BIOSIMILARS COUNCIL™
A DIVISION OF AAM

Increase Patient Access to Low-Cost Biosimilar Medicines by Removing the Arbitrary Distinction Between "Interchangeable Biologics" and "Biosimilars"

Summary:

When Congress created the pathway for FDA approval of biosimilars, it created a subcategory of biosimilars known as "interchangeable biologics". This distinction, which is not based on any scientific differences between the products, has resulted in brand misinformation, patient and provider confusion, and ultimately, hindered biosimilar adoption. Congress should deem all biosimilars to be interchangeable unless determined otherwise by the FDA and remove the distinction between biosimilar and interchangeable biologics.

The Problem:

- The Biologics Price Competition and Innovation Act (BPCIA) provides for the approval of biosimilars that are "highly similar and with no clinically meaningful differences" to high-priced brand biologics.
- It further provides for FDA determination – based on additional data provided by the biosimilar manufacturer – of biosimilars to be interchangeable with the brand biologic, which was intended to signify that the biosimilar can be substituted by a pharmacist without the approval of the treating physician.
    - A "biosimilar" versus "interchangeable biosimilar" designation is a **legal distinction, not a medical one**.
    - Whether a biosimilar is designated as "interchangeable" depends on the choice of the manufacturer. Once a manufacturer develops a biosimilar product and it is rigorously assessed and approved by the FDA, manufacturers can choose to market it immediately or submit additional data for the FDA to review if they want it to be designated "interchangeable." Biosimilars designated interchangeable by the FDA are not more effective, safer, of higher quality or more similar to the reference product than another biosimilar without the designation. Rather, it means that the manufacturer chose to pursue the costly process of submitting additional data to allow for pharmacy-level substitution. This distinction is unique to the U.S., and in places like Japan and EU, interchangeability is established immediately upon approval of the biosimilar.
    - All biologics, including biosimilars, must meet strict quality and safety regulations set by the FDA, but this extra data allows them to be substituted more easily at the pharmacy.[1] **Put simply, an interchangeable designation only impacts ease of access, not the safety, efficacy, or quality of the drug.**
- The U.S. is alone in having this two-tier designation.

1 https://www.goodrx.com/drugs/biologics/interchangeable-biosimilar-drugs

- The result:
  - Few biosimilars have pursued the interchangeability designation because of the high cost associated with it and the low return on investment. This is because most biosimilars are administered by a physician, in which case the "interchangeability" designation is irrelevant.
  - But the distinction has permitted brand misinformation intended to confuse and discourage patients and health care providers from using the biosimilar.
- FDA has emphasized that there is no scientific difference between biosimilars and interchangeable biologics through numerous educational offerings for providers and patients.
- And recently, FDA has proposed legislative changes to address this confusion by deeming currently approved biosimilars to be interchangeable and removing the statutory distinction.

The Solution:

Congress should enact legislation deeming biosimilars to be interchangeable with their reference product unless FDA determines otherwise. As part of this, Congress should eliminate the arbitrary distinction between biosimilars and interchangeable drugs.

This proposal would reduce patient and Medicare spending on costly drugs, while improving patient access to life-saving therapies and encouraging greater competition among biosimilars at a fraction of the cost of original reference biologics.

Current Legislative Initiatives:

The **Biosimilar Red Tape Elimination Act (S. 1954)** was introduced by Sens. Mike Lee (R-UT) and Ben Ray Lujan (D-NM) in June 2025.

- This legislation would remove the distinction between biosimilars and interchangeable biosimilars.
- The bill text is the same as the Senate HELP Manager's Amendment from last Congress that AAM had agreed on with committee staff.

Biosimilars Council, a division of AAM
601 New Jersey Avenue NW, Suite 805
Washington D.C., 20001

Tel: (202) 249-7100
Email: info@biosimilarscouncil.org

@biosimscouncil