September 27, 2023

Senator Mike Lee
363 Russell Senate Office Building
Washington, D.C. 20510

Re: S.6 - Biosimilar Red Tape Elimination Act, 117th Congress (OPPOSE)

Dear Senator Lee,

On behalf of the Alliance for Safe Biologic Medicines (ASBM), and as a former Associate Deputy HHS Secretary under HHS Secretary Mike Leavitt, I write to strongly urge you to **reconsider your sponsorship of S.6 – the Biosimilar Red Tape Elimination Act.** ASBM is an organization of patient advocates, physicians, pharmacists, and manufacturers of both originator and biosimilar products, working together since 2010 to promote the safe use of biosimilars as an important tool to control healthcare costs. We share your goals of achieving savings for the health system through the safe use of biosimilars. **However, we believe that Congress was prescient in acknowledging the complexity involved in determining interchangeability when it granted the FDA authority under the Biologics Price Competition and Innovation Act of 2009 (BPCIA) to determine what data is needed in order to approve a biosimilar as interchangeable. We believe the FDA should retain this ability, as removing it would needlessly weaken the interchangeable biosimilar standard and risk undermining the confidence it has engendered among physicians and patients.**

When discussing potential changes to the interchangeable biosimilar standard, it is critical to first understand it accurately. There is a common misconception that "all biosimilars are interchangeable in Europe", and that the U.S. lags far behind with only four of its biosimilars (roughly 10%) interchangeable. This misunderstanding stems from the fact that the word "interchangeable" has different meanings in the U.S. and Europe.

In the U.S., interchangeable means "substitutable by a pharmacist". It refers to a biosimilar which may under state law be automatically substituted (substituted without prescriber involvement) **at the pharmacy level.** Four such products now exist, and still more are pursuing this designation. *All biosimilars, however, are substitutable by the prescribing physician.*

In Europe however, the term "interchangeable" refers to **physician substitution**, not pharmacy substitution. (Notably, automatic substitution of biosimilars at the pharmacy level is extremely rare in Europe. In nearly every European country, physicians choose freely among many products including the originator and several biosimilars.) For example, in a recent statement, European Medicines Agency (EMA) explained all biosimilars it approves are "interchangeable" in that they "may be **prescribed** interchangeably". It reiterated that this does not refer to pharmacy substitution: "Member States will continue to decide…whether automatic substitution is allowed at the pharmacy level."

In other words, **all U.S. biosimilars are already interchangeable under the European definition**, in that they may be prescribed interchangeably by the physician. Additionally, four of them can be substituted automatically at the pharmacy due to providing extra data to the FDA.

The FDA's interchangeability standard – its extra data requirements - have earned physician and patient confidence: A 2021 survey[1] of U.S. physicians revealed 57% said they'd be more likely to prescribe an interchangeable biosimilar; 59% said that an interchangeable designation makes them more comfortable with a pharmacy-level substitution of that biosimilar in place of the prescribed originator.

Physicians and patients worldwide value data, including switching studies. Surveys of Canadian physicians found that 82% wanted switching studies before automatic substitution was permitted. The figure was nearly identical, 81%, when I shared Australian physician survey findings with officials in their Department of Health, who expressed admiration for the FDA's interchangeability standard in providing such assurances.

However, S.6 would prevent the HHS Secretary from requiring a switching study as part of the data package to receive the interchangeable designation. This would inappropriately limit the FDA's authority to determine what data is scientifically appropriate for a particular biosimilar to provide in order to receive the designation. The FDA has thus far exercised its flexibility in making these determinations and should be allowed to continue to do so.

The interchangeable designation has not only boosted physician and patient confidence, it has done so without becoming a barrier to biosimilar uptake and savings. European biosimilar uptake varies by country and product but hovers within the 20-80% range. Similarly, in the U.S. filgrastim, trastuzumab, and bevacizumab biosimilars have an uptake rate of 80%. Rituximab biosimilars stand at 60% and infliximab, pegfilgrastim, and erythropoietin-stimulating agent (ESA) biosimilars have 40% market share. U.S. biosimilars have generated $21 Billion in savings in the past six years alone.[2]

In conclusion, weakening the interchangeability standard is an unnecessary and potentially harmful step. By limiting the type of data the FDA can consider when determining suitability for automatic substitution it risks undermining the data-driven confidence physicians and patients have developed in interchangeables.

We urge you to reject this proposed change and to stand with patients, physicians, and manufacturers who are all invested in the responsible use of biosimilars.

Thank for the opportunity to voice our concerns on this critical matter.

Sincerely,

Michael S. Reilly

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

[1] http://gabi-journal.net/us-prescribers-attitudes-and-perceptions-about-biosimilars.html
[2] https://www.amgenbiosimilars.com/commitment/2022-Biosimilar-Trends-Report

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[1] http://gabi-journal.net/us-prescribers-attitudes-and-perceptions-about-biosimilars.html
[2] https://www.gabionline.net/biosimilars/research/Sustainable-biosimilar-policies-in-Europe
[3] http://gabi-journal.net/a-white-paper-us-biosimilars-market-on-pace-with-europe.html
[4] https://www.amgenbiosimilars.com/commitment/2022-Biosimilar-Trends-Report