Bayh-Dole COALITION

Celebrating the past. Protecting the future.

May 10, 2023

The Honorable Vern Buchanan
Chairman
Subcommittee on Health
House Ways and Means Committee
1139 Longworth House Office Building
Washington, D.C. 20515

The Honorable Lloyd Doggett
Ranking Member
Subcommittee on Health
House Ways and Means Committee
1139 Longworth House Office Building
Washington, D.C. 20515

Dear Chairman Buchanan and Ranking Member Doggett:

On behalf of the Bayh-Dole Coalition, I appreciate having the opportunity to provide comments in advance of your May 10 hearing "Examining Policies that Inhibit Innovation and Patient Access." Specifically, I'd like to draw your attention to past policies and present proposals that deter companies from commercializing medical technologies that originate at federally-funded academic research centers and federal laboratories which are at the cutting edge of life science research.

The coalition is a diverse group of innovation-oriented organizations committed to celebrating and protecting the Bayh-Dole Act, which jumpstarted American innovation by allowing federally-funded research universities, small companies, and nonprofit labs to retain and license the patents on the discoveries they made. Nowhere has this impact been greater than in the creation of badly-needed drugs, vaccines, and other medical therapies.

Prior to that 1980 law, the federal government retained the patent rights for the research discoveries it fully or partially funded. Bureaucrats licensed less than 5% of those patents to companies that could turn good ideas into real-world products for consumers. Even worse, not a single new drug was developed despite the billions of taxpayer dollars invested in National Institutes of Health R&D under those policies, policies which destroyed incentives for the private sector to assume the tremendous risk and expense necessary to turn federally-funded inventions into useful products. And nowhere are these risks and costs greater than in drug development which can easily cost companies $2.6 billion on average with little chance the drug will make it through the development pipeline.

Thanks to our system of public-private sector R&D alliances made possible by Bayh-Dole, today, the United States leads the world in the life sciences. We are particularly unique in that half of our new drugs originate in small companies. While no drugs were developed under prior government patent policies, under Bayh-Dole, at least 300 new drugs and vaccines are now fighting disease here and abroad.

By allowing universities to own and manage their federally-funded inventions, we launch three new companies and nearly three new products based on academic patents every day of the year. No other country comes close to this success. Currently, more than 15,000 startup companies spun out of campuses help drive our economy, keeping us at the forefront of innovation.

Despite these successes, there are those who want to return us to the pre-Bayh-Dole era of stagnation. We have seen firsthand that such efforts do not work. For example, the federal government found out the hard way that undermining patent licenses would cause companies to pull back from public-private partnerships. In the late 1980s, the National Institutes of Health began inserting a "reasonable pricing" clause in licensing deals known as cooperation research and development agreements, or CRADAs. The clause essentially gave the NIH the ability to relicense a patent if it objected to the price of any commercialized product. Proponents predicted that this provision would lead to reducing drug prices. That never happened. What did happen was companies walked away from NIH partnerships.

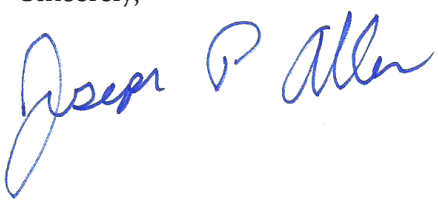
The policy change caused the number of CRADAs signed to plummet, and the NIH reversed course in 1995 after concluding that "the pricing clause has driven industry away from potentially beneficial scientific collaborations with PHS (public health service) scientists without providing an offsetting benefit to the public. Eliminating the clause will promote research that can enhance the health of the American people."

There are also those who urged the Biden administration to abuse the Bayh-Dole Act's "march-in" rights and invoke them to relicense patents on drugs they deem too expensive. Because the law provides no such authority, every petition filed on this basis has been correctly dismissed by every administration, Democratic or Republican, which considered them. The Biden administration was the most recent, dismissing a petition to march in on the prostate cancer drug, Xtandi. That was the fourth time this particular petition has been appropriately dismissed.

Unfortunately, such attempts to misuse the law make many industry partners, particularly small companies, wonder if the government can be trusted to enforce the law as written. If this confidence is lost, we face great peril as evidenced by the unprecedented rallying of our public and private sectors to combat the Covid-19 pandemic. That effort will not be replicated if we ever allow the Bayh-Dole Act to be misused by its opponents.

Our patent-based Bayh-Dole system works. It is a recognized international best practice. For these reasons, I urge the committee to recognize that strong and predictable intellectual property protections are necessary for public-private partnerships to succeed and produce new lifesaving therapies for patients.

Sincerely,



Joseph P. Allen
Executive Director
Bayh-Dole Coalition

CC: Chairman Jason Smith