

S 4185

RARE Act

Congress: 117 (2021–2023, Ended)

Chamber: Senate

Policy Area: Health

Introduced: May 11, 2022

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. (May 11, 2022)

Official Text: <https://www.congress.gov/bill/117th-congress/senate-bill/4185>

Sponsor

Name: Sen. Baldwin, Tammy [D-WI]

Party: Democratic • **State:** WI • **Chamber:** Senate

Cosponsors (1 total)

Cosponsor	Party / State	Role	Date Joined
Sen. Cassidy, Bill [R-LA]	R · LA		May 11, 2022

Committee Activity

Committee	Chamber	Activity	Date
Health, Education, Labor, and Pensions Committee	Senate	Referred To	May 11, 2022

Subjects & Policy Tags

Policy Area:

Health

Related Bills

No related bills are listed.

Retaining Access and Restoring Exclusivity Act or the RARE Act

This bill specifies that the seven-year market exclusivity period for drugs for rare diseases or conditions (i.e., orphan drug exclusivity period) prohibits the approval of the same drug for the same approved use or indication with respect to the disease or condition.

Current law grants a seven-year period of market exclusivity for an approved orphan drug, during which the Food and Drug Administration (FDA) may not approve an application from another manufacturer for the same drug for the same disease or condition. The FDA's regulations provide that this exclusivity is specific to the same approved use or indication of the drug, rather than all uses or indications, for the disease or condition. However, in *Catalyst Pharmaceuticals, Inc. v. Becerra*, a court held that exclusivity did extend to all uses or indications for the disease or condition.

The bill provides statutory authority for the FDA's regulations.

Actions Timeline

- **May 11, 2022:** Introduced in Senate
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