July 11, 2022

The Honorable Charles E. Schumer
Majority Leader, U.S. Senate
322 Hart Senate Office Building
Washington, DC 20510

Dear Leader Schumer:

The Association for Accessible Medicines (AAM) and its Biosimilars Council share in the goal of lowering prescription drug costs for America's patients and seniors. However, in an effort to target high prices on brand-name drugs, the proposed prescription drugs reforms – in particular the Medicare negotiations framework – being considered as part of a revised reconciliation package will reduce patient savings from lower-cost generic and biosimilar medicines. Even though competition from generic and biosimilar medicines is the only proven solution to consistently lower the cost of prescription drugs, the proposed price setting scheme will reduce competition, harm future savings from generic and biosimilar medicines, and increase costs for employers and patients with private insurance. **We thus urge all U.S. Senators to oppose the prescription drug reforms under consideration as part of a revised Build Back Better reconciliation package.**

America's patients rightfully expect Congress to address the ever-increasing prices of brand-name prescription drugs. High launch prices on new brand biologics, combined with an increasing trend of anti-competitive patent and rebate ploys designed to delay or prevent competition from more affordable biosimilars and generics, are keeping access to medicines out of reach for too many patients. These dynamics are compounded by flawed policies that reward health plans and pharmacy benefit managers (PBMs) for the use of high-cost, high-rebate brand drugs and that allow plans and PBMs to raise out-of-pocket costs for generics, even as the prices for those same generics are falling. As a result, patients, including Medicare's seniors, are missing out on billions of dollars in savings from biosimilars and generic drugs each year. However, the proposed price setting approach fails to adequately address these challenges, while dampening future competition and reducing savings from generic and biosimilar medicines.

**Negotiations Framework Increases Uncertainty for Generic and Biosimilar Developers**

The proposal increases the risks associated with developing generic and biosimilars without addressing the fundamental barriers to competition from lower-cost medicines, such as abuses of the patent system and brand rebate traps.[1] The proposed timelines for when the Secretary can initiate the price setting process will significantly increase the risk to develop new lower-cost generics and biosimilars. Although the proposal exempts drugs with generic or biosimilar competition from the price setting process, the bill only does so through unrealistic timelines for

[1] AAM, "The Evidence is Clear: Biosimilar Competition Will Achieve More Savings for Patients Than Build Back Better's Negotiations," December 2021 (link).

that competition to enter the market. For many complex generics and biosimilars, it can take 8-10 years to develop new, more affordable medicines. And it can take many more years to conclude patent litigation and then launch a complex generic or biosimilar medicine. But the new price setting process would not begin until years after a developer commits to developing a lower-cost generic or biosimilar. This means that generic and biosimilar manufacturers will have no way to know whether a brand-name drug will be selected for negotiation or what the negotiated price may be. This dynamic fundamentally changes the ability of generic and biosimilar manufacturers to plan and make investment decisions that can be up to and exceed $250 million per drug.[2]

While the revised bill includes a provision that could allow for a temporary delay of the negotiated price if the Secretary determines a biosimilar launch was imminent, there are a number of limitations on the provision make it difficult to utilize. By way of example, a biosimilar developer would need to show a "high likelihood" of biosimilar competition by a "clear and convincing" evidentiary standard. Moreover, the narrow two-year window to launch does not appropriately account for how long it takes developers to challenge brand-name patents. Large patent estates and time-consuming patent litigation are currently and will continue to prevent biosimilars from being able to launch within two years of receiving FDA approval. These dynamics will likely deter manufacturers from making investments in biosimilar and generic medicines in some instances – and will result in less competition and ultimately higher costs for patients.

**Generic and Biosimilar Medicines Savings Exceeds Potential from Negotiations Framework**

After years of high-risk investment, biosimilar developers are poised to deliver tremendous savings to the U.S. health care system, improving access for patients and lowering prescription drug costs. New biosimilars are expected to launch for a range of treatments for patients with diabetes, arthritis, macular degeneration, oncology and more. In the next few years, 42 biosimilars are on track to launch.[3] Gold-standard data firm IQVIA estimates biosimilar savings of $30 billion annually as a result. In comparison, the Congressional Budget Office estimates the negotiations framework saves $18-24 billion per year from 2028 to 2031. Thus, more savings is projected from market-based competition than from the Build Back Better proposal and it starts now. In addition, as more complex generics, biosimilars, and interchangeable biologics become available, there is the potential for even greater savings to the U.S. health care system as providers and payers take advantage of the opportunities to increase access and reduce costs for patients.

**Negotiations Framework Increases Costs on Employers and Patients with Private Coverage**

Reduced competition from generic and biosimilar medicines impacts all patients, not only Medicare beneficiaries. The dampening effect this legislation would have on competition would cause employers and patients with private insurance to lose savings these populations have historically enjoyed from robust generic competition and growing biosimilar competition. Instead,

[2] Erwin Blackstone, PhD and P. Fuhr Joseph, Jr., PhD, "The Economics of Biosimilars," Am Health Drug Benefits, September-October 2013 (link).
[3] Cardinal Health, "2022 Biosimilars Report," February 2022 (link).

there may be fewer new, more affordable generic and biosimilar medicines, leaving the commercial and employer markets captive to the high cost of brand-name drugs.

When reviewing a nearly identical proposal in the House-passed Build Back Better Act, AAM's Biosimilars Council assessed the potential lost savings to the commercial market for medicines used to treat asthma (Xolair) and rheumatoid arthritis (Orencia), as examples.[4] For just two products, lost savings would be between $4-$7 billion between 2027-2030. This is lost savings that would otherwise be used to lower patient out of pocket costs and reduce insurance premiums for employers and employees.

For these reasons, we must oppose the Medicare negotiations framework and its impact on patient access to lower-cost medicines. There are other bipartisan steps to address patent abuse and brand rebate traps that are already under discussion in Congress that can meaningfully reduce drugs costs without harming generic and biosimilar savings.[5] We strongly encourage Congress to reconsider its approach.

Sincerely,

Dan Leonard
President and CEO

[4] AAM, "Proposed BBB Negotiation Framework Discourages Biosimilar Competition, Imposes Higher Costs on Commercially Insured Patients and Their Employers," December 2021 (link).
[5] AAM, "Senate Finance Hearing Highlights Ways to Reduce Drug Prices without Harming Patients," March 2022 (link).