July 26, 2023

Lyric Jorgenson, Ph.D.
NIH Office of Science Policy
6705 Rockledge Dr #750
Bethesda, MD, 20817

Dear Director Jorgenson,

The Bayh-Dole Coalition appreciates the opportunity to submit comments to the National Institutes of Health (NIH) in advance of the agency's workshop on Transforming Discoveries into Products: Maximizing NIH's Levers to Catalyze Technology Transfer on July 31, 2023.

Perhaps the easiest way for the NIH to continue promoting successful technology transfer is to uphold the agency's longstanding commitment and respect for the Bayh-Dole Act of 1980. Partnerships under Bayh-Dole have made the U.S. the unquestioned leader in the life sciences. When the Covid-19 pandemic hit, the world looked to us for a solution, and we didn't let them down. NIH should be very proud of your role in that achievement.

As you are aware, NIH advances America's scientific progress and well-being not only by conducting research in its own labs, but also by funding R&D at universities and nonprofits across the country. For over 40 years, resulting discoveries have been turned into breakthrough therapies thanks to the Bayh-Dole Act. The law gives universities, small companies, and federal laboratories the ability to retain the patents on their discoveries and license them for their development and commercialization. That process is extremely risky and expensive. Most times even the best efforts fail. When they do, companies take the hit. But under our system, taxpayers receive a tremendous return on their investment in public research in the form of life-saving and life-improving technologies, medical devices, and drugs, benefitting people here and around the world.

We should keep in mind the critical factor in our success—finding private sector companies, primarily small businesses, which are willing to assume the risk and expense of turning NIH-supported inventions into useful therapies. As you know all too well, many times it is very difficult to attract even one company as a potential licensee because most of the resulting discoveries are at such an early stage. It was to help bridge this gap that NIH created your newest institute, the National Center for Advancing Translational Sciences, which states the realities you all face very well: "A novel drug can take 10 to 15 years and more than $2 billion to develop, and failure rates occur in about 95 percent of human studies." (https://ncats.nih.gov/about). Many academic institutions have created programs to move their technologies further down the R&D pipeline, reducing the risk of development for their industrial partners. Finding effective means to lessen the risk of developing new therapies would be the most significant improvement we could make to increase the impact of NIH-funded R&D.

More times than not, the companies who take on the burden of commercializing NIH-funded inventions are entrepreneurial start-ups, which risk everything to get a product to market. These are also the entities which should be consulted about how NIH is performing and where improvements can be made.

As you consider today's recommendations, it would be well to keep in mind this criteria for evaluating the comments you are receiving -- does this make it easier or harder to find industry partners which drive our innovation system?

It might also be well to keep in mind why the Bayh-Dole Act has worked day in and out for 43 years. When we were creating the law, we didn't go to people with theories, we went to people with decades of hands-on experience funding and managing federally-funded inventions. Indeed, the experience we particularly drew upon was that of NIH. Two of the principal architects were Norman Latker, NIH's patent counsel, and Howard Bremer of the Wisconsin Alumni Research Foundation, one of the creators of the profession of academic technology management. Both Latker and Bremer knew from personal experience why the pre Bayh-Dole era failed to commercialize NIH-funded inventions and how to create the authorities and incentives to correct the problem. The resulting success of the Bayh-Dole Act and its extension to the federal laboratories through the Federal Technology Transfer Act (which Latker wrote) speaks for itself.

Thus, you would do well to put the recommendations you are receiving into two buckets -- one for those with theoretical knowledge and another for those who have actually licensed, managed, and most importantly, commercialized federally funded inventions. Hopefully, it goes without saying which bucket deserves greater weight.

More than any other agency, NIH should be commended for preserving Bayh-Dole. NIH has consistently rejected attempts to undermine the law through the misuse of "march-in" rights by opponents who claim it allows the government to set prices on successfully developed products. As someone who was in the room when Bayh-Dole was conceived, who staffed the bill for Senator Birch Bayh, putting together the hearings of the Senate Judiciary Committee, writing the Committee's report on the legislation, and later overseeing its implementation at the Department of Commerce, I can say with some authority that is not how the law works. But you don't have to take my word for it. Every Administration which has received petitions to "march in" for price controls has rejected them as not sanctioned under the statute. The Biden Administration is only the latest to confirm that view.

NIH deserves considerable credit for your steadfast commitment to the rule of law, even though incredible political pressures have been applied against you. Some of you have even been attacked personally for not giving in to those who seek to overturn Bayh-Dole. At a time when many have lost faith in our institutions, your conduct illustrates what public service is all about.

Now those who oppose Bayh-Dole have disinterred a failed policy last seen in the 1990s. Then bowing to political pressures, NIH inserted "reasonable pricing clauses" stipulating how resulting products would be priced if they were based on inventions arising from its Cooperative R&D Agreements (CRADAs) or exclusive licenses. Contrary to the predictions of its proponents, this provision didn't lower drug costs -- it collapsed industry partnerships.

Realizing the disaster unfolding before its eyes, NIH scrapped this policy in 1995 declaring "the pricing clause has driven industry away from potentially beneficial scientific collaborations with PHS [public health service] scientists without providing an offsetting benefit to the public." The number of CRADAs increased fourfold in the years following that repeal. NIH knows firsthand that "reasonable pricing" provisions are

counter-productive. They will only deny the public access to new discoveries protecting the public health.

Our system works. It deserves to be preserved and defended. Hopefully, today's exercise will help make NIH commercialization even more effective. The Bayh-Dole Coalition stands ready to help achieve that goal in any way that we can.

Again, thank you for all that you have done -- and continue to do -- to protect and defend public health.

Thank you,

Joseph P. Allen
Executive Director
Bayh-Dole Coalition