the creators of the law itself have explicitly said price should not be considered a factor in the government's ability to use its march-in rights.

In a Washington Post op-ed, penned by the sponsors of the Bayh-Dole Act, Former Senators Bob Dole and Birch Bayh, it was made clear that a "reasonable price" standard was *intentionally omitted* [3]:

> *"The law makes no reference to a reasonable price that should be dictated by the government. This omission was intentional; the primary purpose of the act was to entice the private sector to seek public-private research collaboration rather than focusing on its own proprietary research."*

Joseph P. Allen, the executive director of the Bayh-Dole Coalition and previous staff member of the U.S. Senate Judiciary Committee, helped draft the Bayh-Dole Act. In an op-ed entitled, "President Biden: Don't misuse Bayh-Dole march-in rights[4]," Allen says the following:

> *"While making health care more affordable is a laudable goal, it can't be done on the back of Bayh-Dole. That's not how the law works — and pretending it does would have disastrous consequences…*
>
> *Allowing the government to march in because someone believes the price a company charges for its therapy isn't "reasonable" — a completely undefined term — would be a devastating blow to the U.S. economy and the health of Americans."*

It is *explicitly* not the job of federal agencies to create law – they must only enforce laws written by Congress. The law does not give federal agencies the authority to factor in price as the reason to exercise march-in rights. In fact, pricing was intentionally omitted from the law to avoid such an abuse of power.

Further, the prices pharmaceutical companies set for drugs are largely established to recoup their initial, substantial investments. Oftentimes, the government's financing comes nowhere close to the amount privately invested in the creation of the drug. In this way, it would be radically unreasonable for price to be a sole standard for the use of march-in authority.

For example, previously, leftist special interest groups sent a letter[5] to HHS urging the agency to use march-in rights to lower the price of *six* different products/classes of drugs, including Xtandi, a prostate cancer medication. Additionally, progressive lawmakers, including Senators Elizabeth Warren (D-Mass.) and Angus King (I-Maine) and Representatives Peter DeFazio (D-Ore.) and Lloyd

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[3] Bayh, B., & Dole, B. (2002, April 11). Our law helps patients get new drugs sooner . https://www.washingtonpost.com/archive/opinions/2002/04/11/our-law-helps-patients-get-new-drugs-sooner/d814d22a-6e63-4f06-8da3-d9698552fa24/

[4] Allen, J. P. (2021, September 16). President Biden: Don't misuse bayh-dole march-in rights. STAT. https://www.statnews.com/2021/09/17/president-biden-dont-misuse-bayh-dole-march-in-rights/

[5] Petition to Make Meds Affordable (March 24, 2022) https://makemedsaffordable.org/wp-content/uploads/2022/03/Make-meds-affordable-petition-March-22-2022-1.pdf

Doggett (D-Texas), sent a letter[6] to HHS Secretary Xavier Becerra urging him to use the Bayh-Dole Act's "march-in" provision in order to manipulate the price of Xtandi. This drug has been a primary driver of calls for the NIST to draft a framework like the one they are considering now.

In the case of Xtandi, the federal government provided just $500,000 to fund research for its creation, while Astellas, a private company, then invested $1.4 billion in research and development expenses on the drug.

If this is the use of march-in authority we have to look forward to under this framework, all Americans should be deeply troubled.

Prior to Bayh-Dole, thousands of government-funded inventions were never put to use and not a single new drug funded with government support was developed.

The purpose of Bayh-Dole was to ensure consumers had access to new drugs sooner.

Before Bayh-Dole, the government took ownership over inventions that were supported by federal funding. However, this meant that tens of thousands of government-funded inventions were never put to use. By 1980, the U.S. government had accumulated 28,000 patents, fewer than 5 percent of which were commercially licensed.[7]

The U.S. government has already proven that, when it retains the patents on federally funded inventions, it does not have the resources nor competence to deliver those important cures and treatments to consumers.

This Draft Framework, by opening the door to such an arbitrary standard such as pricing, and therefore ensuring more patents will be seized by federal agencies, sets the U.S. on track to return to a time when Americans were barred access to important innovations.

The Draft Framework would threaten medical innovation.

Undermining IP protections will weaken manufacturers' incentives to innovate new cures and treatments and will reduce investment in medical innovation.

Developing new medicines is a costly, risky, and time-consuming process. Without IP protections, there is no guarantee that manufacturers will recoup the time and money they invested in the project. During an average drug development process, a manufacturer must invest an average of $2.6 billion[8] and spend 11.5 to 15 years in research and development.[9]

Even so, most drug development programs fail.

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[6] Brennan, Z. (2022, February 22). Democrats urge HHS to "march-in" or enable "government-use" rights to make xtandi less expensive. Endpoints News. https://endpts.com/democrats-urge-hhs-to-march-in-or-enable-government-use-rights-to-make-xtandi-less-expensive/

[7] Information on the Government's Right to Assert Ownership Control Over Federally Funded Inventions (July 27, 2009), Government Accountability Office (GAO). https://www.gao.gov/assets/gao-09-742.pdf

[8] Sullivan, Thomas. "A Tough Road: Cost to Develop One New Drug Is $2.6 Billion; Approval Rate for Drugs Entering Clinical Development Is Less than 12%." Policy & Medicine, 21 Mar. 2019, www.policymed.com/2014/12/a-tough-road-cost-to-develop-one-new-drug-is-26-billion-approval-rate-fordrugs-entering-clinical-de.html.

[9] Stephen J. Ezell, "The Bayh-Dole Act's Vital Importance to the U.S. Life-Sciences Innovation System" (ITIF, March 2019), 24–25, https://itif.org/publications/2019/03/04/bayh-dole-acts-vitalimportance-us-life-sciencesinnovation-system.

As detailed by Stephen Ezell of the Information Technology & Innovation Foundation (ITIF), for 5,000 to 10,000 compounds screened during basic drug discovery phases, 250 molecular compounds (2.5 to 5 percent) make it to preclinical testing. Of the 250 molecular compounds, five make it to clinical testing. Thus, as little as 0.05 percent of drugs make it from drug discovery to clinical trials.[10]

Of the few medicines that make it to clinical testing, only about 12 percent of medicines that begin clinical trials are approved for introduction by the FDA.[11]

Even if a drug is approved, it is likely that the profits from said drug will not recoup its R&D costs. One study in the Health Economics journal found that 80 percent of new drugs made less than their capitalized R&D costs.[12]

Certainly, drug development is a high-risk business. The last thing this industry and its investors need are more disincentives to innovate.

In healthcare, the consequences of a lack of medical innovation are a matter of life and death. Reduced investments mean less research into cures and/or treatments for cancer, Alzheimer's, heart disease, brain disorders, HIV/AIDS, and more.

If innovators can expect their property rights to be seized on the government's arbitrary determination of what the price *should* be, then this certainly would quell innovation. It would also harm the pharmaceutical industry, which supports millions[13] of high-paying jobs.

By allowing the government to seize IP rights for such arbitrary and subjective reasons, life-saving innovations would be stifled and the federal government would be operating outside of its authority under the law.

Americans for Tax Reform urges the National Institute of Standards and Technology to withdraw its draft interagency guidance framework which would direct federal agencies to consider the price of a product when evaluating its authority to exercise march-in rights.

Onward,

Grover Norquist
President, Americans for Tax Reform

Isabelle Morales
Federal Affairs Manager, Americans for Tax Reform

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10 Stephen J. Ezell, "Ensuring U.S. Biopharmaceutical Competitiveness" (ITIF, July 2020), https://itif.org/publications/2020/07/16/ensuring-us-biopharmaceutical-competitiveness.

[11] "Research and Development in the Pharmaceutical Industry." Congressional Budget Office, Apr. 2021, www.cbo.gov/publication/57126.

[12] Vernon JA, Golec JH, Dimasi JA. Drug development costs when financial risk is measured using the FamaFrench three-factor model. Health Econ. 2010 Aug;19(8):1002-5. doi: 10.1002/hec.1538. PMID: 19655335.

[13] "The Economic Impact of the U.S. Biopharmaceutical Industry: 2020 National and State Estimates." PhRMA, Mar. 2022, https://phrma.org/-/media/Project/PhRMA/PhRMA-Org/PhRMA-Org/PDF/0-9/2020-BiopharmaJobs-ImpactsMarch-2022-Release.pdf.