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December 20th, 2021

The Honorable Charles E. Schumer
Majority Leader
United States Senate
Washington, D.C. 20510

Re: Drug Pricing Provisions of the Build Back Better Bill

Dear Majority Leader Schumer,

The Global Healthy Living Foundation is excited to see lowering drug prices for patients prioritized in the Build Back Better Act. We do have some questions regarding the potential implementation of the bill that we hope your office considers as the bill progresses to a final vote. We have long believed that the most important price in healthcare is the price that the patient ultimately pays, and we hope that this bill will help reduce that burden.

By way of background, the Global Healthy Living Foundation (GHLF) is a 501(c)(3) New York-based patient group that works to improve the quality of life for people with chronic disease, often focusing on those least able to advocate for themselves. Through our websites, social media channels, and conventional media, GHLF reaches more than 10 million chronically ill people monthly in the United States – in English and Spanish. Our patient community is among the hardest hit by high drug prices, and we have long championed ways to reduce these costs. It is our hope that the final Build Back Better Act will accomplish just that, and finally begin to improve our healthcare system.

Who will set prices?

As the bill currently stands, the Secretary of Health of Human Services appears to be the arbiter in determining the price of certain medications. While the bill gives the Secretary this power, it does not provide information on whether there will be any rulemaking or public comment period to allow for outside input into these decisions. Additionally, without a defined process or system for oversight, these pricing decisions could be subjected to largescale changes when a new Secretary or federal administration takes over, ultimately hurting patients. We are also concerned that the lack of specific guidelines could lead to a Secretary that chooses to use disreputable Value Assessment Models such as Quality Adjusted Life Years (QALYs) to set the price. Whenever these metrics are used, patients lose. As the National Council on Disability recently stated regarding the QALY “...it’s use in the US would result in rationing care to seniors and people with disabilities”.¹ To address these issues, we believe a formal process for either public comment or oversight should be included in the final bill

¹ NCD Letter to House Committees with Concerns Regarding H.R. 3,
<https://ncd.gov/publications/2021/ncd-letterhouse-committees-concerns-regarding-hr-3>

language, and we hope to see an explicit ban on the use of QALYs or similar metrics which could be used to set prices.

Impact on generics and biosimilars

The current bill utilizes the power of the government to lower the cost of specific medications rather than allowing for traditional market competition to lower the prices. This could have the adverse impact of disincentivizing the production of generic and biosimilar drugs. If a biosimilar of a negotiated biologic enters the market, it will do so competing against a medication that already has a significant market share and a (presumably now) drastically reduced price. Perhaps there could be a commission to review the impact of specific price negotiation on the current generic and biosimilar market, as well as the impact the negotiation would have on biosimilars that are preparing to enter the market. This commission would also help address our first concern by adding an additional layer of public input into these discussions and negotiations.

Drug rebates and formulary construction

If HHS can pick and choose specific treatments that they will set the price for, but not other similar drugs or drugs that share the same classification, the negotiated drugs will no longer be able to offer rebates as a way to incentivize PBMs to place them on their formulary. The current bill language tries to get around this by mandating the inclusion of negotiated treatments on a formulary, but it does not address where on a formulary, or what utilization management practices may or may not be used on it. As we have seen countless times across the country, just because a treatment is on a formulary does not mean that patients have immediate access to that treatment. We would like to see more clear language around the formulary placement of negotiated drugs, and how utilization management practices like step therapy and prior authorization can or cannot be utilized by PBMs.

Overall, while we are concerned about how quickly the drug pricing language has been added to this legislative effort, without debate or sufficient hearings, GHLF remains encouraged by the direction of the Build Back Better Act. We hope that the concerns we raised will be addressed in the final language of the bill and are excited to help ensure the ultimate goal of this legislation is achieved. Please reach out if you have any questions or would like to further discuss any of the points raised here.

Sincerely,



Steven Newmark, J.D., MPA
Director of Policy

