



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Guidance Framework for Considering the Exercise of March-In Rights (Federal Register/Vol. 88, No. 235/Dec. 8, 2023) (“Draft Guidance”)*

Dear Dr. Locascio:

On behalf of COGR, I thank you for the opportunity to provide comments on the proposed “Framework for Considering the Exercise of March-In Rights” developed by the Interagency Working Group for Bayh-Dole (hereafter “the Framework”). COGR is an association of over 200 public and private U.S. research universities and affiliated academic medical centers and research institutes. We focus on the impact of federal regulations, policies, and practices on the performance of research conducted at our member institutions, and we advocate for sound, efficient, and effective regulations that safeguard research and minimize administrative and cost burdens.

COGR participated in drafting and jointly submitted comments by several higher education associations expressing concerns about the Framework.¹ We also concur with the comments submitted by the Association of University Technology Managers (AUTM).²

We believe that the proposed Framework will cause irrevocable damage to the 40+ year success story of the Bayh-Dole Act, and our nation’s successfully tried and true technology transfer practices will be undermined. The Framework will harm the ability of research institutions to license patents vital to new products, processes, and technologies that start-up companies and others rely on to commercialize products and services that benefit our nation’s health, security, and economy. Consequently, we recommend that the Framework be withdrawn, for the reasons stated in the joint higher education associations’ and AUTM comments and as further expanded on below.

First, we want to underscore the response to Question #4 of the RFI, namely, whether the draft Framework sufficiently addresses “concerns about public utilization of products developed from subject inventions, taking into account that encouraging development and commercialization is a central objective of the Bayh-Dole Act.” The addition of price as a factor for agencies to consider in evaluating march-in under the first two statutory criteria of Bayh-Dole unquestionably will have a chilling effect on the ability of federal funding recipients to partner with industry to commercialize federally-funded inventions, for the reasons stated in the joint higher education association and AUTM comments. This will undermine Administration priorities such as the CHIPS and Science Act programs that are premised on industry co-investments and public-private partnerships.

¹ COGR, AAMC, AAU, APLU, AUTM joint comment letter: [University Association Comments to NIST.pdf \(cogr.edu\)](#)

² AUTM comment letter: https://autm.net/AUTM/media/About-Tech-Transfer/Documents/AUTM-Comments_NIST-1-23-24_revised.pdf

Second, the points discussed in response to Question #5 of the RFI warrant careful attention. While the Framework does not explicitly address the pricing of drugs and therapeutics, it is widely perceived as having been motivated by those concerns. It also is the case that all previous march-in requests have involved those types of products. However, the proposed Framework largely will be ineffectual in affecting drug prices. Almost all drugs on the market are covered by multiple patents and other intellectual property, much of which is not subject to Bayh-Dole. As the Framework itself recognizes, a complicated intellectual property landscape would weigh against march-in, since march-in under those circumstances cannot be successfully exercised. However, the Framework applies to all types of technologies, many of which may not present the same complicated intellectual property landscape that is typical of drugs and therapeutics. This will undermine the utilization of Bayh-Dole subject inventions, since companies will be reluctant to invest in licensing and development when faced with the increased uncertainty associated with the potential of march-in on pricing grounds.

To further compound the problem, as noted in the joint association response to question #1, the RFI uses vague and unclear terms with regard to consideration of product pricing, such as “unreasonable,” “extreme,” “unjustified” and “exploitative.” These terms are not defined, and have no clear objective meaning. It also is not clear how such determinations would be made, or by whom. This could lead to significant and confusing inconsistencies due to different determinations by officials in the various federal agencies.

Third, we wish to emphasize an additional concern: the potential for “gamesmanship.” The Framework may provide a roadmap for large companies and others to challenge and harass small companies, including Small Business Innovation Research (SBIR) firms, by threatening to initiate march-in proceedings to undercut their product pricing. This could have national security implications by providing a mechanism for unfriendly foreign entities to undermine U.S. innovation.

In summary, once any march-in is exercised on the grounds that the price of a product is not “reasonable,” companies will be much more hesitant to license federally-funded inventions if at all. Even if march-in petitions continue to be denied on these grounds, the mere existence of a framework suggesting that such march-in is possible will have a chilling effect on licensing and startup formation. The licensing process already is difficult and challenging, as discussed in the AUTM comments. Any further complications will adversely affect the ability of academic research institutions to move federally-funded technologies to the marketplace where society can benefit from them. This in turn will harm U.S. innovation and the Administration’s priorities in critical technology fields.

For these reasons we respectfully urge that the draft Framework be withdrawn. I appreciate your consideration, and we welcome the opportunity for continued discussion on this important matter.

Sincerely,

A handwritten signature in black ink that reads "Matt Owens". The signature is written in a cursive, slightly slanted style.

Matt Owens
President