November 23, 2020

The Honorable Mitch McConnell
Senate Majority Leader
U.S. Capitol, S-230
Washington, D.C. 20510

The Honorable Charles Schumer
Senate Democratic Leader
322 Hart Senate Office Building
Washington, D.C. 20510

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

To Leader McConnell, Leader Schumer, Speaker Pelosi, and Leader McCarthy:

Since the Food and Drug Administration (FDA) approved the first biosimilar medicine in 2015, important progress has been made to increase access to more affordable, advanced treatments for patients. Millions of patients living with cancer, diabetes, rheumatoid arthritis, Crohn's disease, anemia, psoriasis and other conditions are benefiting from the 17 biosimilars, including insulin, that are now FDA-approved and on the market.[1] Moreover, patients are beginning to realize savings from biosimilar medicines and overall savings totaled $2.2 billion last year.[2]

Biosimilar medicines, however, continue to face significant barriers to competition. As Secretary of Health and Human Services (HHS) Alex Azar stated when announcing the FDA's Biosimilars Action Plan, "… competition from biosimilars is desperately needed. The challenges to building a market for biosimilars are even more complex than others in the drug space."[3] One barrier is the misaligned financial incentives within the Medicare program where payment policies currently encourage physicians to use high-cost brand biologics even when a lower-cost biosimilar medicine is available.

In 2019, a bipartisan effort to fix this problem was advanced in Congress. The Senate Finance Committee, under the leadership of Chairman Charles Grassley and Ranking Member Ron Wyden, included a provision to increase reimbursement for biosimilars by two percent (ASP+8%) in the *Prescription Drug Pricing Reduction Act*.[4] The additional reimbursement would only apply when the biosimilar's price is lower than the brand-name biologic's price. In addition, Congressman Kurt Schrader and Congressman Greg Gianforte introduced *The BIOSIM Act* (H.R. 4455) and were successful in getting the provision included in *The Lower Drug Costs Now Act* (H.R. 3).[5]

As Congress considers its end-of-the-year priorities, the undersigned organizations representing patients, providers, and taxpayers strongly encourage you to enact this bipartisan fix to encourage greater adoption and use of lower-cost biosimilar medicines. We believe this modest

[1] https://biosimilarscouncil.org/resource/fda-biosimilars-approvals/
[2] https://accessiblemeds.org/2020-Access-Savings-Report
[3] https://www.hhs.gov/about/news/2018/07/18/hhs-secretary-azar-praises-fda-announcement-of-biosimilars-action-plan.html
[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

proposal – which the Congressional Budget Office scored as revenue neutral[6] – would move us closer to fulfilling the promise of biosimilars and helping millions of patients who live with chronic conditions.

Thank you for considering our views,

Allergy & Asthma Network
Alliance for Aging Research
American Consumer Institute
American Pharmacists Association
Center for Freedom and Prosperity
Consumer Action
The Endocrine Society
International Pemphigus and Pemphigoid Foundation
R Street Institute
Sjögren's Foundation
The Society of General Internal Medicine

[6] https://www.grassley.senate.gov/news/news-releases/grassley-wyden-release-cbo-score-prescription-drug-bill