

S 3545

Reciprocity Ensures Streamlined Use of Lifesaving Treatments for Coronavirus Patients Act of 2020

Congress: 116 (2019–2021, Ended)

Chamber: Senate

Policy Area: Health

Introduced: Mar 19, 2020

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. (Mar 19, 2020)

Official Text: <https://www.congress.gov/bill/116th-congress/senate-bill/3545>

Sponsor

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

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

Cosponsors (2 total)

Cosponsor	Party / State	Role	Date Joined
Sen. Braun, Mike [R-IN]	R · IN		Mar 19, 2020
Sen. Lee, Mike [R-UT]	R · UT		Mar 19, 2020

Committee Activity

Committee	Chamber	Activity	Date
Health, Education, Labor, and Pensions Committee	Senate	Referred To	Mar 19, 2020

Subjects & Policy Tags

Policy Area:

Health

Related Bills

Bill	Relationship	Last Action
116 S 4537	Related bill	Sep 8, 2020: Read twice and referred to the Committee on Finance.
116 HR 6258	Related bill	Mar 12, 2020: Referred to the House Committee on Energy and Commerce.
116 HR 6260	Identical bill	Mar 12, 2020: 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.
116 S 2161	Related bill	Jul 18, 2019: Read twice and referred to the Committee on Health, Education, Labor, and Pensions.

Reciprocity Ensures Streamlined Use of Lifesaving Treatments for Coronavirus Patients Act of 2020

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 for the treatment or prevention of COVID-19 (i.e., coronavirus disease 2019) and there is an unmet need relative to certain diseases.

Specifically, the bill requires the product's sponsor to demonstrate, among other things, that

- the product has been approved for the treatment or prevention of COVID-19 or another disease of epidemic potential,
- the approval is 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- the FDA and listed countries have not withdrawn approval because of safety or effectiveness concerns, and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

- **Mar 19, 2020:** Introduced in Senate
- **Mar 19, 2020:** Read twice and referred to the Committee on Health, Education, Labor, and Pensions.