



Cornell University

Research&Innovation

February 6, 2024

*Via Electronic Submission*

Dr. Laurie E. Locascio

Director

National Institute of Standards and Technology

100 Bureau Drive

Gaithersburg, MD 20899

**RE: Comments submitted by Cornell University in response to the *Request for Information Regarding the Draft Interagency Guidance Framework for Considering the Exercise of March-In Rights***

Dear Director Locascio:

On behalf of Cornell University, we respectfully submit the following comments to the National Institute of Standards and Technology (NIST) in response to the agency's *Request for Information Regarding the Draft Interagency Guidance Framework for Considering the Exercise of March-In Rights* ("Draft Guidance Framework"). Cornell appreciates your diligence in seeking public input on the proposed changes and welcomes this opportunity to comment.

[Cornell University](#) is a privately endowed research university and a partner of the State University of New York. As the federal land-grant institution in New York State, Cornell has a responsibility to make contributions in all fields of knowledge in a manner that prioritizes public engagement to help improve the quality of life in our state, the nation, and the world. Cornell's research expenditure in 2022 was \$1.18 billion dollars, supporting cutting edge research and discoveries in a broad array of areas in medicine, engineering, agriculture, computing and information, veterinary medicine, chemistry, among many others.

[Weill Cornell Medicine](#) is a professional school of Cornell University, offering a Doctor of Medicine (MD) degree, Doctor of Philosophy (PhD) degrees across a range of biological and immunological areas of inquiry, and six master's degrees. Our core mission is to improve the lives of citizens in our communities and around the world through patient care and innovative research. Our clinical faculty provide care in outpatient locations throughout New York City and at our affiliate hospitals, while the medical breakthroughs that have been discovered by the physician-scientists at our institution have had global impact.

The [Center for Technology Licensing \(CTL\)](#) is Cornell's central technology transfer office, and a

key part of the university's ecosystem to bring innovation from lab to the marketplace. In the past five years, entrepreneurs launched 78 new ventures based on Cornell inventions and those companies raised \$2.2 billion in funding to grow those businesses; industry partners entered 457 licenses and options to commercialize Cornell technologies; and more than 300 products based on Cornell technologies are currently in the marketplace.

Like other universities in the United States, Cornell relies on the system created by the Bayh-Dole Act for technology transfer. Since its passage in 1980, the Bayh-Dole Act has brought tremendous value and innovation to the U.S. economy. It is responsible for adding nearly [\\$2 trillion to the US GDP](#) by enabling tech transfer from universities and non-profits to the private sector, mobilizing private investments to translate and commercialize inventions that benefit the American public. It is essential to continue the success of the Bayh-Dole Act if our country is to retain its leadership in innovation and technological advancements.

In general, Cornell has serious concerns about the Draft Guidance Framework. We believe, based on our long history with the Bayh-Dole Act, that it would not reduce prescription drug prices, but would rather hinder American innovation and the U.S. economy. Cornell applauds the Biden Administration's efforts to address prescription drug affordability as one of the central concerns with health care in our country. We believe, however, that using march-in rights through the Bayh-Dole Act is ill-suited for this purpose. Not only will it fail to achieve the intended goal of reducing prescription drug prices, but it will also undo the success of the Bayh-Dole Act in translating innovation funded by government into the engine for the growth of the knowledge-based economy and job creation.

The comment letters from the Association of American Universities (AAU), Association of Public Land-grant Universities (APLU), Association of University Technology Managers (AUTM), Bayh-Dole Coalition, and National Venture Capital Association (NVCA) have addressed many important factors in response to the Draft Guidance Framework. Cornell endorses those comments, and place special emphasis on the following points:

**The Draft Guidance Framework will not result in reduced drug costs. Instead, it will drive away investment in federally funded technologies for new ventures and commercialization partnerships.**

Drug affordability is an important health policy priority for the country and Cornell applauds the Biden Administration's determination to address this important issue. We believe, however, that exercise of march-in rights are ill-suited for this purpose. Not only will they fail to achieve their intended goal, but they could also result in unintended consequences detrimental to the policy and objectives of the Bayh-Dole Act.

University-invented technologies, although groundbreaking at times, are usually below the technology readiness level (TRL) optimal for commercialization. Low TRL significantly impedes the licensing rate of university technologies to companies. This problem is even more acute in the therapeutic area. Licensees or investors in startups typically invest tens to hundreds of millions of dollars and more than a decade of time and resources to develop and bring to market a new drug predicated on basic university research. In recent years, many universities

have tried to increase the prospects of licensing of these early-stage technologies with the help of new mechanisms such as gap funding, incubators, accelerators, and other programs. Since Cornell has engaged in activities and programs that improve TRL, we have seen improvements in licensing and venture creation.

The risk of price-based march-in rights will discourage potential licensees, disincentivize the commercialization of federally funded inventions, and decrease the likelihood of university technology adoption. This will likely lead to the scenario where new products, particularly new drugs, will no longer be based on the technologies of federally funded intellectual property to the detriment of the U.S. economy, consumers, and U.S. global competitiveness. This would have a negative impact on Cornell's technology transfer enterprise, making it much harder to find willing commercial partners and significantly less likely that Cornell startups looking forward five years would be able to keep pace with the \$2.2 billion raised from 2019 to 2023 – the funding invested into those companies to de-risk and bring safe, new products to market and to patients.

University technologies often serve as the foundational discoveries that drive the drug development programs of commercial entities and new ventures. By the time most drugs reach the market after lengthy and costly clinical development, however, they are protected by multiple patent families and other classes of regulatory exclusivity. In many cases, just one or two patents in a drug's intellectual property portfolio would be subject to march-in rights, making it highly unlikely that exercising those rights would act as an effective means of price control. A [2023 study](#) found that only five of the 361 novel therapies studied had government interests in patents for the mechanism of action and composition matter of the drugs, and only 1 percent would be subject to march-in rights.

In addition, the Draft Guidance Framework puts at risk federal programs that aim to shorten or enhance the commercialization pipeline, such as the highly successful Small Business Innovation Research (SBIR) and Small Business Technology Transfer (STTR) programs, the CHIPS & Science Act's ambitious goals to reimagine the domestic semiconductor industry, and the administration's visionary Executive Order on Advancing Biotechnology and Biomanufacturing Innovation. Success of all these programs relies on access to federally funded university research, discovery, and innovation.

If the Draft Guidance Framework is adopted, resulting in fewer public-private partnerships in drug discovery, development costs and timelines are likely to increase as the incentive to form effective partnerships falls away.

### **The Draft Guidance Framework does not align with the intent and the successful 40-year history of Bayh-Dole Act.**

The Bayh-Dole Act's provision for march-in rights allows seizure only for egregious failure to engage in developing federally-funded patents. [Senators Bayh and Dole specifically stated](#) *“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. This omission was intentional...Government alone has never developed the new advances in medicines and*

*technology that become commercial products. For that, our country relies on the private sector. The purpose of our act was to spur the interaction between public and private research so that patients would receive the benefits of innovative science sooner."*

The Draft Guidance Framework mistakenly assumes that the pricing of a product is a relevant consideration for whether a federal agency can or should exercise the Bayh-Dole Act's march-in provision. This inappropriate presumption would effectively amend the Bayh-Dole Act and directly contradict the U.S. government's interpretation and application of the march-in provision during the last 43 years.

If adopted, the Draft Guidance Framework will severely chill the willingness of commercial entities and new ventures to license, and of investors to invest in, technologies arising from federally funded academic research due to the uncertainty and risk created by the possibility that price controls could be used as the reason for the exercise of march-in rights. This will be particularly true for industries that have been historically reliant on federally funded intellectual property across many verticals including life sciences, agriculture, renewable energy, telecommunications, and emerging industries. Undermining the Bayh-Dole Act will threaten our country's position as the world leader in innovation and knowledge-based economy in an increasingly competitive global environment.

Thank you again for the opportunity to provide comments. For the reasons laid out in this letter, we respectfully request you withdraw the Draft Guidance Framework as written. We would be pleased to elaborate on any of the points made in this letter and look forward to working with you going forward.

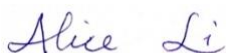
Sincerely,



Krystyn Van Vliet, Ph.D.  
Vice President for Research and Innovation  
Professor, Meinig School of Biomedical  
Engineering and Materials Science &  
Engineering



Hugh Hemmings, Jr., M.D., Ph.D., FRCA  
Senior Associate Dean for Research  
Joseph F. Artusio, Jr. Professor and Chair,  
Department of Anesthesiology  
Professor of Pharmacology



Alice Li, Ph.D.  
Executive Director  
Center for Technology Licensing



Lisa Placanica, Ph.D.  
Senior Managing Director  
Center for Technology Licensing,  
Weill Cornell Medicine