SafeBiologics
ALLIANCE for SAFE BIOLOGIC MEDICINES

December 2, 2021

The Honorable Nancy Pelosi
Speaker, U.S. House of Representatives
U.S. Capitol, H-232
Washington, D.C. 20515

The Honorable Kevin McCarthy
Republican Leader, U.S. House of Representatives
U.S. Capitol, H-204
Washington, D.C. 20515

Re: H.R. 5376, §139404 - Temporary Payment Increase for Biosimilars (oppose)

Speaker Pelosi and Leader McCarthy:

We write to you today to raise our concerns with a provision in **H.R. 5376 ("Build Back Better")** that would provide for a temporary payment increase under the Medicare program for certain biosimilar biological products to encourage the development and use of such products.

Over the past six years, the U.S. has made rapid progress in approving and launching biosimilars. Since 2015, 31 have been approved and at least 20 are now available to patients with cancer, rheumatoid arthritis, Crohn's disease, psoriasis and other conditions.[1] This includes two "interchangeable" biosimilars which can be substituted at the pharmacy level without physician involvement.

Biosimilars launch at wholesale acquisition cost (WAC) 15% to 37% lower than their reference products and up to 40% below the reference product's average sales price (ASP). Biosimilars have already achieved significant US market share, around 80% for filgrastim biosimilars, 70% for trastuzumab and bevacizumab biosimilars, and 55% for rituximab biosimilars. As more become available, the increased competition has driven down prices of both biosimilars and innovator biologics. According to the FDA's Janet Woodcock[2], the savings from biosimilars was $2.5 billion in 2019, and *more than three times* that much in 2020. Simply put, the system is working.

These successes demonstrate there is no need to artificially incentivize biosimilar uptake. Yet H.R. 5376 would increase reimbursement for biosimilars in Medicare Part B to Average Sale Price (ASP) plus 8%, up from the current ASP plus 6%. This troubling proposal is not new, appearing in 2019's *Prescription Drug Pricing Reduction Act*[3], *The BIOSIM Act* (H.R. 4455) and *The Lower Drug Costs Now Act* (H.R. 3), and 2021's BIOSIM Act (H.R. 2815).

We, the undersigned patient advocates and health care practitioners, continue to have serious concerns with the potential negative impacts of this policy on patient care. It would create financial incentives for physicians to prescribe biosimilars; in effect, it would provide the doctor a 33% bonus for using a biosimilar instead of an originator product.

[1] https://biosimilarscouncil.org/resource/fda-biosimilars-approvals/
[2] https://www.raps.org/news-and-articles/news-articles/2021/11/fda-touts-success-and-challenges-in-biosimilar-dev
[3] https://www.finance.senate.gov/chairmans-news/grassley-wyden-release-updated-prescription-drug-pricing-reduction-act-reach-agreement-on-health-extenders

Treatment decisions can and should take into consideration a number of factors, including economic factors such as the affordability of the drug for the patient, but the physician-patient relationship could be seriously undermined when physicians are rewarded financially for choosing one medicine over another. Every patient should be confident that their physician will prescribe the product that is in their best interest, not the one that is the most profitable to the physician personally.

We share the goal of increasing biosimilar uptake and increasing patient access to biologic therapies. We also firmly believe this proposal is unnecessary, misguided, and potentially harmful.

Instead, all products should continue to compete on a level playing field. Advantaging one manufacturer's product over another not only distorts the treatment-decision making process and undermines the physician-patient relationship, but also undermines the competition-based policies that are currently lowering prices and expanding patient access.

Sincerely,

Michael S. Reilly, Esq.
Executive Director, Alliance for Safe Biologic Medicines.

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