

HR 724

Reciprocity Ensures Streamlined Use of Lifesaving Treatments Act of 2021

Congress: 117 (2021–2023, Ended)

Chamber: House

Policy Area: Health

Introduced: Feb 2, 2021

Current Status: Referred to the Subcommittee on Health.

Latest Action: Referred to the Subcommittee on Health. (Feb 3, 2021)

Official Text: <https://www.congress.gov/bill/117th-congress/house-bill/724>

Sponsor

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

Party: Republican • State: TX • Chamber: House

Cosponsors (1 total)

Cosponsor	Party / State	Role	Date Joined
Rep. Green, Mark E. [R-TN-7]	R · TN		Feb 23, 2021

Committee Activity

Committee	Chamber	Activity	Date
Energy and Commerce Committee	House	Referred to	Feb 3, 2021

Subjects & Policy Tags

Policy Area:

Health

Related Bills

Bill	Relationship	Last Action
117 S 154	Identical bill	Feb 2, 2021: Read twice and referred to the Committee on Health, Education, Labor, and Pensions.

## **Reciprocity Ensures Streamlined Use of Lifesaving Treatments Act of 2021**

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 (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has been approved in one of the specified countries, (2) neither the FDA nor any of the specified countries have withdrawn approval for the product because of safety or effectiveness concerns, and (3) there is a public health or unmet medical need for the product.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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- **Feb 3, 2021:** Referred to the Subcommittee on Health.
- **Feb 2, 2021:** Introduced in House
- **Feb 2, 2021:** Referred to the House Committee on Energy and Commerce.