

## HR 3532

Reciprocity Ensures Streamlined Use of Lifesaving Treatments Act of 2023

**Congress:** 118 (2023–2025, Ended)

**Chamber:** House

**Policy Area:** Health

**Introduced:** May 18, 2023

**Current Status:** Referred to the Subcommittee on Health.

**Latest Action:** Referred to the Subcommittee on Health. (May 19, 2023)

**Official Text:** <https://www.congress.gov/bill/118th-congress/house-bill/3532>

### Sponsor

**Name:** Rep. Roy, Chip [R-TX-21]

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

### Cosponsors

*No cosponsors are listed for this bill.*

### Committee Activity

Committee	Chamber	Activity	Date
Energy and Commerce Committee	House	Referred to	May 19, 2023
Rules Committee	House	Referred To	May 18, 2023

### Subjects & Policy Tags

**Policy Area:**

Health

### Related Bills

Bill	Relationship	Last Action
118 S 1712	Related bill	<b>May 18, 2023:</b> Read twice and referred to the Committee on Health, Education, Labor, and Pensions.

## **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has been approved in one of the specified countries, (2) neither the FDA nor any of the specified countries have withdrawn approval for the product because of safety or effectiveness concerns, and (3) there is a public health or unmet medical need for the product.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**

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- **May 19, 2023:** Referred to the Subcommittee on Health.
- **May 18, 2023:** Introduced in House
- **May 18, 2023:** Referred to the Committee on Energy and Commerce, and in addition to the Committee on Rules, for a period to be subsequently determined by the Speaker, in each case for consideration of such provisions as fall within the jurisdiction of the committee concerned.