Congress of the United States
Washington, DC 20515

August 29, 2022

The Honorable Xavier Becerra
Secretary
U.S. Department of Health and Human Services
200 Independence Avenue SW
Washington, DC 20201

Dear Secretary Becerra,

We write to request additional information and regular Congressional briefings regarding the implementation of P.L. 117-169. We are disappointed that this version of the legislation did not benefit from any hearings, markups, or technical briefings featuring expert witnesses or you and members of the Department of Health and Human Services (HHS) who are now tasked with implementing this legislation. We request timely information and your commitment to transparency throughout the implementation process so that we, and the seniors who rely on medications, know how you plan to execute this law and the impact those decisions will have on their access to innovative medicines.

We know there will be less medical innovation and fewer medicines for Americans due to this law, no matter how it is implemented. The Congressional Budget Office (CBO),[1] the University of Chicago,[2] and many other independent analyses [3] have all confirmed this will lead to fewer cures amid the current reality of a recession and record-setting inflation. We likewise know that the inflation rebate penalties imposed by the law will result in higher launch prices and invite drug companies to manipulate their prices in other ways by tying price increases to the new statutory rate of inflation or spreading price increases across multiple drugs. That is not partisan hyperbole or speculation, but rather comes directly from CBO, which projected that the inflation-rebate and negotiation provisions would "increase the launch prices for drugs that are not yet on the market relative to what such prices would be otherwise."[4] This finding is also supported by previous analysis from the Centers for Medicare and Medicaid Services (CMS) Office of the Actuary, who concluded that an earlier version of the price control legislation would result in higher launch prices that would subsequently increase net Medicaid spending. [5]

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[1] The Congressional Budget Office (CBO), "Estimated Budgetary Effects of Subtitle I of Reconciliation Recommendations for Prescription Drug Legislation" (July 6, 2022), *available at* https://www.cbo.gov/publication/58290.

[2] Philipson, J. Tomas and Durie, Troy. (Nov. 29, 2021), The University of Chicago, *Issue Brief: The Impact of HR 5376 on Biopharmaceutical Innovation and Patient Health*, *available at* https://ecchc.economics.uchicago.edu/2021/11/30/issue-brief-the-impact-of-hr-5376-on-biopharmaceutical-innovation-and-patient-health/.

[3] Vital Transformation, Build Back Better Act: Total market impact of price controls in Medicare parts D and B, *available at* https://vitaltransformation.com/2022/07/build-back-better-act-total-market-impact-of-price-controls-in-medicare-parts-d-and-b/.

[4] The Congressional Budget Office (CBO), "Additional Information About Prescription Drug Legislation," (Aug. 4, 2022), *available at* Additional Information About Prescription Drug Legislation | Congressional Budget Office (cbo.gov).

[5] The Centers for Medicare and Medicaid Service (CMS), Office of the Actuary, Updated Financial Impacts of Titles I and II of H.R. 3, "Lower Drug Costs Now Act of 2019," *available at* https://www.cms.gov/Research-Statistics-Data-and-Systems/Research/ActuarialStudies/Downloads/HR3-Titles-I-II.pdf.

Our fear is that drug companies will divert more resources to complying with and gaming this new law than investing in the next generation of cures here in the U.S.

This legislation would be made even more damaging by a lack of transparency or the further politicization of an already tenuous process. If patients were to lose a voice in this process or if innovators and their real-world business perspective were to take a backseat to political calculations and bureaucratic hubris, countless Americans would lose access to even more potentially life-saving medicines or be forced to seek treatment from overseas. Therefore, we urge you to prioritize transparency and forthright communication throughout this process, especially since Democrats have prohibited any check on your power through the standard remedies of judicial review and administrative review, which are prohibited in this law.

The Committees seek ongoing information regarding HHS' implementation of this law. We therefore request a monthly briefing for staff from the Energy and Commerce Committee and Ways and Means Committee to update us of your plans and progress in implementing the law. We request the first briefing by September 19, 2022 and ask that you answer the following questions in writing by September 12, 2022.

1. Have you, or the staff you plan to designate to lead this process, had any prior experience setting prices for pharmaceutical products?
    a) Will there be any training related to the pharmaceutical products you, or the staff you plan to designate to lead this process, will be responsible for negotiating or any of the underlying economics involving the products and the underlying research, development, and supply chain issues that affect their costs?
2. Will HHS go through notice and comment rulemaking to set up this so-called negotiation process? If not, please explain.
    a) Will you commit to a public process in advance so that generic and biosimilar manufacturers know what they have to do and how they can anticipate price targets so they can bring competition to the market?
    b) Will you make transparent any guidance or formulas used by HHS to set the prices of medicines?
3. How does HHS intend to report to and keep informed its authorizing Committees on activities designated under Subtitle B in its implementation of the newly established Drug Price Negotiation Program?
4. While there is a variable statutory price ceiling for negotiated drugs, there is no explicit price floor. Will you commit to set a price floor for "negotiated" drugs with public input?
5. How will HHS plan for and respond to drug shortages if the price setting process leads to less access to necessary drugs, as we have seen in other markets where governments set the prices for a large percent of the market?
6. Section 11004 provides $3 billion to CMS for Fiscal Year (FY) 2022 and beyond to carry out the provisions of the negotiation provisions.
    a) What are HHS' implementation priorities for FY 2022 and FY 2023?
    b) How much does HHS plan to spend in FY 2022 and FY 2023, respectively?
    c) What guardrails and oversight mechanisms will be put in place to ensure this funding is not diverted to other agency functions or misused for other purposes?
    d) Do you anticipate hiring any new full-time equivalents (FTEs)? If so, how many do you plan to hire?

    e) Do you plan to transfer staff from existing functions within HHS or from other government entities to work on the program? If so, how many and which offices or programs will they be transferred from to work on this so-called negotiation program?

7. Does HHS intend to contract out any of the pricing analysis? If so, what controls will be in place to ensure funding is not excessive or improperly used by contractors?
    a) Will HHS commit that any external analysis shall include a diversity of viewpoints – including those who may be skeptical of the negotiation process's purported benefits – and not rely on any one foundation or entity for its analysis?
    b) What function will contractors have in the drug selection process, and will those contractors be competitively bid?
8. Will HHS select drugs based exclusively upon the criteria provided in section 1192 of P.L. 117-169, according to the highest total expenditures under Medicare Parts B and D? If not, what other criteria will be used to select "negotiation-eligible" drugs?
    a) If HHS plans to use other criteria, it will be even more important to make public the list of drugs subject to negotiation and those that may be subject to negotiation in the following years.
9. Are there any additional factors, other than those prescribed in section 1194 (e), which will be used for the price offers in the process?
    a) Section 1194 (e)(1) includes manufacturer-specific data that you shall consider when determining your "offers" and "counteroffers" including research and development costs. How will HHS' consideration of these factors prioritize and incentivize domestic manufacturing while preventing drug development and manufacturing from being transferred to China?
    b) Can you confirm, per section 1194 (e), that in setting prices, HHS will not at any point use Quality Adjusted Life Years (QALYs) or other comparative clinical effectiveness research or foreign price methodologies that treat the lives of elderly, disabled, or terminally ill patients as of lower value than those who are younger, non-disabled, or not terminally ill?
10. Notably absent from the statute is the Centers for Medicare and Medicaid Innovation (CMMI). Will you commit to keeping CMMI resources out of this new program and will HHS refrain from using CMMI resources and authorities to backfill any of the functions of this new program?
11. What actions or authorities is HHS considering to prevent drug manufacturers from "gaming" or avoiding the so-called negotiation program?
    a) Specifically, what sorts of actions might HHS take to prevent manufacturers from suspending the excise tax and pulling their products from both Medicare and Medicaid once they terminate the relevant Part D discount programs and Medicaid rebate agreements?
    b) Could a brand drug manufacturer terminate the relevant rebate agreements, thereby suspending the excise tax, and then re-enter the respective markets once generic competition comes to market in order to escape the so-called negotiation process for their branded product? If so, what will HHS be doing to address these issues?
12. Will HHS undertake any analysis of how these pricing policies will affect physician reimbursement?

a) Will HHS follow the President's Executive Order on Promoting Competition in the American Economy and undertake any analysis related to health care consolidation before finalizing its drug selections or prices?[6]

13. How will HHS incorporate patient feedback in the negotiation process, including the drug selection process?
    a) Will HHS be convening a patient advocacy panel to ensure patient access to drugs? If not, why not?
    b) Will patient advocates be empowered to have a say – and veto power – over which drugs are subject to the negotiation process?
14. Please elaborate on the process through which a Medicare beneficiary can still receive timely access to a drug if there is a negotiation delay or impasse.
15. Please provide any documents or records relating to a cost-effectiveness analysis of H.R. 3 and the related policy provisions on so-called price negotiations for prescription drugs in Medicare, which was ultimately included in P.L. 117-169. If no such analysis has been done, please explain why.
16. Please provide a plan for spending the $3 billion provided by Congress to implement the so-called price negotiation provision in P.L. 117-169.
17. Has HHS done any analysis for extending so-called price negotiations beyond the 20 drugs authorized in P.L. 117-169?
18. Does HHS plan to use any legislative authority, other than that provided in P.L. 117-169. to implement the so-called prescription drug negotiation provision? If so, please identify any such legislative authority.

Please contact Alec Aramanda or Brittany Havens of the Energy and Commerce Committee Minority staff and Jay Gulshen, Rachel Kaldahl, or Sean Clerget of the Ways and Means Committee Minority staff with any questions and to schedule the requested briefings.

Sincerely,

Cathy McMorris Rodgers
Republican Leader
Committee on Energy and Commerce

Kevin Brady
Republican Leader
Committee on Ways and Means

[6] The White House, Executive Order on Promoting Competition in the American Economy, (July 9, 2021), *available at* https://www.whitehouse.gov/briefing-room/presidential-actions/2021/07/09/executive-order-on-promoting-competition-in-the-american-economy/.