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 authors[1] 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.

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[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]

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[5] https://bayhdolecoalition.org/digital-library/

[6] 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

[8] https://www.washingtonpost.com/archive/politics/2001/10/21/drug-firm-plays-defense-in-anthrax-scare/21e1bf4c-0070-4b00-bdb6-459a9642f219/ and https://www.nytimes.com/2001/10/24/business/a-nation-challenged-cipro-us-says-bayer-will-cut-cost-of-its-anthrax-drug.html

[9] 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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[12] 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/

[16] 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

February 1, 2024

Dr. Laurie E. Locascio
Under Secretary of Commerce for Standards and Technology
Director, National Institute for Standards and Technology

Re: Comments in response to NIST's *Request for Information Regarding the Draft Interagency Guidance Framework for Considering the Exercise of March-In Rights* (Federal Register/Vol. 88, No. 235/Dec. 8, 2023) ("Draft Guidance")

The Association of American Universities (AAU), Association of Public and Land-grant Universities (APLU), the Association of American Medical Colleges (AAMC), the American Council on Education (ACE), AUTM, and COGR write in response to the NIST Request for Information (RFI) on Regarding the Draft Interagency Guidance Framework for Considering the Exercise of March-In Rights (Docket No. 230831-0207). Our organizations and member institutions represent the majority of academic institutions and medical schools, including those with very high research activity, which act in partnership with the federal government to carry out research and science development activities to address national priorities, such as healthcare, agricultural sciences, and groundbreaking engineering. We appreciate the opportunity to provide comments on the proposed framework developed by the Interagency Working Group for Bayh-Dole (hereafter "the framework"), which we believe would alter well-established and successful practices around federally funded research, especially for research universities and academic medical centers.

In our full comments below, we emphasize the following major points:

- ***No changes to the Bayh-Dole Act are necessary.*** Bayh-Dole was established by statute over 40 years ago and has been successful in allowing for the development of important intellectual property and inventions arising from federally funded research, most of which happens at our member institutions. Because of this success, and the importance of allowing this work to continue, the statute should be considered to enshrine a set of core principles that must be protected.

- ***This framework increases uncertainty and ambiguity around the criteria for Bayh-Dole march-in consideration, which will have a detrimental and destabilizing effect on university and medical school technology transfer efforts and planning.*** This will result in disincentivizing private sector partners from licensing advancements made through federally funded research, which would have severe consequences for the technology transfer ecosystem and is contrary to Bayh-Dole's intent.

- ***Agency considerations on petitions for march-in should be based on the original intention of the Bayh-Dole Act, not a reinterpretation to achieve certain market goals.***

- ***We recommend a complete and timely rescission of this framework by the administration.***

Our associations appreciate the efforts of NIST and the Interagency Working Group for Bayh-Dole's (IAWGBD), and we stand ready to answer any questions regarding the issues and recommendations we raise in our response to this RFI. Please note that this joint letter represents the consensus

recommendations of the signatory associations and that each association may also submit separate letters with additional, association-specific considerations and recommendations.

Introduction

Together, AAU, APLU, AAMC, ACE, AUTM, and COGR represent all major U.S. research universities and medical schools – including their technology transfer offices – in the United States. Universities and related nonprofit research institutions conduct over half of the basic research in the United States, and approximately 55% of university research is federally funded.[1] Since passage of the Bayh-Dole Act of 1980, universities have increasingly licensed the fruits of their research to the private sector for commercialization. This academic institution technology transfer process provides a rich return on public and private funding for basic research, in the form of countless innovative products and processes that benefit the public, create jobs, and contribute to U.S. economic competitiveness and technological leadership internationally. The CT scan, MRI, FluMist and many other commonly used vaccines, GPS, bar codes, Doppler radar, web browsers, and the Internet are some of the best-known academic institution innovations.

The Bayh-Dole Act has been responsible for the creation and fostering of a robust technology transfer ecosystem in the U.S. and serves as a model internationally, having been adopted in similar fashion in more than sixteen countries, including Norway, the United Kingdom, Malaysia, Korea, the Philippines, Japan, Singapore, Denmark, Finland, and Brazil.

We appreciate NIST's intention to evaluate existing practices, policies, regulations, and/or laws that promote the transfer of federal technologies and their practical application through commercialization by the private sector. Our member institutions long have engaged in the transfer of federally funded technologies for commercialization. These activities have been remarkably successful. They create jobs, contribute to U.S. economic competitiveness and global technological leadership, improve public health, and strengthen national security.

To put this in perspective, in 2022 alone, the U.S. Patent and Trademark Office (USPTO) issued U.S. universities 7,739 patents. Additionally, American universities spun off 998 startup companies (most of which have their primary place of business in the home state of the licensing university) and generated 850 new commercial products.[2] The report, "The Economic Contribution of University/Nonprofit Inventions in the United States: 1996-2020," documents the sizable return that US taxpayers receive on their investment in federally funded research. It shows that, during a 25-year period, nonprofit patents, and the subsequent licensing to business bolstered US industry gross output by up to $1.9 trillion, US GDP by up to $1 trillion and supported up to 6.499 million jobs.[3] Academic institutions bear the responsibility to be good stewards of discoveries and intellectual property developed by federally funded research.

There are areas where improvements could be made to remove obstacles and impediments in the technology transfer ecosystem could be improved. Some involve public policies directly whereas others include promoting best practices within the licensing agreement lifecycles themselves. To this end, our

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[1] https://ncses.nsf.gov/pubs/nsf24307

[2] Association of University Technology Mangers, "2022 Licensing Survey," https://autm.net/AUTM/media/Surveys-Tools/Documents/AUTM-Infographic-22-for-uploading.pdf.

[3] Biotechnology Innovation Organization, "The Economic Contribution of University/Nonprofit Inventions in the United States: 1996-2015," available at https://www.bio.org/sites/default/files/files/BIO_2015_Update_of_I-O_Eco_Imp.pdf.

organizations have conducted research and convened working groups that have previously provided stakeholder advice and information to federal agencies, such as our community response to NIST Docket No. 18022019-819-01.

Responses to RFI Questions

1. After reading through the framework and example scenarios, if needed, how could the guidance about when an agency might want to exercise march-in and the factors that an agency might consider be made clearer?

While we appreciate NIST's intent to harmonize agency approaches to adjudications of petitions for march-in, we are deeply concerned this framework introduces significant uncertainty into the foundational principles of Bayh-Dole that will have a deep and lasting negative impact on the technology transfer ecosystem in the United States. This would have severe domestic and global consequences in both the short and long term for American economic competitiveness, especially in areas of emerging and critical technologies.

While the framework states that "nothing should be treated as a mandate that an agency exercise its march-in right and that...it provides a more comprehensive outline of the factors that an agency may weigh," (page 12) the framework includes guidance as follows:

> *Whether an action may be needed to meet the needs of the Government or protect the public against nonuse or unreasonable use of the subject invention may include consideration of factors that* ***unreasonably limit availability of the invention to the public, including the reasonableness of the price and other terms*** *at which the product is made available to end-users.* [emphasis added]

This guidance, and other mentions of reasonable price and other unspecified terms throughout the framework, is a marked departure from the underlying statutory and regulatory authority of the Bayh-Dole Act, the clear original statutory intent, as well as previous agency decisions on past march-in petitions. The addition of this factor for consideration introduces a significant amount of uncertainty and heightened risk into the incentives for private sector entities and their funders to license subject inventions for commercialization. Asking agencies to rely on this framework as guidance for their decision-making process creates an untenable expansion of factors that are beyond the scope of the statute, one that may effectively chill future partnerships between universities and the private sector due to the inability to mitigate the risk of being subject to a petition for march-in on the basis of 'reasonable price.'

The usage of 'reasonable pricing' in petitions for march-in has long been denied as a basis for which march-in rights can be exercised by a federal agency, despite several attempts to do so by various advocates. To now include 'reasonable pricing,' an undefined and inherently subjective term, in a framework for agency decision-making undermines the balance of the delicate mutualistic relationship amongst research institutions, start-ups licensing their nascent technologies, and venture capital that helps bring these technological advancements to society.

Additionally, the framework provides a roadmap for potential abuse and corporate gaming of the innovation system. Given that there is no requirement that entities have standing to file petitions for march-in, nor a penalty for the filing of petitions that are ultimately rejected, allowing reasonable pricing as a consideration factor for agencies may embolden corporate entities to file petitions in bad faith or to undercut competitors in commercialization efforts. As the framework states, agency decisions involving march-in are extremely fact-dependent and involve considerable efforts by agencies to investigate and

adjudicate petitions, as well as subjecting the contractor and licensee to an inquiry into both the provenance of the potential subject invention and research and development efforts, but also their commercialization decisions and modeling. As demonstrated by previous march-in efforts, these inquiries take years to adjudicate and considerable contractor and licensee resources to defend, which is valuable time and patent life lost for the invention or technology to be brought to market and could ultimately bankrupt the licensee even if the petition is ultimately denied. The knowledge that such levels of interference are possible under this framework creates heightened risk levels beyond the risks already inherent in the licensing and commercialization process.

2. The framework contains many terms which have specific meanings under Bayh-Dole or in technology development and commercialization. Are the definitions provided at the beginning of the framework easy to understand? Do they aid in your ability to interpret the framework?

The majority of the definitions included in the framework are already defined either by 35 U.S.C. 203, 37 CFR 401, or other federal regulations. However, not all the framework definitions identify the derivation of the definition, which creates confusion as to whether this is a new or existing definition. We ask that the formatting of the definitions in this framework be standardized in a way that clarifies whether the definition exists in statute or regulation or is specific to the framework. For example, the definitions for "Practical Application" and "Funding Agreement" in the framework contain only definitional language and do not include a reference to 37 CFR 401.2, where the definitions are set forth in regulation.

Conversely, the term "shelving" does not have an existing definition in statute or regulation but is used throughout the hypothetical scenarios in this framework to describe contractor conduct, condensing the entirety of Criterion 1 down to a single word that invokes conclusions of both fact and law. Given the gravity of such a definition assigned to contractor conduct, we advise removing the term "shelving" from the framework altogether.

3. How could the framework be improved to be easier to follow and comprehend?

The framework is overly complicated and highly likely to be interpreted differently at each federal agency which will bring even more complexity to technology transfer efforts. The framework should be withdrawn. A new framework could be written that 1) focuses on the operational elements of adjudicating petitions for march-in filed with federal agencies, and 2) provides guidance on the "nuts and bolts" of potential infrastructure, training, and technology needed by agency personnel during the lifecycle of a petition, which is already mandated by 37 CFR 401.11(c).

4. Does the framework sufficiently address concerns about public utilization of products developed by from subject inventions, taking into account the fact that encouraging development and commercialization is a central objective of the Bayh-Dole Act?

We are concerned that, in addressing factors for consideration of Criterion 1, the framework places too much emphasis on 'reasonable pricing' to end-users when considering public availability in a way that differs from past agency practice and regulation. Under Criterion 1, the framework in essence creates a new layer of consideration outside of previously permitted considerations under public availability, with an outsized emphasis on the end-user price. Again, the guidance contains no definition for the highly subjective term 'reasonable,' which creates uncertainty as to how this term will be interpreted by agencies during march-in deliberations relying on this framework. Pricing is a complex commercialization decision that is far removed from the licensing component. The ability to second-guess pricing beyond what has already been established in statute and regulation, continues to heighten the risk calculation for future private sector partnering and investment. Public utilization and factors for consideration are already

sufficiently addressed in Bayh-Dole regulations and past agency decisions and an expansion or shift in emphasis is unwarranted. As discussed above, this change will directly impede the central objectives of development and commercialization at the heart of the Bayh-Dole Act. As the RFI itself recognizes, the potential chilling effect on industry relationships and Administration priorities is a crucial consideration.

5. 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. Does the framework ask questions and capture scenarios applicable across all technology sectors and different stages of development? How could any gaps in technology sectors or stages of development be better addressed?

While the framework's tech-agnostic aspirations are understandable, the overly broad nature of the framework demonstrates why there have been no prior attempts to provide a general framework for the adjudication of petitions for march-in. It is precisely because the wide spectrum of research advancements and emerging technologies, which encompasses everything from agriculture,and pharmaceuticals to semiconductor processes, advanced chemical compounds, and alternative energy sources, that such a framework will inherently be unable to properly address all stages of development and types of technology that are subject to the Bayh-Dole Act. As the framework itself emphasizes, march-in decisions are very fact-specific, with a plethora of variables existing for each technological sector at each stage of development. We recommend an operational framework, not a decisional framework, on the handling of petitions for march-in for all affected agencies, as well as a tailored approach for specific technological sectors that reflect the variables and obstacles to development and commercialization for that sector. Stakeholders throughout those sectors, from research communities, start-ups and venture capital, and established corporations could assist agencies with the development of those tailored frameworks to inform their decision-making with the core principles of the Bayh-Dole Act and regulations to guide them.

Conclusion

We urge NIST to consider our concerns as the Interagency Working Group continues to improve and streamline the technology transfer process. This framework will not solve the identified problem. Instead, it will cause far too much collateral damage to be justifiable.

American innovation, economic competitiveness, and national economic security are best served by protecting and enhancing the robustness of the American academic research and technology transfer ecosystem in the U.S. Unnecessary, vague, and unwarranted changes to the Bayh-Dole Act and its implementation cannot be allowed to harm one of the greatest public policy achievements in U.S. history. We urge NIST to withdraw and definitively rescind this unnecessary framework.

Barbara R. Snyder
President, Association of American Universities

Mark Becker
President, Association of Public and Land-grant Universities

David J. Skorton, MD
President & CEO, Association of American Medical Colleges

Ted Mitchell
President, American Council on Education

Steve Susalka
Chief Executive Officer, AUTM

Matt Owens
President, COGR

The Association of American Universities (AAU) is an organization of 71 leading U.S. and Canadian public and private research universities on the leading edge of innovation, scholarship, and solutions that contribute to scientific progress, economic development, security, and well-being.

The Association of Public and Land-grant Universities (APLU) is a research, policy, and advocacy organization with a membership of more than 250 public research universities, land-grant institutions, state university systems, and affiliated organizations in the U.S., Canada, and Mexico, that is dedicated to strengthening and advancing the work of public universities.

The Association of American Medical Colleges (AAMC) is a not-for-profit association dedicated to transforming health through medical education, health care, medical research, and community collaborations. Its members are all 158 accredited U.S. and 13 accredited Canadian medical schools; more than 400 teaching hospitals and health systems, including Department of Veterans Affairs medical centers; and more than 70 academic societies.

ACE is the American Council on Education, the major coordinating body for American higher education. Its more than 1,700 members reflect the extraordinary breadth and contributions of public and private colleges and universities. ACE members educate two out of every three students in accredited, degree-granting U.S. institutions.

AUTM is the non-profit leader in efforts to educate, promote and inspire professionals to support the development of academic research that changes the world and drives innovation forward.

COGR is an association with over 200 research universities and affiliated academic medical centers and research institutes. COGR focuses on the impact of federal research regulations, policies, and practices and advocates for sound, efficient and effective regulation that safeguards research and minimizes administrative and cost burden.

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January 31, 2024

The Honorable Gina M. Raimondo
Secretary, U.S. Department of Commerce

The Honorable Laurie E. Locascio
Director and Undersecretary of Commerce for
Standards and Technology, U.S. Department of Commerce

Re: December 8, 2023 Request for Information Regarding Draft Interagency Guidance Framework for Considering the Exercise of Bayh-Dole Act "March-In Rights" ("Guidance Framework")

Dear Secretary Raimondo and Director Locascio:

On behalf of the ABA IP Section, I am submitting this comment to express our strong opposition to the proposed "march-in" Guidance Framework published in the Federal Register on December 8, 2023. The views expressed herein have not been reviewed or approved by the House of Delegates or the Board of Governors of the American Bar Association and, accordingly, should not be construed as representing the policy of the American Bar Association. These comments do not represent the policy or views of any government employee who is a member of the Section, its Council, or its Interest Groups.

Since 1894, the American Bar Association's Intellectual Property Law Section ("the ABA IP Section") has advanced the development and improvement of intellectual property laws, their fair and just administration, related policy issues, and, where necessary, litigation. As a major forum fostering a balanced view of legal issues and related policy initiatives concerning the U.S. economy, the ABA IP Section has earned trust of the Executive, Congressional, and Judicial Branches of our Government and the public as a respected and trusted nonpartisan substantive voice. Our membership includes private attorneys in law firms who represent small and large corporations; inventors; universities and research institutions; federal and state government agencies; academics; policy experts; and other attorney-"thought leaders" who are nationally recognized in this field of law.

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In 1980, the bipartisan Bayh-Dole Act was enacted "to use the patent system to promote the utilization of inventions arising from federally supported research or development...[and] ensure that inventions made by nonprofit organizations. . . are used in a manner to promote free competition and enterprise." In short, the law allows federally funded researchers or their institutions to claim "clear title" to patents they secured to enable the invention to be licensed, thereby attracting venture capital and other seed investors to undertake the development and commercialization of these innovations. Today, research universities and other non-profit associations across the U.S. now have technology transfer offices with considerable licensing expertise with private businesses, usually small startup firms. These tech transfer offices have ensured that no circumstances have arisen to warrant the exercise of "march-in" for a failure to comply with the development and commercialization requirements of the Bayh-Dole Act.

Therefore, no federal agency has ever invoked "march-in." As the *Economist* reported in 2002: "Possibly, the most inspired piece of legislation to be enacted in America over the past half-century was the Bayh-Dole Act of 1980...[which] unlocked all the inventions and discoveries that had been made in laboratories throughout the United States with the help of taxpayers' money. More than anything, this single policy measure helped to reverse America's precipitous slide into industrial irrelevance."[1]

Since the Bayh-Dole Act is credited with adding over $12.3 trillion to the U.S. gross domestic product, creating 4.2 million jobs, and enabling over 11,000 new startup ventures,[2] the Department of Commerce's decision to issue this "Guidance Framework" is ill-conceived and should be withdrawn.

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The "Guidance Framework," however, has significant substantive and procedural deficiencies.

First, as a matter of law, no federal agency can exceed its delegated authority.[3] Nevertheless, the "Guidance Framework" provides that a federal agency can exercise "march-in" to confiscate property rights conveyed by the United States Patent and Trademark Office, if "the price or other terms at which the product is currently offered to the public are not reasonable." In essence, the "Guidance Framework" would authorize any federal agency to determine "[a]t what price and on what terms the product utilizing the subject invention been sold or offered for sale in the U.S. [4]" Congress, however, has not

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[1] Innovation's Golden Goose, The Economist (Dec. 14, 2002) (available at: https://economist.com/technology-quarterly/2002/12/14/innovations-golden-goose).

[2] G. Athanasia, The Legacy of Bayh-Dole's Success on U.S. Global Competitiveness Today, Center for Strategic & Internationals Studies (January 12, 2022) (available at: The Legacy of Bayh-Dole's Success on U. S. Global Competitiveness Today | Perspectives on Innovation | CSIS).

[3] Lyng *v.* Payne, 476 U.S. 926, 937 (1986) ("an agency's power is no greater than that delegated to it by Congress.").

[4] 88 Fed. Reg. 85593, 85598 (Dec. 8, 2023).

repealed nor amended the Bayh-Dole Act to include the reasonableness of price as a factor to be considered in exercising "march-in" authority. Therefore, any federal agency that would "march-in" under the Guidance Framework will directly violate the Bayh-Dole Act. In addition, the "Guidance Framework" ignores that both Senator Bayh and Senator Dole stated that the 1980 Act "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 was intentional, as the primary purpose of the Act was to entice the private sector to engage in public-private research collaboration rather than focusing on its own proprietary research." [5] The Senators added: "[t]he 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 invention as a product."[6]

Second, the "Guidance Framework" allows anyone to file a "march-in" petition, in conflict with traditional principles of standing to challenge a property right. [7] For example, a well-financed larger competitor or even domestic entities backed by China, Iran, Russia, or North Korean investment, with no "legally protected interest" in the patented invention commercialized under Bayh-Dole Act, simply could file a petition to instigate a federal agency investigation thereby damaging the market for the innovative technology, and then seek to obtain that technology, avoiding the financial risk of early development. No rational investor nor venture capital firm would fund any entity developing a business where the essential patent underlying the technology could be seized at will.

Third, the "Guidance Framework" fails to provide a definition of a "reasonable price" or what "other terms" may or may not be considered "reasonable." As such, this provision is entirely subjective and sufficiently vague as to implicate both the Administrative Procedures Act and the Due Process Clause.

Fourth, the "Guidance Framework" necessarily would adversely affect existing commercialized inventions. Therefore, any federal agency decision to "march-in" and revoke preexisting patent rights would give rise to breach of contract, breach of the dual duties of good faith and fair dealing, and Takings Clause lawsuits in the U.S. Court of Federal Claims where damages awarded ultimately would be paid by U.S. taxpayers.

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[5] Birch Bayh and Robert Dole, "Our Law Helps Patents Get New Drugs Sooner," Washington Post, 11 Apr. 2002: A28.

[6] *Id.*

[7] *See e.g.,* Lujan *v.* Defenders of Wildlife. 504 U.S. 555 560–61 (1992)("First, the plaintiff must have suffered an injury in fact—an invasion of a legally-protected interest which is (a) concrete and particularized and (b) actual or imminent, not conjectural or hypothetical. Second, there must be a causal connection between the injury and the conduct complained of—the injury has to be fairly traceable to the challenged action of the defendant, and not the result of the independent action of some third party not before the court. Third, it must be likely, as opposed to merely speculative, that the injury will be redressed by a favorable decision.")

Fifth, no evidenced-based record has been developed to justify the issuance of the "Guidance Framework," such as that required when an agency proposes to issue a regulation. In addition, the most relevant federal agencies, such as the U.S. Patent and Trademark Office, the National Institutes of Health, the National Academy of Sciences, the National Academy of Engineering, the National Academy of Medicine, and the Department of Education, among others were not listed as participating in the "Interagency Working Group." Further, no economic or cost-benefit analysis has been undertaken, either by the Office of Management and Budget or the independent Congressional Research Service, on the effect of the proposed "Guidance Framework" on the U.S. economy. These omissions individually and collectively evidence agency conduct that facially is "arbitrary and capricious."

Finally, you are well aware that our country is engaged in geopolitical competition in the fields of quantum computing, artificial intelligence, semi-conductors, broad band and digital telecommunications, telehealth, and clean and renewable energy---all of which are essential for national security. The "Guidance Framework" directly undermines this essential work and is contrary to the objectives of recent joint Administration and Congressional action to authorize significant new federal grants[8] and establish thirty one new Tech Hubs across the country to build on the achievements of the Bayh-Dole Act.

For all of these reasons, the Section requests the Department of Commerce abandon the "Guidance Framework" in light of this comment and those of the Association of American Universities, Association of University Technology Managers, U.S. industry groups from almost every sector in the economy, including the Chamber of Commerce, the National Association of Manufacturers, United Inventors Association, and leading intellectual property academics and redirect the resources of the National Institute of Standards and Technology to its congressionally authorized and core mission "to promote American innovation and industrial competitiveness."

Sincerely,

Steven P. Caltrider, Chair
ABA Section of Intellectual Property Law

[8] Melba Romero, "Key Industries Poised to Benefit from Federal Infrastructure Grants in 2023," (available at: https://www.linked.com/pulse/key-industries-posed-to-benefit-from federal-grants-2023-melba-romero/).

January 17, 2024

Via Electronic Submission
Laurie E. Locascio
National Institute of Standards and Technology
100 Bureau Drive
Gaithersburg, MD 20899

Dear Director Locascio,

On behalf of the Bayh-Dole Coalition -- a diverse group of innovation-oriented organizations and individuals committed to celebrating and protecting the Bayh-Dole Act -- I urge you to withdraw the recently published Draft Interagency Guidance Framework for Considering the Exercise of March-In Rights. The proposed framework violates both the letter and spirit of the Bayh-Dole Act and would cause untold harm to American companies, workers, and consumers if implemented.

I've spent the majority of my professional life helping to enact, implement, and defend the Bayh-Dole Act. As the former Senate Judiciary Committee staffer to Senator Birch Bayh (D-IN), I was present at the inception of the law, put together its hearings, wrote the report of the Senate Judiciary Committee, staffed its passage through Congress, and worked with Senator Bob Dole (R-KS) to move the oversight authority to the Department of Commerce.

After doing so, I served as the Director of the Office of Technology Commercialization at the Department of Commerce and worked with Secretary Malcolm Baldrige to form the Interagency Committee on Technology Transfer, which I ran for many years. I now serve as the executive director of the Bayh-Dole Coalition, which aims to inform policymakers and the American public of the law's many benefits.

Simply put, the framework would irreparably undermine one of the most successful laws in American history. It attempts to inject a concept into the law that was expressly rejected by its authors and voted down repeatedly in Congress, including by then-Senator Joe Biden.[1]

The draft framework is being justified as a weapon to lower drug costs. It is no such thing. It is unlikely to have much, if any, impact on drug costs. What it will do is turn the Bayh-Dole Act and the innovation that it spurs across every other industry on its head.

As the bill's official name -- the University and Small Business Patent Procedures Act -- implies, one main objective was to encourage entrepreneurial small companies to accept government research contracts and to license federally-funded inventions. That effort was remarkably successful. Bayh-Dole is the foundation of the Small Business Innovation Research (SBIR) and Small Business Technology Transfer (STTR) programs touted by the Small Business Administration as "America's Seed Fund."[2][3] Small companies license more than 70% of academic patents.[4] The proposed framework puts all that in jeopardy.

The guidelines return us to the pre-Bayh-Dole days when federal funding was toxic. Under the guidelines, anyone founding a start-up company or licensing a federally-funded invention has a target on their back as competitors, the unscrupulous, and even foreign adversaries can file march-in petitions objecting to the price of a successfully developed product based on a government-supported invention. The issuance of the guidelines is already casting a cloud over public/private sector partnerships at a time when we need them to promote public welfare by solving pressing problems, growing our economy, and meeting the threat posed by rivals such as China to eclipse our lead in the technologies that will determine who leads the 21st century.

The guidelines should immediately be withdrawn.

Just a cursory glance at the proposal reveals its serious flaws. The document begins by asking whether "its application will both fulfill the purpose of march-in rights and uphold the policy and objectives of the Bayh-Dole Act." It would do neither.

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[1] https://www.govtrack.us/congress/votes/96-1980/s592
https://www.senate.gov/legislative/LIS/roll_call_votes/vote1062/vote_106_2_00168.htm

[2] https://www.sbir.gov/about

[3] https://seedfund.nsf.gov/

[4] https://autm.net/AUTM/media/Surveys-Tools/Documents/AUTM-Infographic-22-for-uploading.pdf

Twenty years after its enactment, opponents of the law claimed they had discovered a hidden meaning in the march-in rights clause. They alleged that it gave the government the authority to march in if a successfully-developed product wasn't reasonably priced.[5] That claim was immediately rejected by Senators Bayh and Dole, who wrote to The Washington Post:

> "Bayh-Dole 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; 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."[6]

When the critics of Bayh-Dole began filing march-in petitions based on the flawed theory, the National Institutes of Health (NIH) held its only public meeting on the issue. Senator Bayh was the first speaker. He demonstrated how the petitioners were deliberately distorting the Senate Judiciary Committee report on Bayh-Dole, which I wrote. Petitioners claimed the report endorsed the concept of using march-in rights to control prices. But in reality, they were quoting and combining two unrelated portions of the report -- portions that had nothing to do with march-in rights -- out of context to create a misleading picture of what the law permits.

Senator Bayh concluded by saying:

> "If Congress does decide to amend Bayh-Dole someone must clearly define what is a 'reasonable price.' Congress must keep in mind that the vast majority of technologies developed under the law are commercialized by small companies that 'bet the farm' on one or two patents. Copycat companies are always waiting until an entrepreneur has shown the path ahead. They can always make things cheaper since they have no significant development costs to recover.
>
> "What will happen to the start-up companies arising from Bayh-Dole that are driving our economy forward with this sword hanging over their heads? What

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[5] http://www.cptech.org/ip/health/bd/arnodavis012001.pdf

[6] https://www.washingtonpost.com/archive/opinions/2002/04/11/our-law-helps-patients-get-new-drugs-sooner/d814d22a-6c63-4f06-8da3-d9698552fa24/

> evidence is there that large drug companies will not simply walk away from collaborations with our public sector? That is what happened to NIH."[7]

Because the law does not mention pricing as a march-in trigger, NIST lacks the authority to direct federal agencies "to further assess whether march-in is warranted" when "the contractor or licensee has commercialized the product, **but the price** or other terms **at which the product is offered to the public are not reasonable."**

The framework also misinterprets other sections of the law. For instance, in the "Definitions" section of the framework, NIST fails to note that "practical application" in the march-in section **only applies to the contractor** (normally the academic institution making the invention), **not the licensee** (which sets the price).[8]

Similarly, the statutory definition of practical application -- that the benefits of the product are "available to the public on reasonable terms" -- **clearly refers to the terms of the license, not to the price of a product**. If Congress had intended this clause to apply to the price of a product, it would have included the licensee in this trigger, as in the other three triggers.

The framework contradicts more than 40 years of precedent set by both Democratic and Republican administrations. Every administration that has considered a march-in petition on the basis of price since Bayh-Dole's enactment has rightfully rejected it, including the Biden administration just last spring.

Here's what NIH said in March 2023 while rejecting the sixth march-in petition for the prostate cancer drug, Xtandi (which was denied three times by the Obama-Biden administration):

> "NIH's analyses in response to the petition request have found Xtandi to be widely available to the public on the market. In addition, given the remaining patent life and the lengthy administrative process involved for a march-in proceeding, NIH does not believe that use of the march-in authority would be an effective means of lowering the price of the drug. For these reasons, NIH has determined that initiation of a march-in proceeding is not warranted in this case. This decision is consistent

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[7] https://bayhdolecoalition.org/wp-content/uploads/2023/05/2004-Bayh-Statement-to-NIH.pdf, page 5

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

> with NIH's determination in 2016, in which KEI and the Union for Affordable Cancer Treatment requested NIH and the Department of Defense march-in based on the price of Xtandi, but each declined. In responding to the march-in request for Xtandi in 2016, NIH explained that, consistent with march-in determinations for Cell Pro (1997), Norvir (2004, 2013), and Xalatan (2004), practical application is evidenced by the "manufacture, practice, and operation" of the invention and the invention's "availability to and use by the public...." Astellas, the maker of Xtandi, estimates that more than 200,000 patients were treated with Xtandi from 2012 to 2021. **Therefore, the patent owner, the University of California, does not fail the requirement for bringing Xtandi to practical application,** as the drug is manufactured and on the market in the manner of other prescription drugs. NIH has reviewed the information submitted by the current petitioners, which is substantially the same as that submitted in 2016, and reached the conclusion that Xtandi is still widely available as a prescription drug.[9]"

Note that NIH said that the University of California, not the licensee Astellas, had met its obligation under the statute.

Notably, in the "Definitions" section, the framework does not list "reasonable pricing" as a term defined in the law -- for good reason.[10] As Senators Bayh and Dole noted, this term has no standing under their statute. But under the pending guidelines, that concept becomes the pivot point of the law. This is already causing venture capitalists and potential licensees to again be wary of commercializing federally-funded inventions, as they were before Bayh-Dole.[11]

In one stroke, the framework would turn the law on its head.

The request for information asks whether use of the new standards will "have wider implications," "unintended consequences," cause prospective licensees to "avoid future collaborations with federally-funded research institutions, organizations, small businesses,

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[9] https://www.keionline.org/wp-content/uploads/NIH-rejection-Xtandi-marchin-21march2023.pdf

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

[11] https://www.biospace.com/article/jpm-2024-on-the-ground-in-san-francisco/

and other investigators," or "send a clear signal to industry so other contractors and licensees can rely on that agency's prior decisions to avoid similar issues in the future."[12]

History proves that it would.

Once before, in 1989, an administration bowed to political pressure to include "reasonable pricing" in its technology transfer programs. NIH adopted that term in its exclusive licenses and cooperative R&D agreements (CRADAs) until the mid-1990s. The result wasn't a golden age of cheaper drugs. Instead, industry walked away from such partnerships.

Here's what then-NIH Director Harold Varmus said as he ended this disastrous experiment in 1995:

> "An extensive review of this matter over the past year indicated that the pricing clause has driven industry away from potentially beneficial scientific collaborations with PHS scientists without providing an offsetting benefit to the public," said Dr. Varmus.
>
> "Eliminating the clause will promote research that can enhance the health of the American people," he said.
>
> "Over the past year, NIH analyzed its CRADA activities including the scope of scientific research under CRADAs, the resources brought to the collaborations by NIH scientist and industry, intellectual property arising from the CRADAs, and the effect of the "reasonable pricing" clause on products developed under CRADAs. NIH also sought advice from scientists, patient advocacy groups, and representatives of academic institutions and industry on how the clause has affected research and development collaborations and the advancement of scientific discoveries."[13]

In its statement announcing the removal of this "reasonable pricing" clause from its exclusive licenses and CRADAs, NIH included this astute observation: "**No law or regulation requires or expressly authorizes the inclusion of the 'reasonable pricing' clause.**"[14]

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[12] 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.techtransfer.nih.gov/sites/default/files/documents/pdfs/NIH-Notice-Rescinding-Reasonable-Pricing-Clause.pdf

[14] https://www.techtransfer.nih.gov/sites/default/files/documents/pdfs/NIH-Notice-Rescinding-Reasonable-Pricing-Clause.pdf

That was true then, and it's true now. There is no statutory authority for this misguided effort. When attempts were made to reinstate the failed "reasonable pricing" experiment by statute, they were uniformly rejected by Congress. One of those wisely opposing this misguided effort was then-Senator Joe Biden.[15]

Ironically, even the draft framework implicitly acknowledges that misusing the march-in provision for price controls will have little, if any, impact on lowering drug costs -- the purported reason for this exercise. For example, the guidelines ask agencies to consider: "What intellectual property, in total, is needed to make the product in question? Does making the product or performing the service also require use of intellectual property that was not government funded and is not subject to Bayh-Dole?"

When it comes to pharmaceuticals, that question is easy to answer. A new study looked at 361 novel, non-generic, small and large molecule drugs listed in the FDA's Orange and Purple Books between 2011 and 2020, and found that:

> "92% of the therapies in our cohort have no mechanism of action or composition of matter patents with a government interest statement or federally funded co-development program in connection to them.
>
> "99% of the therapies in our cohort cannot be marched-in upon, as the key patents studied do not cover the entire asset's intellectual property. There are only 5 out of 361 pharmaceutical products in which all available MoA (mechanism of action) and CoM (composition of matter) patents include a government interest statement and could be subject to march-in rights."[16]

The draft framework will do effectively nothing to lower drug costs, but it will lower American innovation. Bayh-Dole inventions are essential in meeting our energy, environmental, food production, and other needs, as it is a uniform policy for all federal agencies, not just NIH. Because it applies to all government-funded R&D, the draft framework opens a Pandora's box, providing a mechanism for competitors, the unscrupulous, or even our foreign adversaries to harass the innovative small companies that drive our technological progress.

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[15] https://www.senate.gov/legislative/LIS/roll_call_votes/vote1062/vote_106_2_00168.htm

[16] https://vitaltransformation.com/wp-content/uploads/2023/11/march-in_v11_BIO-approved-30Nov2023.pdf, slide 19

As there is no definition of what constitutes a "reasonable price," prospective licensees or those founding start-up companies around Bayh-Dole inventions have no idea what standards they will be judged by if they commercialize a product under these guidelines. What they do know is that they can be challenged by those claiming they could make their product cheaper. Even if these march-in petitions are ultimately unsuccessful, the broad notification that they have been filed could cause potential funders or partners to stay away.

The draft framework would return us back to the bad old days before Bayh-Dole, when government-funded inventions were considered toxic.

The Bayh-Dole Act also sought to end government micromanagement of federally-funded inventions and the documented inefficiencies of a "Washington knows best" approach to patent licensing that left tens of thousands of federally-funded inventions gathering dust rather than being turned into useful products. Bayh-Dole has succeeded beyond our wildest expectations. A key reason why the government has never needed to invoke march-in rights is that universities are successfully monitoring their licenses.

Even Bayh-Dole proponents were not sure that would be the case when the law was written, as most schools did not have technology transfer offices for a good reason -- the government took their patents away from them. As a safeguard, Congress created the first march-in trigger to ensure that the terms of academic licenses were 1) reasonable and 2) included monitoring mechanisms that licensees were making good faith efforts to bring federally-funded inventions to the marketplace where they benefit the public. It was not by happenstance that this trigger only applies to the patent owner (i.e. the university) and not the licensee which sets the price.

There is no reason for the government to now re-insert itself in micro-managing academic patent licensing. The framework does not cite a single real-world case in over 40 years where march-in rights should have been used. Instead, the framework relies only on hypotheticals.

The Bayh-Dole system is a keystone of American innovation. *The Economist Technology Quarterly* aptly described it as: "Possibly the most inspired piece of legislation to be enacted in America over the past half-century was the Bayh-Dole Act of 1980... More than anything,

this single policy measure helped to reverse America's precipitous slide into industrial irrelevance."[17]

It would be enormously counterproductive to undermine the law that has served American innovators, workers, and consumers so well. The Bayh-Dole Coalition urges you to withdraw the framework and would be happy to discuss these concerns at your convenience.

Sincerely,

Joseph P. Allen
Executive Director
Bayh-Dole Coalition

[17] https://www.economist.com/technology-quarterly/2002/12/14/innovations-golden-goose