SafeBiologics
ALLIANCE for SAFE BIOLOGIC MEDICINES

July 28, 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.2815 - temporary payment increase for biosimilars (oppose)

Speaker Pelosi and Leader McCarthy:

We write to you today to raise our concerns with **H.R.2815** – a bill "to amend title XVIII of the Social Security Act to 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 five years, the U.S. has made rapid progress in approving and launching biosimilars. Since 2015, 29 have been approved and at least 18 are now available to patients with cancer, rheumatoid arthritis, Crohn's disease, psoriasis and other conditions.[1] To put this tremendous progress in perspective, the European Medicines Association approved only 13 products during the first five years of its biosimilar program.

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). Filgrastim biosimilars (on the market for five years) have achieved a 72% share, while bevacizumab and trastuzumab biosimilars, launched in 2019, have already achieved approximately 40% share. Biosimilar competition and originator manufacturer responses are translating into significant savings. Annualized savings reached $6.5 billion in Q2 of 2020.[2] Biosimilar savings over the next 5 years are projected to exceed $100 billion.[3]

Despite these successes, some have proposed to artificially incentivize biosimilar uptake by increasing reimbursement for biosimilars in Medicare Part B to ASP plus 8%, up from the current ASP plus 6%. This troubling proposal is not new, and has wisely been rejected by the Senate several times. In 2019 alone, this policy was defeated in the *Prescription Drug Pricing Reduction Act*[4], *The BIOSIM Act* (H.R. 4455) and *The Lower Drug Costs Now Act* (H.R. 3).[5]

We, the undersigned patient advocates and health care practitioners, have serious concerns with the potential negative impacts of this policy on patient care. It would create financial

[1] https://biosimilarscouncil.org/resource/fda-biosimilars-approvals/
[2] Fein AJ. Drug Channels Institute®; The Booming Biosimilar Market of 2020. Available at: https://www.drugchannels.net/2020/10/the-booming-biosimilar-market-of-2020.html. October 6, 2020.
[3] QVIA. Biosimilars in the United States 2020-2024. Competition, Savings and Sustainability. Available at: https://www.iqvia.com/-/media/iqvia/pdfs/institute-reports/iqvia-institute-biosimilars-in-the-united-states.pdf. October 2020.
[4] https://www.finance.senate.gov/chairmans-news/grassley-wyden-release-updated-prescription-drug-pricing-reduction-act-reach-agreement-on-health-extenders
[5] https://schrader.house.gov/newsroom/documentsingle.aspx?DocumentID=392607

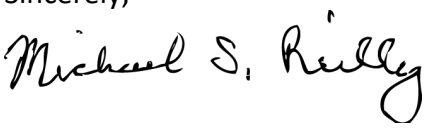
incentives for physicians to prescribe biosimilars; in effect, it would provide the doctor a 33% bonus for using a biosimilar instead of an originator product.

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,



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