

## HR 6241

Reciprocity Ensures Streamlined Use of Lifesaving Treatments Act of 2016

**Congress:** 114 (2015–2017, Ended)

**Chamber:** House

**Policy Area:** Health

**Introduced:** Sep 28, 2016

**Current Status:** Referred to the Committee on Energy and Commerce, and in addition to the Committee on Rules, for a p

**Latest Action:** 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. (Sep 28, 2016)

**Official Text:** <https://www.congress.gov/bill/114th-congress/house-bill/6241>

### Sponsor

**Name:** Rep. DeSantis, Ron [R-FL-6]

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

### Cosponsors (1 total)

Cosponsor	Party / State	Role	Date Joined
Rep. Mulvaney, Mick [R-SC-5]	R · SC		Nov 17, 2016

### Committee Activity

Committee	Chamber	Activity	Date
Energy and Commerce Committee	House	Referred To	Sep 28, 2016
Rules Committee	House	Referred To	Sep 28, 2016

### Subjects & Policy Tags

#### Policy Area:

Health

### Related Bills

Bill	Relationship	Last Action
114 S 2388	Related bill	<b>Dec 10, 2015:</b> Read twice and referred to the Committee on Health, Education, Labor, and Pensions.

## **Reciprocity Ensures Streamlined Use of Lifesaving Treatments Act of 2016**

This bill amends the Federal Food, Drug, and Cosmetic Act to establish 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 a product to be granted reciprocal marketing approval, the product's sponsor must submit a request to the FDA that demonstrates: (1) the product may be sold in at least one country from a specified list of countries, (2) the FDA and listed countries have not withdrawn approval of the product because of safety or effectiveness concerns, and (3) there is a public health or unmet medical need for the product.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: (1) require postmarket studies of a product granted reciprocal marketing approval, or (2) decline to approve a product that is not safe and effective.

The FDA must grant or decline reciprocal marketing approval not later than 30 days after receiving a request. During that period, the FDA and product sponsor must negotiate and finalize product labeling and, for a medical device, classify the device.

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

User fees apply to requests for reciprocal marketing approval.

The FDA must encourage the sponsors of potentially eligible products to request reciprocal marketing approval.

### **Actions Timeline**

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- **Sep 28, 2016:** Introduced in House
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