

February 5, 2024

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

**RE: GW's comments in response to NIST's *Request for Information Regarding the Draft Interagency Guidance Framework for Considering the Exercise of March-In Rights* (Federal Register/Vol. 88, No. 235/Dec. 8, 2023) ("Draft Guidance")**

The George Washington University (GW) is a global, comprehensive research institution and a member of the Association of American Universities (AAU). GW faculty and their students carry out cutting-edge research and scholarship in diverse fields. We partner with government, industry, community-based organizations, city leaders, and our academic peers in the U.S. and around the world to investigate some of the world's most complex challenges, including climate change, infectious diseases, education and health equity, trustworthy AI, gender-based violence, disinformation, cancer, financial literacy and more. State-of-the-art research facilities, such as the nanofabrication and imaging center in our 500,000-sq-ft Science & Engineering Hall or our biosafety labs, advance important discoveries and innovations. More than 35 cross-disciplinary institutes and dozens of school-based centers foster cutting-edge research projects in science and technology, engineering, public health, medicine, policy, and the arts and humanities.

GW strongly believes in promoting public access to inventions and technologies created by universities, including drugs and other medical innovations for which the federal government funded some of the basic research. Many GW faculty, staff, and students work at hospitals that treat patients and understand the impact of high drug prices on patients and their families. The draft guidance proposes using march-in rights to address this pressing problem. However, using this mechanism would likely have the unintended consequence of chilling innovation and disrupting collaboration between universities and industry. Investors would potentially avoid commercializing federally funded inventions because of the risk march-in would pose to their investment. In time, this would result in fewer beneficial drugs and other medical innovations being made available to the public.

U.S. taxpayers and the U.S. economy have greatly benefited from the public-private partnerships enabled by the Bayh-Dole Act. Before Bayh-Dole, 33,000 patents that were developed at least in part based on federal funding sat on the shelf without any investors, startups, or companies taking an interest in developing them into products and services that could benefit Americans. The Bayh-Dole Act encouraged academic research institutions to work with industry to explore if and how federally funded innovations could reach and benefit the public. The Draft Guidance make it less likely that industry will license and devote time, effort, and resources to developing federally funded innovation.

GW researchers have used federal funding in the process of inventing two drugs for cancer patients that are currently undergoing clinical trials. If march-in rights can be used for pricing purposes, it will be more

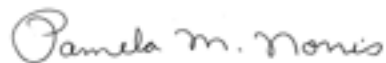
difficult for the companies developing these drugs to raise enough funds from investors to complete the clinical trials, obtain Food and Drug Administration approval, and make the drugs available to the public. It is possible that the added risk to licensees and investors from the Draft Guidance will prevent these drugs from reaching patients. This is one example of how, under the Draft Guidance, promising medical innovations could wither in academic research laboratories. It is possible that investors and shareholders would be unwilling to expend millions of dollars and years of effort for the testing and approvals that are necessary to bridge the gap between the research laboratory and the marketplace.

The federal innovation ecosystem thrives on collaboration. The Draft Guidance could slow technological progress and economic growth by disincentivizing companies from licensing technologies from government-funded research. GW is proud that our university can play an active role in technological advancement and economic growth in partnership with government, other universities, our community, and industry.

Please refer to the comments submitted by AUTM for additional details related to each of the points above.

Thank you for considering this input.

Sincerely,

A handwritten signature in cursive script that reads "Pamela M. Norris".

Pam Norris  
Vice Provost for Research  
The George Washington University