

February 2, 2024

The Honorable Joseph R. Biden
President of the United States
The White House
1600 Pennsylvania Avenue NW
Washington, DC 20500

Dear President Biden,

We write to express our concerns with the *Draft Interagency Guidance Framework for Considering the Exercise of March-In Rights* (Docket No.: 230831-0207), published by the National Institute of Standards and Technology (NIST) on December 8, 2023.

The authors¹ of this letter include former Secretaries of Commerce, former heads of the U.S. Patent and Trademark Office (USPTO), and former heads of the National Institute of Standards and Technology (NIST):

- Gary Locke served as the Secretary of the Department of Commerce under President Barack Obama from 2009-2011. He also served as the 21st governor of Washington from 1997 to 2005 and as U.S. Ambassador to China from 2011 to 2014.
- Carlos Gutierrez served as the Secretary of the Department of Commerce under President George W. Bush from 2005-2009.
- Andrei Iancu served as the Under Secretary of Commerce for Intellectual Property and Director of the USPTO under President Donald J. Trump from 2018-2021.
- David J. Kappos served as the Under Secretary of Commerce for Intellectual Property and Director of the USPTO under President Barack Obama from 2009-2013.
- Jon W. Dudas served as the Under Secretary of Commerce for Intellectual Property and Director of the USPTO under President George W. Bush from 2004-2009.
- Walter G. Copan, Ph.D., served as the Under Secretary of Commerce for Standards and Technology and Director of NIST under President Donald J. Trump from 2017-2021.
- Willie E. May, Ph.D., served as the Under Secretary of Commerce for Standards and Technology and Director of NIST under President Barack Obama from 2015-2017.
- Patrick D. Gallagher, Ph.D., served as the Under Secretary of Commerce for Standards and Technology and Director of NIST under President Barack Obama from 2009-2014. He also served as the Acting Deputy Secretary of Commerce from 2013-2014.

¹ The views expressed herein are personal to the signatories, and do not represent the views of firms, companies, institutions, clients, or any others with whom they may be affiliated.

- William A. Jeffrey, served as Director of the National Institute of Standards and Technology under President George W. Bush from 2005-2007.

As former leaders at the Commerce Department from Democratic and Republican administrations during the past two decades, our collective experience affords us important insight into both the policy and administrative implications of this proposal. We believe the adoption of the Draft Framework would destabilize our nation's entire technology transfer system which is central to U.S. innovation, and we thus implore you to withdraw the framework in its entirety.

Strong patent protections incentivize innovation and enable our economy to thrive. The Bayh-Dole Act proves this.

Before Bayh-Dole was enacted in 1980, the overwhelming majority of discoveries facilitated by federal funding were never turned into products that benefited the public. In fact, before 1980, fewer than 5% of federally owned patents were ever licensed for commercialization.² Today, approximately 60% of technologies arising from federal funding are licensed for commercial development.³

Thanks to Bayh-Dole – and the incentives it offers to universities, national laboratories, research institutes, and their licensees – thousands of federally funded inventions have made the transition from laboratory to marketplace.⁴ Since its enactment some 43 years ago, not once did the government exercise its march-in rights with respect to any of these federally funded inventions. The proposed framework reinterprets the statute and, for the first time, suggests multiple scenarios where the government could march in.

To understand the danger of reinterpreting Bayh-Dole, it is important to first understand why it was successful in the first place. At its core, the law reflected a central truth of the U.S. economy: the private, not public, sector drives most innovation.

Recognizing this, Senators Bayh and Dole intentionally designed the law to decentralize the management of patents on inventions backed by government funding. March-in rights were only envisioned in four extreme circumstances, all of which are clearly enumerated in the law's text. So limited are the circumstances that they have never been triggered despite thousands of inventions commercialized pursuant to the statute over the last four decades. This government restraint has empowered the private sector and energized the innovation economy.

Now, for the first time, the proposed framework identifies new criteria under which the government can exercise its march-in rights. They are all problematic.

² <https://itif.org/publications/2019/03/04/bayh-dole-acts-vital-importance-us-life-sciences-innovation-system/>

³ <https://autm.net/AUTM/media/Surveys-Tools/Documents/AUTM-Infographic-22-for-uploading.pdf>

⁴ <https://autm.net/surveys-and-tools/tech-transfer-infographic>

To start, the Draft Interagency Guidance Framework now asserts that a product's price is a legitimate trigger – a unilateral move that turns our technology transfer system on its head. Never before has any administration, of either party, believed it has the power to relicense patents based on the price of the commercially available products in question. In fact, the administrations of Presidents Bill Clinton, George W. Bush, Barack Obama, Donald Trump, and most recently, Joe Biden, in spring 2023, all rejected march-in petitions after concluding that they do not have this power.⁵

We served in virtually all of these administrations – and can confirm that it was well-accepted policy that price is not a trigger.

That price was *never* meant to be one of the triggers for march-in rights is not in doubt. In 2002, Senators Bayh and Dole – the original authors – made clear that this omission was purposeful.⁶ And earlier, in the late 1990s, Congress rejected amendments that would have added price as a fifth trigger. The repeated, failed attempts clearly demonstrate that even *proponents* of using march-in rights as price controls recognized that only Congress, not the executive branch, has the authority to amend the Bayh-Dole Act and add price as a trigger.

In addition to adding price as a trigger, the proposed framework also distorts the meaning and intent of the Bayh-Dole Act's second trigger, which allows federal agencies to march-in when "necessary to alleviate health or safety needs which are not reasonably satisfied by the contractor, assignee, or their licensees."⁷

Previously, the bar for whether something constituted a "health or safety need" was universally recognized to be extremely high. For instance, the government briefly considered invoking march-in rights on Cipro, an antibiotic capable of counteracting anthrax, in the aftermath of 9/11 and the ensuing anthrax scare, when the prospect of a terrorist attack using the deadly pathogen loomed large and necessitated building a stockpile of millions of doses quickly. However, the government was ultimately able to secure sufficient quantities of the drug without resorting to such an extraordinary measure.⁸

The new framework dramatically lowers that bar. One of the framework's hypothetical scenarios, for example, suggests that agencies could march-in on a vehicle communication technology that enables road crews to warn drivers of "icy or wet roads" ahead.⁹

⁵ <https://bayhdolecoalition.org/digital-library/>

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<https://www.washingtonpost.com/archive/opinions/2002/04/11/our-law-helps-patients-get-new-drugs-sooner/d814d22a-6e63-4f06-8da3-d9698552fa24/>

⁷ <https://www.govinfo.gov/content/pkg/USCODE-2011-title35/html/USCODE-2011-title35-partII-chap18.htm>

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<https://www.washingtonpost.com/archive/politics/2001/10/21/drug-firm-plays-defense-in-anthrax-scare/21e1bf4c-0070-4b00-bd66-459a9642f219/> and

<https://www.nytimes.com/2001/10/24/business/a-nation-challenged-cipro-us-says-bayer-will-cut-cost-of-its-anthrax-drug.html>

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<https://www.federalregister.gov/documents/2023/12/08/2023-26930/request-for-information-regarding-the-draft-interagency-guidance-framework-for-considering-the#:~:text=Scenario%207,satisfy%20industry%20demand.>

Reducing traffic accidents is a worthy objective, of course. But if the government can point to a potential marginal dip in accidents as a valid "health and safety" justification for overturning the patent licensing agreements relevant to a vehicle transponder, then virtually no product in any industry would be immune to march-in challenges.

Knowing that exclusive licensing agreements may not be upheld, although not knowing ahead of time which ones, private businesses will no longer take risks to invest and commercialize the products of federally funded research. The hard work of scientists in academic labs across the country will go to waste because of the chilling effect this increased uncertainty will create for startups and existing companies alike, as well as for public-private partnerships.

The administration's proposed framework essentially recentralizes the commercialization process, with government officials supervising, investigating, and judging university and research institute licensing agreements – *ex post facto*.

Importantly, this change also places a severe burden on federal agencies. They have neither the capacity nor depth of knowledge to successfully manage the nation's technology transfer system, with the potentially wide range of new march-in petitions, investigations, litigation actions, and appeals processes that could be spawned. Tasking federal agencies to manage technology transfer would invite disaster – for agencies, research institutions, private companies, and investors, and for the general public. The government needs to act with humility and restraint in the face of a massive innovation industry that has been advanced over the decades and is currently functioning well in service to the American people and economy.

The Bayh-Dole Act has produced breakthroughs in fields as diverse as energy, agriculture, information technology, aerospace, materials, transportation, and healthcare.¹⁰ The administration's proposed framework would jeopardize innovation in all these industries. Although it has been proposed that the government's exercise of march-in rights could permit an agency to break patents to lower drug prices, it will not actually achieve this alleged benefit. The Bayh-Dole Act applies only to "subject inventions," which represent a small fraction of the inventions related to FDA-approved pharmaceuticals.¹¹ Rather, the Draft Framework's implementation will create uncertainties that undermine U.S. technology investment, innovation, and entrepreneurship across all sectors, in the event any federal funding has been involved and contributed to licensed subject inventions.

The impact of the proposed framework is far-reaching and will touch virtually all industries. Indeed, the draft guidance states that "the framework is not meant to apply to just one type of technology or product or to subject inventions at a specific stage of development" – and goes on to envision exercising its march-in powers on products as

¹⁰ <https://autm.net/about-tech-transfer/advocacy/legislation/bayh-dole-act/bayh-dole-innovations>

¹¹ <https://pubmed.ncbi.nlm.nih.gov/31190582/>;

disparate as construction materials, wireless communication technologies, and water filters.¹²

Making this framework even more volatile is the fact that there are no restrictions on who may file a march-in petition. Previously, the clear and demanding conditions required to march in prevented the provision from being deployed as a weapon by competing businesses. However, if the trigger levels were drastically reduced, as the Draft Framework proposes, or if price were added to these triggers, new avenues of obstruction and commercial gamesmanship would open.

Large companies will be highly incented to file petitions against smaller ones, arguing that their greater manufacturing resources enable them to provide products at more "reasonable" prices than the innovator that originally shouldered the risk. Predatory actors or foreign companies could file petitions against U.S.-based competitors as a means to harass them, or to influence market valuations. Agencies would be obliged to consider such petitions. And universities, research institutes, and innovators will be required to spend precious resources fending them off – an investment of time, money, and hassle that will disincentivize corporations, investors, and entrepreneurs from entering into licensing agreements with federally funded research institutions in the first place.

We emphasize in the strongest possible terms: the proposed framework poses a major threat to America's prosperity. And it undermines numerous other initiatives by the Biden administration to improve America's economy.

The Tech Hubs program, for example, seeks to bolster innovative, job-creating startups,¹³ but the administration's proposed framework undermines small businesses and startups, which license 73% of university patents.¹⁴ The Cancer Moonshot program has increased public funding for oncology research,¹⁵ but the proposed framework discourages private drug companies from making use of it. The CHIPS and Science Act was designed to help America's semiconductor industry compete with China's,¹⁶ but this Draft Framework would discourage American companies from making certain uses of the funds provided under the Act. As a result, China will be afforded ample opportunities to develop the promising federally funded technologies that American entrepreneurs refuse to touch.

These initiatives – and many others put forward by President Biden – would be much better served by a firm recommitment to the original principles of the Bayh-Dole Act.

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<https://www.federalregister.gov/documents/2023/12/08/2023-26930/request-for-information-regarding-the-draft-interagency-guidance-framework-for-considering-the>

¹³ <https://www.eda.gov/funding/programs/regional-technology-and-innovation-hubs>

¹⁴ <https://autm.net/surveys-and-tools/tech-transfer-infographic>

¹⁵ <https://www.whitehouse.gov/cancermoonshot/>

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<https://www.whitehouse.gov/briefing-room/statements-releases/2022/08/09/fact-sheet-chips-and-science-act-will-lower-costs-create-jobs-strengthen-supply-chains-and-counter-china/>

The present Draft Framework would create a plethora of risks and uncertainties that will ultimately be damaging to U.S. innovation and industrial competitiveness.

We appreciate your attention to our concerns. We are prepared to assist the administration in any way possible as it seeks to address important intellectual property issues and ensure the future flourishing of America's innovation ecosystem.

At this time, however, we must ask that you withdraw the Draft Interagency Guidance Framework before its detrimental effects are felt across the U.S. economy, and issue a clear statement that the administration will not reinterpret the considerations for exercising march-in rights pursuant to the Bayh-Dole Act.

Sincerely,

Gary Locke, Secretary of Commerce (2009-2011)

Carlos Gutierrez, Secretary of Commerce (2005-2009)

Andrei Iancu, Under Secretary of Commerce for Intellectual Property and Director, U.S. Patent and Trademark Office (2018-2021)

David J. Kappos, Under Secretary of Commerce for Intellectual Property and Director, U.S. Patent and Trademark Office (2009-2013)

Jon W. Dudas, Under Secretary of Commerce for Intellectual Property and Director, U.S. Patent and Trademark Office (2004-2009)

Walter G. Copan, Under Secretary of Commerce for Standards and Technology and Director, National Institute of Standards and Technology (2017-2021)

Willie E. May, Under Secretary of Commerce for Standards and Technology and Director, National Institute of Standards and Technology (2015-2017)

Patrick D. Gallagher, Under Secretary of Commerce for Standards and Technology and Director, National Institute of Standards and Technology (2009-2014)

William A. Jeffrey, Director, National Institute of Standards and Technology (2005-2007)

cc:

The Honorable Gina M. Raimondo, Secretary of the Department of Commerce
The Honorable Laurie E. Locascio, Under Secretary of Commerce for Standards and Technology and Director of the National Institute of Standards and Technology
The Honorable Kathi Vidal, Under Secretary of Commerce for Intellectual Property and Director of the United States Patent and Trademark Office