Congress of the United States
Washington, DC 20515

November 16, 2021

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

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

Dear Secretary Becerra and Administrator Brooks-LaSure:

We are writing today to request that you (or your designee) brief us and our staff as soon as possible on how the Department of Health and Human Services (HHS) and the Centers for Medicare and Medicaid Services (CMS), would implement the drug pricing provisions of Sections 139001 through 139003 in H.R. 5376 released November 3[1] and further amended November 4 if enacted into law.

As lawmakers, it is our duty to understand the details of legislation that we are being asked to vote on and how it will impact people and families. Due to significant changes and rewrites that have occurred since the policies in H.R. 5376 were voted on by the House Committees on Energy & Commerce and Ways & Means, prior technical assistance that we have received from your agencies is no longer up to date or applicable to the legislation now before us. Based on our understanding, these provisions, as currently drafted, would dramatically change how the United States pays for drugs and upend the incentives that exist today for innovation and generic and biosimilar competition.

Many of these new policies seem to provide the Secretary vast discretion in carrying out the law. One policy of particular concern is giving the Secretary the discretion to set the minimum price for negotiation of a drug at $0, meaning there is no price floor for the supposed negotiation. We are interested in how the administration will approach the pricing process, including how a floor will be determined and justified by the agency, the plan to deal with firms who do not accept a price offer that is below the ceiling, and how the prices set by HHS for drugs chosen for the "Drug Price Negotiation Program" will affect other federal drug price programs. We would also need to know how the methodology and justification for price offers will be made transparent, as well as the available remedies for parties involved if the prices are not agreeable.

[1] Committee on Rules, Rules Committee Print 117-18, Text of H.R. 5376, Build Back Better Act. *Available at* https://rules.house.gov/sites/democrats.rules.house.gov/files/BILLS-117HR5376RH-RCP117-18.pdf.

Further, given changes to the proposed language that would ratchet down reimbursement for cures and treatments after a set number of years, we would be interested in any analysis that your agencies have conducted on the number of generic drugs and biosimilars that would fail to come to market over the next 10 years, 20 years, and 50 years compared to the baseline of current law. We also request analysis on how these policies might impact the incentives for pediatric studies and dosage form changes, especially in the area of mental health and substance use disorder drugs or drugs that affect those with chronic diseases.

The American people also deserve to know how your Department's implementation of this legislation could impact their loved ones with disabilities and debilitating diseases. Earlier this year you came before our Committees to discuss the President's Budget and you were asked about the use of Quality Adjusted Life Years (QALYs) as a drug pricing tool that would put a price tag on lives and discriminate against Americans with disabilities and debilitating diseases. Unfortunately, this legislation may still allow for discriminatory tools such as QALYs to be used in the drug price setting framework. On November 12, the National Council on Disability, an independent federal agency who advises the President, Congress, and other federal agencies, wrote Democratic Congressional leaders about the updated legislation to "strongly encourage the inclusion of an unambiguous ban on the quality adjusted life year (QALY) within the text of the Build Back Better Act (H.R. 5367) and located within the bill text in such a way as to convey unequivocal application to the entire Sec. 1194. "Negotiation and Renegotiation Process."[2] They also wrote that efforts to lower drug prices, "should not be based on the use of a pricing methodology that devalues the lives of people with disabilities in its design and has been proven to be discriminatory in its impact in access to treatments for people with disabilities and chronic illnesses." [3]

It is of the utmost importance to our constituents that we understand whether and how this negotiation process could import these discriminatory policies into drug prices in the Medicare program. For example, could the non-federal Average Manufacturer Price (NFAMP) discounts offered by other federal departments and agencies utilize QALYs, and could those prices be used by your Department to set Medicare prices? If so, we would like to understand how you might operationally incorporate those prices and discounts into the Medicare program. And if not, we would like to know where in the statute it precludes you from doing so and what kind of assurances the American people have that QALYs will not be used in the setting of Medicare drug prices.

We are also interested in any updated analyses from the CMS Office of the Actuary related to the impact that this legislation, including the updated inflation rebate penalties, might have on Medicare beneficiaries' premiums and drug launch prices. As you know, the CMS Office of the Actuary released its analysis of H.R. 3 in November 2019 and found that the inflation rebate penalty provisions would have resulted in $30 billion in additional spending on behalf of seniors, including more than $24 billion in increased premiums, over the initial 10-year

[2] National Council on Disability, "NCD Letter to Congress recommending QALY ban in Build Back Better Act." (Nov. 12, 2021). *Available at* https://www.ncd.gov/publications/2021/ncd-letter-qaly-ban.
[3] *Ibid.*

period.[4] The analysis also anticipated "higher brand name prices associated with higher expected launch prices and higher list prices to partially offset the Medicare inflation rebate," in the private health insurance market.[5] Knowing that there have been substantial changes to the drug pricing provisions since then, it is critical that we have updated analysis of these provisions including their impact on our seniors and the impact on drug prices, including incentives for higher launch prices.

While ideally our committees would hold public hearings on such transformative legislation so that all stakeholders could understand the intended and potential unintended consequences of this proposal, it seems the Democrats intend to potentially hold a floor vote the week of the 15th.[6] It is imperative we meet with you or your designee before such vote. Please have your staff follow up with Grace Graham of the Energy and Commerce Committee staff and Stephanie Parks of the Ways and Means Committee staff to schedule this meeting.

Sincerely,

Cathy McMorris Rodgers
Ranking Member
Committee on Energy and Commerce

Kevin Brady
Ranking Member
Committee on Ways and Means

[4] Centers for Medicare & Medicaid Services, Office of the Actuary. "Updated Financial Impacts of Titles I and II of H.R. 3, "Lower Drug Costs Now Act of 2019." (Nov. 8, 2019). *Available at* https://www.cms.gov/Research-Statistics-Data-and-Systems/Research/ActuarialStudies/Downloads/HR3-Titles-I-II.pdf.
[5] *Ibid.*
[6] Speaker.gov. "Dear Colleague on President Biden's Transformative Build Back Better Agenda." (Nov. 7, 2021). *Available at* https://www.speaker.gov/newsroom/11721.