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Biosimilar Red Tape Elimination Act

Congress: 119 (2025–2027, Current)

Chamber: Senate

Policy Area: Health

Introduced: Jun 4, 2025

Current Status: Placed on Senate Legislative Calendar under General Orders. Calendar No. 521.

Latest Action: Placed on Senate Legislative Calendar under General Orders. Calendar No. 521. (Jul 27, 2026)

Official Text: <https://www.congress.gov/bill/119th-congress/senate-bill/1954>

Sponsor

Name: Sen. Lee, Mike [R-UT]

Party: Republican • **State:** UT • **Chamber:** Senate

Cosponsors (5 total)

Cosponsor	Party / State	Role	Date Joined
Sen. Hassan, Margaret Wood [D-NH]	D · NH		Jun 4, 2025
Sen. Luján, Ben Ray [D-NM]	D · NM		Jun 4, 2025
Sen. Paul, Rand [R-KY]	R · KY		Jun 4, 2025
Sen. Schmitt, Eric [R-MO]	R · MO		Jun 24, 2025
Sen. Ossoff, Jon [D-GA]	D · GA		Jun 16, 2026

Committee Activity

Committee	Chamber	Activity	Date
Health, Education, Labor, and Pensions Committee	Senate	Referred To	Jun 4, 2025
Health, Education, Labor, and Pensions Committee	Senate	Markup By	Jun 17, 2026
Health, Education, Labor, and Pensions Committee	Senate	Reported By	Jul 27, 2026

Subjects & Policy Tags

Policy Area:

Health

Related Bills

Bill	Relationship	Last Action
119 HR 5526	Related bill	Sep 19, 2025: Referred to the House Committee on Energy and Commerce.

Biosimilar Red Tape Elimination Act

This bill deems all biosimilars licensed by the Food and Drug Administration (FDA) interchangeable with their reference products.

A biosimilar is a biological product (e.g., a drug or vaccine) that is very similar to a brand-name biological product (i.e., the reference product). Under current law, a biosimilar that meets additional requirements may be deemed interchangeable with the reference product; this designation allows pharmacists to substitute the interchangeable biosimilar when filling a prescription for the reference product, depending on state law. Further, the first biosimilar deemed interchangeable with a given reference product is awarded a period of marketing exclusivity.

The bill eliminates additional requirements for demonstrating interchangeability so that all licensed biosimilars are deemed interchangeable with their reference products. (Draft guidance released by the FDA in 2024 proposed to make some of these interchangeability requirements optional, including studies related to the safety of switching between use of the biosimilar and reference product. It has not been finalized.)

This change takes effect 60 days after the bill is enacted, and previously licensed biosimilars must be deemed interchangeable with their reference products on that date. However, the bill preserves the exclusivity period for first interchangeable biosimilars licensed before the bill's enactment. For example, if a new biosimilar licensed after the bill takes effect relies on the same reference product as an existing biosimilar that is subject to an unexpired exclusivity period, the new biosimilar is not deemed interchangeable with the reference product until the exclusivity period has ended.

Actions Timeline

- **Jul 27, 2026:** Committee on Health, Education, Labor, and Pensions. Reported by Senator Cassidy with an amendment in the nature of a substitute. Without written report.
- **Jul 27, 2026:** Placed on Senate Legislative Calendar under General Orders. Calendar No. 521.
- **Jun 17, 2026:** Committee on Health, Education, Labor, and Pensions. Ordered to be reported with an amendment in the nature of a substitute favorably.
- **Jun 4, 2025:** Introduced in Senate
- **Jun 4, 2025:** Read twice and referred to the Committee on Health, Education, Labor, and Pensions.

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