



March 1, 2022

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Dear Secretary Becerra:

I understand you have received a request by a group of Members of Congress to adjudicate a drug price by revoking intellectual property rights granted under the 1980 Bayh-Dole Act. On behalf of Research!America, the nation's largest not-for-profit advocacy and public education alliance committed to faster medical and public health progress, I urge you to reject that request.

The Bayh-Dole Act grew out of a recognition that breakthrough discoveries funded by the federal government were not making their way from universities and small businesses into the marketplace because the federal government retained the right to the intellectual property that arose from those discoveries. Before Bayh-Dole's enactment in 1980, no new drugs or vaccines had been commercialized from the results of federally funded research. By modifying patent policy to enable universities and small businesses to retain the title to innovations developed under federally funded research programs, the Act incentivized innovators and investors to make the additional, often risky, investments needed to move these technologies from basic research to the marketplace.

The innovations unlocked by Bayh-Dole support 6 million jobs today, helped launch 15,000 start-up companies and contributed \$1.7 trillion to US economic output¹. The Economist called the Bayh-Dole Act "perhaps the most inspired piece of legislation to be enacted in America over the past half-century." In an editorial entitled "[Innovation's Golden Goose](#)"², the publication states, "Together with amendments in 1984 and augmentation in 1986, this unlocked all the inventions and discoveries that had been made in laboratories throughout the United States with the help of taxpayers' money. More than anything, this single policy measure helped to reverse America's precipitous slide into industrial irrelevance."

While concern over healthcare affordability and access is warranted, the 1980 Bayh-Dole Act is not the vehicle to address that complex set of issues. It makes no sense to pit the drive for innovation against the need for affordable healthcare. The Bayh-Dole Act gives the federal government the right to "march in" and force universities and small businesses to license their innovations to

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additional companies under a carefully proscribed set of circumstances, none of which includes misappropriating this law to adjudicate prescription drug prices. In a 2002 Washington Post oped, Senators Bayh and Dole made clear that the Act did not include invoking “march-in” provisions to set drug prices: “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..... The law instructs the government to revoke such licenses only when the private industry collaborator has not successfully commercialized the invention as a product.”

We believe that health care affordability and access are systemic issues that require an assessment of all levers that influence both factors and that involve all stakeholders. It would be a privilege to be part of that conversation as the Department of Health and Human Services, under your leadership, pursues policies to maximize the return on every healthcare dollar. In that context, we urge you to refrain from misappropriating provisions of the Bayh-Dole Act by "marching in" on intellectual property protections under the auspices of adjudicating prescription drug list prices, and in so doing discourage the technology transfer that has fostered so many of the medical advances patients today and tomorrow need.

Thank you very much for your leadership on these critically important issues.

Sincerely,

A handwritten signature in cursive script that reads "Mary Woolley".

Mary Woolley
President and CEO
Research!America