

## S 2161

### Reciprocity Ensures Streamlined Use of Lifesaving Treatments Act of 2019

**Congress:** 116 (2019–2021, Ended)

**Chamber:** Senate

**Policy Area:** Health

**Introduced:** Jul 18, 2019

**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 18, 2019)

**Official Text:** <https://www.congress.gov/bill/116th-congress/senate-bill/2161>

### Sponsor

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

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

### Cosponsors (3 total)

Cosponsor	Party / State	Role	Date Joined
Sen. Johnson, Ron [R-WI]	R · WI		Jul 18, 2019
Sen. Lee, Mike [R-UT]	R · UT		Jul 18, 2019
Sen. Ernst, Joni [R-IA]	R · IA		Jun 3, 2020

### Committee Activity

Committee	Chamber	Activity	Date
Health, Education, Labor, and Pensions Committee	Senate	Referred To	Jul 18, 2019

### Subjects & Policy Tags

#### Policy Area:

Health

### Related Bills

Bill	Relationship	Last Action
116 S 4537	Related bill	<b>Sep 8, 2020:</b> Read twice and referred to the Committee on Finance.
116 S 3545	Related bill	<b>Mar 19, 2020:</b> Read twice and referred to the Committee on Health, Education, Labor, and Pensions.
116 HR 6258	Related bill	<b>Mar 12, 2020:</b> Referred to the House Committee on Energy and Commerce.
116 HR 6260	Related bill	<b>Mar 12, 2020:</b> 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.

## **Reciprocity Ensures Streamlined Use of Lifesaving Treatments Act of 2019**

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, the bill requires the product's sponsor to demonstrate, among other things, that their product has been approved in one of the specified countries, the FDA and listed countries have not withdrawn approval because of safety or effectiveness concerns, and there is a public health or unmet medical need for the product.

The FDA may only decline approval if the FDA determines that the product is not safe or effective. The FDA must make such a determination not later than 30 days after receiving a 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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- **Jul 18, 2019:** Introduced in Senate
- **Jul 18, 2019:** Read twice and referred to the Committee on Health, Education, Labor, and Pensions.