

February 6, 2024

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

Dear Ms. Bahar:

The Society for Women's Health Research (SWHR) appreciates the opportunity to respond to the National Institute of Standards and Technology's (NIST) Request for Information (RFI) on the *Draft Interagency Guidance Framework for Considering the Exercise of March-in Rights*. SWHR is a more than 30-year-old national nonprofit organization with a mission of advancing women's health through science, policy, and education and promoting research on sex differences to optimize women's health.

SWHR appreciates the intent of the administration to promote patient access to medication and to tackle high drug prices. A key pillar of SWHR's policy work is to support policies that ensure women have an equal opportunity to be healthy, that federal policies reflect the ability of women to access and receive quality health care, and that policies meet the needs of diverse populations of women; access to necessary treatments and medications is a part of that.

However, SWHR is concerned that introducing pricing as a basis for "march-in" criteria under the Bayh-Dole Act of 1980 has the potential to discourage the public-private collaborations that serve as the foundation for the Act itself. Among SWHR's chief concerns with NIST's proposal are the following:

- **Misalignment with Missions of Federal Research Agencies.** Our nation's federal research agencies are tasked with advancing science and technology—ultimately protecting the health and well-being of Americans. The mission of the National Institutes of Health (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."

If the administration were to require agencies like NIH to assess and regulate product pricing, those activities would be outside of the agency's statutory mission and would pull NIH team members, including scientists and managers, away from their core responsibilities, all of which could have a detrimental effect on scientific discovery and advancement. We need research now more than ever – to protect Americans and to keep America scientifically competitive on the world stage; we cannot afford to lose any

momentum across our nation's scientific entities.

SWHR would point NIST to the NIH and Department of Defense's reasoning in rejections of march-in petitions in 1997, 2004, 2013, 2016, and 2023, which state 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.

- **Inconsistency with Congressional Intent.** Additionally, and notably, SWHR believes that the updated framework—as proposed by the administration—is inconsistent with congressional intent. In 2002, Senators Bayh and Dole [in a letter](#) to *The Washington Post* wrote that "Bayh-Dole 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. The 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."

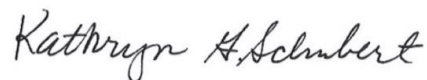
In the more than 40 years that this law has been in place, because the law deliberately makes no reference to pricing, march-in rights have never been exercised by a federal agency. Changing this precedent now could have myriad downstream, unintended consequences.

Again, SWHR appreciates and respects the intent of the administration to ensure that prescription drugs are accessible so that as many people as possible can get the care they need when they need it and lead healthy lives. However, the proposed framework could hinder scientific and medical progress at a time when we need progress most.

Thank you for the opportunity to provide comment in response to this RFI. We hope that the administration will act in a way that will sustain the U.S. federal research enterprise as well as the momentum that the Bayh-Dole Act has lent to scientific, technological, and public health progress.

If SWHR can be of assistance to you in your efforts, please do not hesitate to contact me at kathryn@swhr.org.

Sincerely,



Kathryn G. Schubert, MPP
President and CEO
Society for Women's Health Research