

S 1712

Reciprocity Ensures Streamlined Use of Lifesaving Treatments Act of 2023

Congress: 118 (2023–2025, Ended)

Chamber: Senate

Policy Area: Health

Introduced: May 18, 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. (May 18, 2023)

Official Text: <https://www.congress.gov/bill/118th-congress/senate-bill/1712>

Sponsor

Name: Sen. Cruz, Ted [R-TX]

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

Cosponsors (1 total)

Cosponsor	Party / State	Role	Date Joined
Sen. Lee, Mike [R-UT]	R · UT		May 18, 2023

Committee Activity

Committee	Chamber	Activity	Date
Health, Education, Labor, and Pensions Committee	Senate	Referred To	May 18, 2023

Subjects & Policy Tags

Policy Area:

Health

Related Bills

Bill	Relationship	Last Action
118 HR 3532	Related bill	May 19, 2023: Referred to the Subcommittee on Health.

Reciprocity Ensures Streamlined Use of Lifesaving Treatments Act of 2023

This bill establishes a reciprocal marketing approval process that allows for the sale of a drug, biological product, or medical device that has not been approved by the Food and Drug Administration (FDA) if the product is approved for sale in another country and there is an unmet need.

Specifically, in order to receive reciprocal approval, the bill requires the product's sponsor to demonstrate, among other things, that (1) the product has been approved in one of the specified countries, (2) neither the FDA nor any of the specified countries have withdrawn approval for the product because of safety or effectiveness concerns, and (3) there is a public health or unmet medical need for the product.

The FDA may decline approval if the FDA determines that the product is not safe or effective. The FDA may condition reciprocal approval on the conduct of postmarket studies.

The FDA must issue a decision on whether to grant a request for reciprocal marketing approval within 30 days of receiving the request.

Congress may pass a joint resolution to grant reciprocal marketing approval of a product that the FDA declines to approve through the reciprocal process.

Actions Timeline

- **May 18, 2023:** Introduced in Senate
- **May 18, 2023:** Read twice and referred to the Committee on Health, Education, Labor, and Pensions.