Duke | OFFICE for RESEARCH & INNOVATION

Vice President for Research and Innovation

119 Allen Building, Box 90037
Durham, NC 27708
Office Phone: (919) 681-6438
Email: jennifer.lodge@duke.edu

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Dr. Laurie E. Locascio
Under Secretary of Commerce for Standards and Technology
Director, National Institute for Standards and Technology

RE: Request for Information Regarding the Draft Interagency Guidance Framework for Considering the Exercise of March-In Rights

The public-private partnership among the federal government, research universities and industry remains unparalleled and has resulted in the United States being the premier country for innovation and entrepreneurship. For over forty years, the Bayh-Dole Act has provided support for this partnership by authorizing U.S. universities, nonprofit organizations, and small businesses to retain title to their federally funded intellectual property. The Bayh-Dole Act and its founders never intended that their namesake law could be used to set prices for products that had federal investment. This is not the time, nor the process, for changing the Act. I commend to your attention detailed comments submitted jointly from the following higher education associations: American Council on Education, Association of American Medical Colleges, Association of American Universities, Association of Public and Land-Grant Universities, AUTM and the Council on Government Relations. Duke University supports these comments and agrees that the proposed amendment should be fully withdrawn.

Duke University is one of the country's leading undergraduate and graduate universities. Duke's schools of medicine and engineering are consistently ranked in the top ten of research-intensive schools and are among the top ten recipients of funding from the National Institutes of Health (NIH). Our research and clinical expenditures top $1.3 billion, resulting in over 300 invention disclosures a year from our faculty and clinicians. Duke is successful in translating these research investments into impact. Over the past five years, Duke startups have raised close to $2 billion in public and private financing; a number of these companies are in the public market or soon will be, others have been acquired, and others have entered into partnerships with industry. In addition to a vibrant pipeline of new therapeutics ranging from vaccines, antibodies, mRNA and gene and cell therapy treatments, commercial products from Duke research impacting health and well-being include:

- Myozyme® for treatment of Pompei disease
- Uplinza® for treatment of neuromyelitis optica spectrum disorder (NMOSD)
- Oreserdu® for treatment of metastatic breast cancer
- Kystexxa® for treatment of refractory gout
- Rethymic® the first-ever treatment for congenital athymia.

While some of the above therapeutics were initiated using federal funding, all are licensed to our pharmaceutical partners who invested millions of dollars in clinical trials to move them to FDA approval.

In addition to the above products, Duke scientists, who in many cases with also received federal funding, are making significant contributions to the areas of quantum computing, metamaterials and artificial intelligence applications for health and other applications. Example spinout companies that have partnered with Duke in these areas include:

- IonQ, the first quantum computing company to go public.
- Evolv, which develops advanced sensors and AI for security and screening currently in use in schools and stadiums across the country.
- Kymeta, which develops antennae for satellite and cellular connectivity.
- Pivotal Commware
- Solar Unsoiled, an AI-powered monitoring solution to mitigate soiling in solar panels.

Put simply, creating new medicines and high-tech products is an expensive endeavor with inherent risk. Our partners depend on the revenues of the few successful discoveries to subsidize countless misfires. The investors who take our inventors' research to the commercial marketplace must be confident that when their discoveries and inventions come to market, competitors won't steal their ideas and deprive them of an opportunity to recoup their upfront costs and earn a return on their investment. Enabling a lower barrier for invoking march-in rights results in investors losing the opportunity to recoup their investments, and the next generation of researchers and investors learning that remuneration is far from guaranteed. The effect on innovation and the potential for new life-saving and changing products would be chilling.

Through the Small Business Innovation Research (SBIR)/Small Business Technology Transfer (STTR) programs , the federal government has demonstrated their understanding that public investment in partnership with private companies significantly improves our economy as well as the day-to-day lives of the general public. For example, the newly created Advanced Research Projects Agency-Health (ARPA-H) states that its mission is the "development of high-impact research to drive biomedical and health breakthroughs to deliver transformative, sustainable, and equitable health solutions for everyone." The program recognizes that the activities it funds . . ."cannot be readily accomplished through traditional research or commercial activity." ARPA-H *itself* recognizes the importance of commercial partnership by stating:

> "We measure our success by producing technologies that grow beyond ARPA-H and survive without perpetual ARPA-H funding. These are the most common transition pathways for ARPA-H program performers:
>
> 1. Large, established companies with existing infrastructure for development and sales & distribution.
> 2. Venture capital-backed emerging companies with demonstrated commitment to a technology's domain area.
> 3. De novo startups capable of attracting venture capital or other funding."

In addition to ARPH-H, the CHIPS and Science Act of 2022 states that it "will boost American semiconductor research, development, and production, ensuring U.S. leadership in the technology that forms the foundation of everything from automobiles to household appliances to defense systems."

How can billions in investment by the taxpayer be successful if *any entity*, including foreign companies, can easily file march-in petitions for successful products? Why would a company or investor take the risk of licensing a university technology that had federal funding if their

exclusive rights could be lost in an instant to a potential competitor? The draft guidelines would not only apply to future technologies developed with federal funding, they would also apply to already commercialized inventions, thus betraying the trust licensees, investors, and companies placed in a long-established system. For that matter, any company that collaborates with or spins out from a recently named Economic Development Administration (EDA) Tech Hubs, 31 hubs across 32 states which will share $500 million in grant funding from the CHIPS and Science Act, would be at risk having their entire business subject to future "march-in" by the government. This could discourage potential collaborators and unnecessarily stifle innovation. While the public rhetoric surrounding these proposed amendments, focuses on drug pricing, in reality, march-in rights will have little to no impact on drug prices. A recent study by the group Vital Transformation reviewing drugs approved between 2011 and 2020 in the United States found that 99% of approved drugs would not be subject to "march-in" -- only 5 out of 361 would. In all, 92% of approved drugs received no federal funding at all; and for the remainder, the government did not fund research into all the active patents.

Notable is the recent announcement of Arena BioWorks, which launched January 12, 2024, as a “privately funded, fully independent biomedical institute to shorten the path from insight to therapeutics.” The company’s press release noted: "*Arena's single source of funding frees our scientists* from the typical short-term cycles of grant and venture capital funding. Our aim is to accelerate progression from deep mechanistic human biology to biotech-enabled drug development." While unstated, it is clear that this new venture also frees any resulting innovation from the potential for march-in rights as Arena will not seek or receive federal funding. Is this the future that the administration wishes for the United States – a two-part system of haves and have-nots where those with the financial wherewithal choose not to partner with the federal government and where potentially valuable early innovations at universities and small companies never see the light of day for lack of private investment?

Laurie, I appreciate this opportunity to provide comments, and your consideration of these comments. In emphatic agreement with AAU, APLU, AAMC, ACE, COGR and AUTM, I urge the full withdrawal of the proposed guidance on march-in rights in its entirety.

Best Regards,

Jennifer K. Lodge, PhD
John Strohbehn University Distinguished Professor
Vice President for Research and Innovation
Duke University