United States Senate

WASHINGTON, DC 20510–6200

September 14, 2022

The Honorable Xavier Becerra
Secretary
Department of Health and Human Services
200 Independence Avenue, SW
Washington, D.C. 20201

The Honorable Chiquita Brooks-LaSure
Administrator
Centers for Medicare & Medicaid Services
7500 Security Boulevard
Baltimore, Maryland 21244

Dear Secretary Becerra and Administrator Brooks-LaSure:

Congress recently acted, on a party-line basis, to establish a permanent government price-setting program for prescription drugs, financed with billions of taxpayer dollars and enforced through an unprecedented excise tax of up to 95 percent. We write to express concerns with the disruptive and distortive administrative undertaking that the implementation of this far-reaching federal expansion will inevitably represent, as well as to raise a number of questions regarding your department's plans for putting this new program into practice. Given the outsize risks that the impending government pricing initiative poses for patients, frontline health care providers, small businesses, and the American economy as a whole, we urge you to weigh both direct and indirect impacts on health care access, research and development (R&D), and domestic manufacturing as you take the first steps toward implementing this program.

As the Congressional Budget Office (CBO) has confirmed, the government price controls codified under the recently enacted reconciliation legislation have the potential to increase launch prices for new medications, as well as to trigger fewer new drug approvals in the coming years. Scores of life-threatening conditions, from cancer to Alzheimer's and sickle cell disease, could see a substantial decline in possible treatment options on the horizon. Moreover, based on CBO's analysis, some manufacturers may choose to terminate participation in Medicare and Medicaid altogether as a result of the compulsory new price-setting program, jeopardizing access to a range of therapies and cures for the most vulnerable Americans. Other independent analyses have projected even more catastrophic consequences, from hundreds of thousands of domestic job losses to hundreds of billions in forgone R&D dollars. The innovation ecosystem that has made the United States the world's unquestioned life sciences leader, bolstered by thousands of startups and small businesses, may wither under this partisan legislation, particularly in the absence of careful, deliberative implementation and assertive, consumer-oriented oversight.

Given the profound health care, economic, and national security implications of this anomalous new federal program, we ask that you carefully consider these and other threats, from depressed drug discovery and development to diminished medical access and cascades of health care provider cuts. In light of the urgent importance of clarity and caution regarding the forthcoming implementation of this colossal government initiative, please provide the following information by the close of business on October 28, 2022:

- Consultation with Patient Advocates, Caregivers, Health Care Providers, Researchers, and Small Businesses: In drafting the authorizing legislation for the so-called Drug Price Negotiation Program, our colleagues opted to insulate initial implementation from the standard notice-and-comment rulemaking process typically required for substantive regulatory policymaking. This problematic policy choice will deny patients, caregivers, health care providers, researchers, small businesses, and other stakeholders the opportunity to engage with the Administration on key considerations and decisions regarding the program's operations and methodologies. The exclusion of patient voices from policymaking poses potentially catastrophic consequences, particularly for individuals living with rare diseases or with disabilities.
    - How does the Administration plan to incorporate these and other vital perspectives from the American public into the implementation of the government price-setting program?
    - What specific steps does the Administration plan to take in order to ensure robust consultation with affected entities, both during initial implementation and on an ongoing basis?

- Quality-Adjusted Life Years and other Discriminatory Metrics: A broad range of experts and advocacy organizations, including the National Council on Disability, have rightly criticized the use of so-called quality-adjusted life years (QALYs) and other similar metrics for devaluing the lives of certain populations, including those living with disabilities, as well as older individuals. While the reconciliation legislation includes vague language purporting to bar the use of comparative effectiveness research incorporating discriminatory measures along these lines, a number of analysts have flagged questions and concerns around the potential for government officials to sidestep this alleged prohibition in administering the price-setting program. To that end, CBO, in modeling the proposed pricing process enacted under this law, relied on data using QALYs.
    - What concrete steps does the Administration plan to take in order to implement and enforce the legislation's ban on the use of discriminatory comparative effectiveness research?
    - Does the Administration commit to excluding any and all research and analysis incorporating QALYs and other similar measures from its determinations and actions under this legislation?

- Methodology for Determining Prices: Critics of the reconciliation legislation have justifiably taken issue with the lack of a floor for Secretary-dictated prices under the new program, along with the absence of any meaningful opportunity for appeal. The law's preclusions of administrative and judicial review with respect to a range of key administrative actions and decisions regarding the program have further crystallized these concerns.
    - How does the Administration intend to address these concerns, which would enable penny pricing for even the most innovative therapeutic advances, with the risk of severely undermining and deterring crucial investment in life-saving technologies moving forward?

- What mechanisms for appeals and patient consultation does the Administration plan to establish with respect to the price-setting process?

- Bureaucratic Expansion: Our colleagues have financed this program with a staggering $3 billion in administrative funding. How, in specific terms, does the Administration plan to make use of this massive sum of taxpayer dollars?

- Monitoring Effects: What actionable steps does the Administration plan to take in order to monitor the effects of the new program on patient access, R&D investments, launch prices, new drug approvals, domestic manufacturing jobs, and other health and economic areas?

If you have questions about this request, please contact Conor Sheehey of the Senate Finance Committee staff.

Sincerely,

Mike Crapo
United States Senator

John Cornyn
United States Senator

John Thune
United States Senator

Richard Burr
United States Senator

Rob Portman
United States Senator

Pat Toomey
United States Senator

Tim Scott
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Roger Marshall, M.D.
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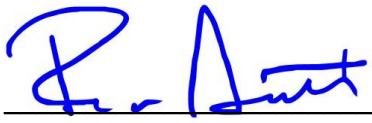
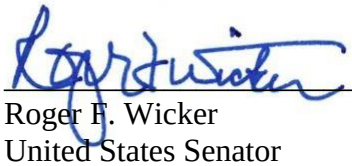
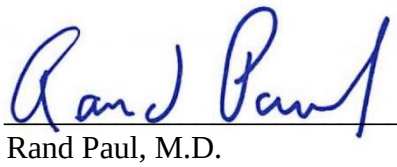


Rick Scott
United States Senator



Roger F. Wicker
United States Senator



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United States Senator

Marsha Blackburn
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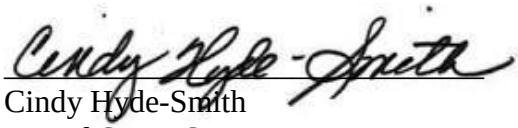
Mitt Romney
United States Senator



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