

S 1214

RARE Act

Congress: 118 (2023–2025, Ended)

Chamber: Senate

Policy Area: Health

Introduced: Apr 19, 2023

Current Status: Placed on Senate Legislative Calendar under General Orders. Calendar No. 109.

Latest Action: Placed on Senate Legislative Calendar under General Orders. Calendar No. 109. (Jun 22, 2023)

Official Text: <https://www.congress.gov/bill/118th-congress/senate-bill/1214>

Sponsor

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

Party: Democratic • State: WI • Chamber: Senate

Cosponsors (1 total)

Cosponsor	Party / State	Role	Date Joined
Sen. Braun, Mike [R-IN]	R · IN		Apr 26, 2023

Committee Activity

Committee	Chamber	Activity	Date
Health, Education, Labor, and Pensions Committee	Senate	Reported By	Jun 22, 2023

Subjects & Policy Tags

Policy Area:

Health

Related Bills

Bill	Relationship	Last Action
118 HR 3433	Related bill	Sep 24, 2024: Received in the Senate and Read twice and referred to the Committee on Health, Education, Labor, and Pensions.
118 HR 7383	Related bill	Feb 16, 2024: Referred to the Subcommittee on Health.

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

- **Jun 22, 2023:** Committee on Health, Education, Labor, and Pensions. Reported by Senator Sanders without amendment. Without written report.
- **Jun 22, 2023:** Placed on Senate Legislative Calendar under General Orders. Calendar No. 109.
- **May 11, 2023:** Committee on Health, Education, Labor, and Pensions. Ordered to be reported without amendment favorably.
- **Apr 19, 2023:** Introduced in Senate
- **Apr 19, 2023:** Read twice and referred to the Committee on Health, Education, Labor, and Pensions.