Congress of the United States
Washington, DC 20515

September 19, 2023

Gina Raimondo
Secretary
Department of Commerce
1401 Constitution Ave. NW
Washington, DC 20230

Xavier Becerra
Secretary
Department of Health and Human Services
200 Independence Ave SW
Washington, DC 20201

Dear Secretary Raimondo and Secretary Becerra,

We write to express the urgent need for the Interagency Working Group for Bayh-Dole (Working Group) to release a draft framework for public comment on the criteria and guidelines for agencies to exercise their authority to protect taxpayer investments in the development of innovative products, including pharmaceuticals. Your departments confirmed to us in a July 28th letter that it is the intent of the Working Group to have a published framework by the end of 2023. With only a little over 3 months left to meet your goal, and the need for a robust comment period, a draft framework must be released without delay.

American taxpayers are the angel investors in pharmaceutical research and development, investing billions of dollars each year. Researchers found every new drug approved from 2010 to 2019 involved taxpayer funding,[1] including during some of the riskiest stages of development.[2] In one recent analysis of 15 high-cost drugs developed with the assistance of National Institutes of Health scientists, it was found that taxpayers are charged an average price of $111,000 for treatments, the development of which they funded.[3] Moreover, Americans are paying up to about six times the amount for these drugs as patients in other developed countries.[4]

Finalizing a framework this year is critical to ensure accountability for the use of taxpayer dollars and deliver on the President's pledge to lower prescription drug prices for more Americans. Though Congress passed overdue reforms to help seniors afford some of their medications, the first negotiated prices will not be available until 2026, and no relief will be delivered to the more than 200 million Americans who do not qualify for Medicare. Under the Bayh-Dole Act, inventions developed with taxpayer funds must be made available to the public on "reasonable terms." The Biden Administration has the authority and responsibility to rein in

[1] https://www.ineteconomics.org/uploads/papers/WP_133-Revised-2021.0719-Cleary-Jackson-Ledley.pdf
[2] https://waysandmeans.house.gov/wp-content/uploads/2023/05/Kesselheim-Testimony.pdf
[3] https://www.sanders.senate.gov/wp-content/uploads/Public-Medicines-Report-updated.pdf
[4] https://www.sanders.senate.gov/wp-content/uploads/Public-Medicines-Report-updated.pdf

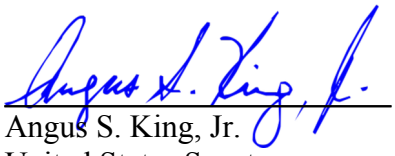
monopoly prices for all Americans and protect taxpayer investments that made these miracle cures and treatments possible.

We strongly urge you to immediately release a draft framework for public comment and finalize the framework this year.

Sincerely,

Lloyd Doggett
Member of Congress

Elizabeth Warren
United States Senator



Angus S. King, Jr.
United States Senator