# Biosimilar Red Tape Elimination Act

Biosimilars, which are "generic" alternatives to name-brand complex biologics, have the potential to significantly reduce the cost of biologic drugs through increased competition. Biosimilars have the potential to save Americans 42.9 billion dollars by 2027.[1] While the future looks promising, major obstacles remain to biosimilars achieving their full cost-saving potential. The FDA's two-tiered system for approval has confused physicians, patients, and states about biosimilars' safety and efficacy.

To gain approval, a biosimilar must undergo clinical testing to establish its safety and efficacy. The FDA's standard for approving a biosimilar is there must be "no clinically meaningful difference" between the biosimilar and its reference biologic. Bringing a new biosimilar to market costs as much as $300 million and can take as long as 9 years with 65% of the costs going to clinical trial development.[2]

However, even after approval, patients may not be able to access biosimilars because Congress created a separate designation: interchangeability. The interchangeable designation signals that biosimilars are significantly different from their reference products if they haven't been deemed "interchangeable" with their name-brand counterpart. Some states have passed laws that disallow pharmacists from automatically substituting a biosimilar for its reference biologic unless they are deemed interchangeable by the FDA. Biosimilars must go through costly and time-consuming studies to receive the interchangeable designation. In the past 14 years, the FDA has only approved 13 interchangeable biosimilars.[3]

Today, it is clear that switching studies is unnecessary. In 2022, after analyzing more than fifteen years of data, the European Medicines Agency (EMA) stated that there is no evidence that switching between a biosimilar and its reference product increases the risk of immunogenicity.[4] Since Congress created the interchangeability designation in 2009, voices in the scientific community have criticized it and its requirement for extra data on switching. In 2020, a published review from BioDrugs determined biosimilars approved in the U.S. and the EU found that comparative clinical studies consistently confirmed the efficacy of biosimilars and provided no new information relevant for approval purposes.[5] Senator Lee's bill would streamline the current regulatory pathway for biosimilar approval and align the law with the current scientific reality.

**Key Provisions**:
This bill would:

- Amend the federal code to state that all biosimilars, upon approval, shall be deemed interchangeable. The bill still uses the term "interchangeable" because states have crafted their own laws around interchangeability. Retaining that word would provide for minimal disruption to current biosimilar distribution.
- Strike the current requirement in code that has been used to justify switching studies.
- Create a cooldown period for certain biologics that were already granted exclusive interchangeable status.
- Instruct HHS and FDA to issue or retract relevant guidance.

[1] https://accessiblemeds.org/wp-content/uploads/2025/01/AAM-2024-Generic-Biosimilar-Medicines-Savings-Report.pdf
[2] https://www.mckinsey.com/industries/life-sciences/our-insights/three-imperatives-for-r-and-d-in-biosimilars
[3] https://www.pharmalawgrp.com/blog/21/fda-proposes-dropping-switching-studies-for-biosimilar-interchangeability/#:~:text=Over%20the%20past%2014%20years,seen%20across%20such%20switching%20studies.
[4] https://www.ema.europa.eu/en/documents/public-statement/statement-scientific-rationale-supporting-interchangeability-biosimilar-medicines-eu_en.pdf
[5] https://link.springer.com/article/10.1007/s40259-020-00422-1