AAP ASSOCIATION OF AMERICAN PUBLISHERS



Advancing trusted research

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Ms. Bahar,

We are writing in response to the Department of Commerce's Request for Information on the Draft Interagency Guidance Framework for Considering the Exercise of March-In Rights ("the Draft Framework"), as published in the Federal Record on December 8, 2023 (88 FR 85593). STM and AAP collectively represent the scientific, medical, and technical publishing community, representing hundreds of scholarly publishers and most of the scientific academy. Our members are devoted to advancing trusted research and ensuring that the latest discoveries are translated into investments that positively impact the public.

We are deeply concerned about several aspects of the Draft Framework, including the presumption that there is a policy failure represented by the fact that no agency has exercised rights to march-in under the University and Small Business Patent Procedures Act of 1980 ("Bayh-Dole"). Public-private partnerships form the core of innovation and creativity. They provide a flexible framework that serves the public through competition, private investment, and an ability to react quickly to market demands. While Bayh-Dole allows for march-in rights, it intentionally does not require them. It is a success of the policy to date that march-in rights have not been exercised; rather, alternative solutions have been utilized to achieve desired policy objectives. We believe the current framework is sufficiently robust and clear to continue to deliver positive outcomes.

We are particularly concerned about language in the Draft Framework suggesting agencies should consider whether "the price or other terms at which a product is currently offered to the public is not reasonable." The prospect of agencies stepping in to set pricing, revoke or overrule licensing agreements, or regulate production of private goods and services would chill future investment based on public research and development. Indeed, private entities would be loath to engage with federally supported researchers or consortia due to fears of federal intervention in the marketing, sale, and recovery of independently funded and developed products or services. This misinterpretation of Bayh-Dole would seriously jeopardize the technology transfer mechanism that has ensured federal investments in research have tangible benefits for the American people. We therefore suggest that Criterion 1 not include the provision in part IV. D. that suggests agencies consider the price of the product as an explicit factor, and also suggest Criterion 2 not include part IV. E. (printed as V. in the Federal Register). We further recommend focusing Scenarios 5 and 6 on the exploitative nature of those scenarios rather than the price itself.

At the same time, we support the language in the section of the Draft Framework on the broader context of Bayh-Dole articulated in part B, noting that the contribution of "intellectual property that was not government funded" to the product or service in question should be weighted in consideration of march-in. This is critical, as it is often the case private investments exceed initial federal investments and strongly contribute to the commercialization, availability, and distribution of products or services related to agency research contributions.

More broadly, we strongly encourage NIST to take a restrained approach to exercising march-in rights that are narrowly limited to the four statutory categories laid out in the Bayh-Dole Act, to ensure that it continues to operate in the way intended by Congress to balance public and private interests. In this, we join with hundreds of colleagues in universities and the research advocacy space who have strongly urged the same. These 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) (https://c4ip.org/wp-content/uploads/2024/02/Fmr-Commerce-Dept-Officials-Letter-to-President-Biden-re-Draft-Interagency-Guidance-Framework-for-Considering-the-Exercise-of-March-In-Rights.pdf) as well as major research advocacy associations like Research!America (https://www.researchamerica.org/press-releases-statements/researchamerica-statement-opposing-march-in-rights/). The private research and development community generates tens of thousands of jobs and billions in taxpayer revenues in advancing and commercializing public research investments. Much of this important scientific research and economic activity could be put at risk by government

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interference in competitive markets.

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