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Dear Ms. Brooks-LaSure and Dr. Seshamani,

Thank you for the opportunity to comment on the initial guidance for implementing the Medicare drug price negotiation provisions of the Inflation Reduction Act.

In considering how to proceed, it would be well to remember the adage: “First, do no harm.” While the issue of making drugs more affordable is well outside the scope of the Bayh-Dole Coalition, one factor stood out to us as posing a very real danger to our ability to continue to lead the world in the creation of life-saving therapies. That is the idea that those who commercialize federally-funded inventions have received some sort of advantage that should be used against them when negotiating drug prices. This is a serious fallacy which can do irreparable harm to the most innovative system in the world. And NIH should know this better than most.

Before 1980, the government took inventions away from their creators. When President Johnson asked the Comptroller General why no drugs were created from the billions of taxpayer dollars funding NIH research, the answer was that the incentives needed for the private sector to undertake the tremendous risk and expense of development had been destroyed. That finding eventually led to the passage of the Bayh-Dole Act, which restored the incentives of our patent system needed for effective public/private sector partnerships. Those alliances make the United States the unquestioned leader in the life sciences.

While partnerships between our academic research institutions, federal laboratories, and the private sector are critical, industry is assuming the risk. Those risks are particularly heavy on the small companies which drive innovation, especially when it comes to developing new drugs. The U.S. is the only country in the world where small companies routinely play crucial roles in creating breakthrough drugs.

Despite the tremendous successes of our system, those who want to return us to the pre-Bayh-Dole era claim that the government is “derisking” inventions it helps to create, giving developers an unfair advantage. That is demonstrably false.

Government discoveries are embryonic, more like ideas than products. That is particularly true for developing new drugs. A new [study](#) “The Relative Contributions of NIH and Private Sector Funding to the Approvals of New Biopharmaceuticals” examined the investment of NIH and industry in 18 FDA-approved

therapies, which cited NIH-supported inventions. NIH provided \$0.670 billion in funding against \$44.3 billion from private industry. And even that can be misleading, as the vast majority of new therapies fail in the development pipeline. Industry eats those costs.

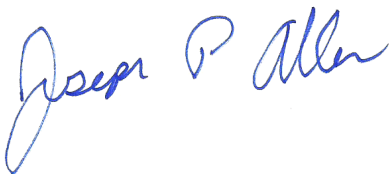
The other fallacy is that companies are lined up to partner with NIH or academic research centers. As those running your programs will attest, most times, it is very difficult to find even one company willing to assume the burden of taking a government-funded invention to market. That's particularly true for drug development because of the enormous costs, decades of research required, and uncertainties in obtaining FDA approval. No company gets an "express lane" because they are working on a government-supported invention.

One of America's key advantages over our foreign competitors is that our system provides the authorities and incentives for entrepreneurial companies to develop government-funded inventions. That makes federal programs more effective at no cost to taxpayers. Companies assume this burden knowing the odds are stacked against them. If we want to continue to be the innovation wonder of the world and the source of new drugs and other therapies, the last thing we should do is make those burdens even heavier.

For these reasons, I urge you not to use the fact that a company beat the odds and made it across the finish line against them in negotiating Medicare drug prices. Any benefits in short-term price reduction will be massively offset by those walking away from working with NIH and our research universities in the future.

That's a price we simply cannot afford to pay.

Sincerely,



Joseph P. Allen  
Executive Director  
Bayh-Dole Coalition