

S 2305

Biosimilar Red Tape Elimination Act

Congress: 118 (2023–2025, Ended)

Chamber: Senate

Policy Area: Health

Introduced: Jul 13, 2023

Current Status: Read twice and referred to the Committee on Health, Education, Labor, and Pensions.

Latest Action: Read twice and referred to the Committee on Health, Education, Labor, and Pensions. (Jul 13, 2023)

Official Text: <https://www.congress.gov/bill/118th-congress/senate-bill/2305>

Sponsor

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

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

Cosponsors (4 total)

Cosponsor	Party / State	Role	Date Joined
Sen. Braun, Mike [R-IN]	R · IN		Jul 13, 2023
Sen. Lujan, Ben Ray [D-NM]	D · NM		Jul 13, 2023
Sen. Vance, J. D. [R-OH]	R · OH		Jul 13, 2023
Sen. Paul, Rand [R-KY]	R · KY		Sep 11, 2023

Committee Activity

Committee	Chamber	Activity	Date
Health, Education, Labor, and Pensions Committee	Senate	Referred To	Jul 13, 2023

Subjects & Policy Tags

Policy Area:

Health

Related Bills

No related bills are listed.

Biosimilar Red Tape Elimination Act

This bill removes certain requirements for biosimilars to be designated as interchangeable. (Biosimilars that are designated as interchangeable may be substituted for the reference product at a pharmacy without a new prescription, depending on state pharmacy laws.)

Specifically, the bill establishes a presumption that an approved biosimilar is interchangeable with the reference product without the need for additional evidence from the manufacturer, and it removes the applicable exclusivity periods for a first interchangeable biosimilar (i.e., a product that is the first interchangeable biosimilar to be approved with respect to the reference product).

The Food and Drug Administration (FDA) may require a manufacturer of a biosimilar to conduct a safety study with respect to switching or alternating between the biosimilar and the reference product, but only after the FDA briefs certain members of specified congressional committees to explain why the study is necessary.

Actions Timeline

- **Jul 13, 2023:** Introduced in Senate
- **Jul 13, 2023:** Read twice and referred to the Committee on Health, Education, Labor, and Pensions.