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OFFICE OF THE VICE PRESIDENT – RESEARCH AND INNOVATION

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February 5, 2024

Mojdeh Bahar
Associate Director for Innovation and Industry Services
National Institute of Standards and Technology
100 Bureau Drive
Gaithersburg, MD 20899

RE: UC Comments to the Request for Information Regarding the Draft Interagency Guidance Framework for Considering the Exercise of March-In Rights (Docket No.: 230831-0207)

Dear Associate Director Bahar:

I write on behalf of the University of California (UC) system responding to the Request for Information (RFI) on the Draft Interagency Guidance Framework for Considering the Exercise of March-In Rights (Draft Framework) issued by the National Institute of Standards and Technology (NIST) on December 8, 2023.

The UC system is comprised of ten campuses, six academic health centers, and three affiliated U.S. Department of Energy national laboratories. UC Health, encompassing the six academic health centers, is the nation's largest provider of health sciences and medical education training programs and the second largest provider of Medicaid inpatient services in California.

UC receives more than $7 billion annually of extramural awards to support research conducted across all UC locations. UC's technology commercialization program takes inventions from the laboratory to the marketplace, benefiting the public in the form of countless innovative products, creating new jobs, training new talents, and contributing to the U.S. economy. UC is a leader in technology transfer and was granted more U.S. utility patents last year than any other university in the world.[1] Many of these patents resulted from research carried out with federal funding, illustrating the continued success of the Bayh-Dole Act and its importance to commercializing discoveries created through federally funded research. By allowing universities and other federal grantees to take title to inventions, the Bayh-Dole Act plays a critical role in ensuring that early-

[1] Source: UC Technology Commercialization Reports

stage technologies have an opportunity to be licensed by capable industry partners, developed, moved through proper regulatory processes, and made available to the public.

UC supports and endorses the comment letter jointly submitted by the Association of American Universities (AAU), the Association of Public and Land-grant Universities (APLU), the Association of American Medical Colleges (AAMC), the American Council on Education (ACE), the Association of University Technology Managers (AUTM), and Council on Government Relations (COGR) on February 1, 2024 in response to this RFI.

I. Call for NIST to NOT Issue the Draft Framework

While the Draft Framework does not specifically mention drug pricing – and would have implications for commercialization across all scientific fields – we recognize that the administration has specifically discussed march-in as an approach to lowering prescription drug costs for patients. UC has a long history of supporting affordable and accessible healthcare, including improving access to drugs and other medical innovations for patients. UC Health's six academic health centers are a critical element of California's health care safety net, providing access to care for low-income patients across the state. Moreover, many UC license agreements include language ensuring access to the licensed products for humanitarian uses. Many license agreements in the therapeutic and diagnostic fields also include language for affordable access plans for licensed products for vulnerable, underserved, and special needs populations in the U.S.

The communities of patients we serve, and the health care system as a whole, have been significantly challenged by the rising costs of prescription drugs. However, attempting to control the price of drugs and other innovations at the initial point of commercialization creates significant challenges and unintended consequences, and is likely to disrupt the technology transfer process at the delicate point of early-stage funding. Such a change may reduce long-run investment by industry in cures and treatments that benefit patients and may have long term impacts on the entire innovation and discovery ecosystem, without necessarily reducing the cost of prescription drugs. Policymakers seeking to reduce the cost of prescription drugs should focus on other mechanisms available to lower prices when products are more mature and when companies face less uncertainty.

UC echoes the comments it made on April 5, 2021, responding to the notice of proposed rulemaking "Rights to Federally Funded Inventions and Licensing of Government Owned Inventions." In its comment letter, UC noted its concern that if pricing were to be added as a march-in factor, the Bayh-Dole Act's march-in criteria could be misused to allow the government to set consumer prices on successfully commercialized products. This action is not supported by the statute itself and the authors, Senators Bayh and Dole, have clarified that this was not the Act's legislative intent.[2] Stakeholders active in the innovation ecosystem (e.g., universities, prospective licensees, and investors) need reassurance that the march-in provision will not be changed. Any perceived possibility for misuse or added uncertainty on the interpretation of this provision will have significant harmful effects on the universities' ability to collaborate with or license federally

[2] Birch Bayh and Bob Dole, "Our Law Helps Patients Get New Drugs Sooner." Letter to the Editor. The Washington Post. April 11, 2002. See: https://www.washingtonpost.com/archive/opinions/2002/04/11/our-law-helps-patients-get-new-drugs-sooner/d814d22a-6e63-4f06-8da3-d9698552fa24/

funded inventions to industry partners, who are critical in converting federally funded innovations into products. Our comments expressed in 2021 are applicable to the proposed Draft Framework.

UC supports the desire for the public to have affordable and equitable access to inventions that result from federally funded research. At the same time, we are concerned that the Draft Framework could disrupt the continued success of the Bayh-Dole Act. **We strongly ask that the federal government continue to rely on the Bayh-Dole Act as currently written and interpreted in accordance with its legislative history and not issue the Draft Framework.** We list our concerns with issuing the Draft Framework below.

1. Reinterpretation of the Bayh-Dole Act

While UC supports actions that would provide greater access to federally funded inventions to the public, we are concerned that the use of march-in for this purpose represents a reinterpretation of the Bayh-Dole Act. As former Senators Birch Bayh and Bob Dole confirmed in 2002, they never intended for the government to use the march-in provision as a price control mechanism.[3]

Furthermore, in 2018, NIST undertook a large-scale stakeholder engagement effort to inform the development of the Lab-to-Market Cross Agency Priority (CAP) goal. This stakeholder engagement led to the NIST Special Publication on *Return on Investment Initiative for Unleashing American Innovation*, in which NIST explained that the Bayh-Dole Act does not provide the government with the authority to set prices for successfully commercialized inventions. Such a possibility would inevitably discourage licensees and provide a disincentive to research collaborations and the commercialization of federally funded inventions.

The NIST Special Publication also detailed the National Institutes of Health's (NIH) experience with march-in proceedings. The report stated that "the National Institutes of Health (NIH) has received 12 requests to initiate march-in proceedings…Ultimately, for each of these requests, NIH determined that the use of march-in to control drug prices was not within the scope and intent of its authority."[4] NIST's attempt to relandscape march-in criteria to bring drug pricing "into scope" is a reinterpretation of the Bayh Dole Act and antithetical to Congressional intent as documented in the Act's legislative history.

2. Concerns on Uncertainty in the Research and Innovation Ecosystem

University inventions are, by and large, early-stage and high-risk. A greater likelihood of federal government march-in, or the threat thereof, adds additional uncertainty, both for universities and their industry partners. This uncertainty will negatively impact opportunities for universities to collaborate with and license federally funded inventions to industry partners. Small businesses and

[3] Birch Bayh and Bob Dole, "Our Law Helps Patients Get New Drugs Sooner." Letter to the Editor. The Washington Post. April 11, 2002. See: https://www.washingtonpost.com/archive/opinions/2002/04/11/our-law-helps-patients-get-new-drugs-sooner/d814d22a-6e63-4f06-8da3-d9698552fa24/

[4] Copan, W., Shyam-Sunder, S., Singerman, P., Zielinski, P., Silverthorn, C., Na, C., Wixon, H. and Cranmer, D. (2019), Return on Investment Initiative for Unleashing American Innovation, Special Publication (NIST SP), National Institute of Standards and Technology, Gaithersburg, MD, https://doi.org/10.6028/NIST.SP.1234. See page 29.

startup companies will be particularly disadvantaged as federal funding becomes a red flag to investors. Absent the substantial investment of time and resources needed to bring forward early-stage discoveries through the commercialization process, the Draft Framework creates the risk that federally funded technologies developed by a university, may never be translated into a product for the benefit of the public, as intended by the Bayh-Dole Act.

UC is concerned that implementation of the Draft Framework as it is currently written may shrink product development and erode public-private partnerships, ultimately deteriorating the Bayh-Dole Act's purpose of bringing new discoveries to the marketplace. The Draft Framework could push industry to focus on internal research and development or look to partners outside of the U.S., instead of advancing technologies developed by federal grantees. Under this scenario, the Draft Framework could ironically result in increased drug pricing.

II. Considerations Should NIST Choose to Issue the Draft Framework

We strongly urge that NIST not issue the Draft Framework. However, should NIST proceed with issuing the Draft Framework, UC asks that NIST consider changes to the Draft Framework and allow the public to comment on those changes prior to issuance. To assist NIST, we provide our specific comments on the prompting questions in the RFI below.

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?

1. Need for Clarification on a "Reasonable" Price under the Draft Framework

While the Draft Framework notes in several places that prices can be a relevant march-in consideration, the Draft Framework does not clearly state what a "reasonable" price is, and how and by whom "reasonable" pricing would be evaluated. The Draft Framework includes these terms without stating how they are tied to the statutory text of the Bayh-Dole Act. Should NIST proceed with issuing the Draft Framework, we ask that NIST develop a definition for reasonable pricing and the method to calculate it. This method must balance the need for incentivizing the development of new products, including discoveries requiring expensive development, testing, and regulatory processes in order to commercialize products. We urge not issuing the Draft Framework until such a definition and method is developed and vetted by the public.

2. Need for Definitions of "extreme," "unjustified," and "exploitative" under the Draft Framework

Similarly, "extreme," "unjustified," and "exploitative" noted in Criterion 2 are undefined and do not appear to be based on the statutory language of the Bayh-Dole Act's march-in factors. UC requests that NIST not issue the Draft Framework with these undefined terms. If these qualitative descriptors are intended to reassure industry that march-in will be invoked consistently across agencies and only under the most egregious circumstances, definitions are needed as well as examples of pricing scenarios that meet or fail to meet the "extreme," "unjustified," and "exploitative" criteria.

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?

Under the definition of Subject Invention in the Draft Framework, NIST mentions plant varieties and refers to the Plant Variety Protection Act 7 U.S.C. 2401(d). We could not find a subsection (d) to 7 U.S.C. 2401 or subsection (d)[1] to Section 41 in the Plant Variety Protection Act.

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?

UC argues that the expanded march-in provision stifles development and commercialization activity in all areas of science, in direct contrast to the central objective of the Bayh-Dole Act.

Thank you for the opportunity to comment. We look forward to continued engagement on this important issue.

Sincerely,

Deborah Motton, Ph.D.
Executive Director
Research Policy Analysis and Coordination
University of California, Office of the President