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February 6, 2024

National Institute of Standards and Technology
100 Bureau Drive
Gaithersburg, MD 20899

RE: Request for Information Regarding the Draft Interagency Guidance Framework for Considering the Exercise of March-In Rights (NIST-2023-0008)

Submitted electronically via regulations.gov.

The American Society for Pharmacology and Experimental Therapeutics (ASPET) appreciates the opportunity to provide comments on the Request for Information Regarding the Draft Interagency Guidance Framework for Considering the Exercise of March-In Rights. ASPET is a 4,000-member scientific society whose members conduct basic and clinical pharmacological research and work in academia, government, industry, and non-profit organizations. ASPET members conduct research leading to the development of new medicines and therapeutic agents to fight existing and emerging diseases.

ASPET urges and recommends that the Department of Commerce through the National Institute of Standards and Technology (NIST) not include pricing as a basis for march-in rights. This potential new factor would create substantial new uncertainty and risks, discouraging public-private collaborations that are incentivized by the Bayh-Dole Act, and thus unduly encumbering future research. ASPET raises its objections in two areas: congressional intent and the impact on and role of the National Institutes of Health.

Congressional Intent

Introducing pricing as a basis for march-in would create substantial new uncertainty and risks, discouraging public-private collaborations that are incentivized by the Bayh-Dole Act. These Bayh-Dole-enabled collaborations are crucial for scientific and technological innovations which is demonstrated by the history of economic growth. For example, since the Act's enactment, American universities alone have generated over \$1.3 trillion dollars in economic growth, along with 2 million jobs, and 11,000 start-ups that can be directly attributed to the Bayh-Dole Act. Another example is that NIH funded research provides generates over \$69 billion each year and supports over 7 million jobs through the U.S. biomedical industry.

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The Draft Guidance Framework abandons decades of policy precedents and binding agency adjudications to adopt a policy that is inherently inconsistent with the legislative intent of the Bayh-Dole Act, which is expressly:

to encourage maximum participation of small business firms in federally supported research and development efforts; **to promote collaboration between commercial concerns and nonprofit organizations**, including universities; **to ensure that inventions made by nonprofit organizations and small business firms are used in a manner to promote free competition and enterprise without unduly encumbering future research and discovery**; **to promote the commercialization and public availability of inventions made in the United States by United States industry and labor**; to ensure that the Government obtains sufficient rights in federally supported inventions to meet the needs of the Government and protect the public against nonuse or unreasonable use of inventions; and to minimize the costs of administering policies in this area. (35 U.S. Code § 200, emphasis added)

NIST's framework proposal is inconsistent with that congressional intent. On April 11, 2002, Senators Bayh and Dole wrote the Washington Post to confirm that "Bayh-Dole [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 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."

Since the law deliberately makes no reference to pricing, march-in rights have never been exercised -- on that or any other basis -- by any Federal agency since the law has been in place over 40 years ago. The Draft Framework is also a stark reversal of NIST's own 2021 proposed regulations that "[m]arch-in rights shall not be exercised exclusively based on... the pricing of commercial goods and services". In Executive Order 14036, President Biden explicitly told the Secretary of Commerce "consider not finalizing ny provisions on march in rights" consistent with the 2021 proposed regulation. Without clear direction through legislation on including pricing as a factor, NIST is inviting litigation and a reversal by Federal courts of this unwarranted change.

The Impact on and Role of the National Institute of Health

Requiring an agency like the National Institutes of Health (NIH) to assess and regulate product pricing is outside of its statutory mission.

The NIH and other research funding agencies' main role is to advance science and technology. The mission of NIH, for example, is to "seek fundamental knowledge about the nature and behavior of living systems and the application of that knowledge to enhance health, lengthen life, and reduce illness and disability." Diverting its scientists and managers from executing this statutory mission to address commercial market considerations (such as assessing the cost-basis of product manufacturing and marketing or analyzing domestic market pricing) that are extraneous to their responsibilities and expertise would be a tragic misstep bearing on the wellbeing of this and future generations.

The new proposed framework would require NIH and every other federal R&D agency to monitor and evaluate the prices of any product researched and developed with any federal funding, rescinding any technology transfer agreements associated with any product if the list price is deemed unreasonable. This policy change is inconsistent with the letter of the Bayh-Dole law and the documented legislative intent behind it; it would change the mission and objectives of every federal R&D agency to include commercial price adjudication and would chill the incentive for investing in any discovery that is subject to a technology transfer agreement. While the underlying goal – affordability, particularly in the prescription drug arena – is a worthy one, this approach is destructive to the pipeline that advances U.S. science & technology.

The Draft Framework provides no evidence or new data to justify changing policy in a manner that would invariably cloud the "clarity of intellectual property ownership for the public good, and incentivizing [of] commercial development of inventions for U.S. economic impact" that NIST attributed to the Bayh-Dole Act in its 2019 Green Paper. Instead, NIST should acknowledge and rely upon the reasoning of both NIH

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and the Department of Defense in rejections of march-in petitions in 1997, 2004, 2013, 2016 and 2023 – that practical application” under 35 USC 203(a)(1) is achieved and Bayh-Dole is satisfied when a prescription drug is clinically developed, FDA-approved, and marketed to the public.

ASPET requests that NIST remove product pricing from the Draft Guidance Framework in accordance with the letter and intent of the Bayh-Dole Act and to sustain the extraordinary momentum that landmark law has lent to scientific, technological, medical, and public health progress.

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