

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Guidance Framework for Considering the Exercise of March-In Rights* (Federal Register/Vol. 88, No. 235/Dec. 8, 2023) ("Draft Guidance")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

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.