Template for Comment to NIST Docket No. 230831–0207
Request for Information Regarding the Draft Interagency Guidance Framework for Considering the Exercise of March-In Rights

- **Comments are due Tuesday, February 6, 2024**
- **Enter your comments directly at https://www.regulations.gov/commenton/NIST-2023-0008-0001**

I am writing to strongly urge NIST to revise the Draft Interagency Guidance Framework for Considering the Exercise of March-In Rights ("Draft Framework") to remove product pricing as a basis for applying the 35 USC 203(a)(1) and (a)(2) "march-in" criteria under the Bayh-Dole Act of 1980. Introducing pricing as a basis for march-in would create substantial new uncertainty and risks, discouraging the public-private collaborations that are the end-goal of the Bayh-Dole Act itself. These Bayh-Dole-enabled collaborations are demonstrably crucial to life science and other scientific and technological innovation.

The Draft 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 promote--

- the utilization of inventions arising from federally supported research or development;"
- collaboration between commercial concerns and nonprofit organizations, including universities;" and
- the commercialization and public availability of inventions made in the United States." (35 USC 200, "Policy and Objective")

I am also concerned that NIST is proposing to use pricing as a new basis for march-in without justification. 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.

Here are several reasons why the Draft Framework should be revised:

- **NIST's proposal is inconsistent with 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 over the <u>more than 40 years</u> this law has been in place.**
- **The Draft Framework is an unwarranted reversal of NIST's own proposal in its 2021 proposed regulations** that ''[m]arch-in rights shall not be exercised exclusively based on… the pricing of commercial goods and services''. Without any reasoning or evidence for this reversal, NIST is inviting litigation and a reversal by Federal courts of this arbitrary change.

- **Requiring an agency like the National Institutes of Health (NIH) to assess and regulate product pricing is outside of its statutory mission and would divert from that mission**. The NIH and other research agencies are charged with advancing 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.

  Instead, NIST should acknowledge and rely upon the reasoning of both NIH 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.

I respectfully request that NIST remove product pricing from the Draft 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.