S 2388

Reciprocity Ensures Streamlined Use of Lifesaving Treatments Act of 2015

Congress: 114 (2015–2017, Ended)
Chamber: Senate
Policy Area: Health
Introduced: Dec 10, 2015
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. (Dec 10, 2015)
Official Text: https://www.congress.gov/bill/114th-congress/senate-bill/2388

Sponsor

Name: Sen. Cruz, Ted [R-TX]
Party: Republican • **State:** TX • **Chamber:** Senate

Cosponsors (2 total)

Cosponsor	Party / State	Role	Date Joined
Sen. Lee, Mike [R-UT]	R · UT		Dec 10, 2015
Sen. Johnson, Ron [R-WI]	R · WI		May 10, 2016

Committee Activity

Committee	Chamber	Activity	Date
Health, Education, Labor, and Pensions Committee	Senate	Referred To	Dec 10, 2015

Subjects & Policy Tags

Policy Area:

Health

Related Bills

Bill	Relationship	Last Action
114 HR 6241	Related bill	**Sep 28, 2016:** 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.

Summary (as of Dec 10, 2015)

Reciprocity Ensures Streamlined Use of Lifesaving Treatments Act of 2015

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may be sold in at least one country from a specified list of countries, (2) the FDA and listed countries have not withdrawn approval of the product because of safety or effectiveness concerns, and (3) there is a public health or unmet medical need for the product.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

- **Dec 10, 2015:** Introduced in Senate
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