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Fairness in Orphan Drug Exclusivity Act

Congress: 117 (2021–2023, Ended)

Chamber: Senate

Policy Area: Health

Introduced: Feb 4, 2021

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. (Feb 4, 2021)

Official Text: <https://www.congress.gov/bill/117th-congress/senate-bill/250>

Sponsor

Name: Sen. Cassidy, Bill [R-LA]

Party: Republican • **State:** LA • **Chamber:** Senate

Cosponsors (2 total)

Cosponsor	Party / State	Role	Date Joined
Sen. Baldwin, Tammy [D-WI]	D · WI		Feb 4, 2021
Sen. Shaheen, Jeanne [D-NH]	D · NH		Feb 4, 2021

Committee Activity

Committee	Chamber	Activity	Date
Health, Education, Labor, and Pensions Committee	Senate	Referred To	Feb 5, 2021

Subjects & Policy Tags

Policy Area:

Health

Related Bills

Bill	Relationship	Last Action
117 HR 1629	Related bill	May 20, 2021: Received in the Senate and Read twice and referred to the Committee on Health, Education, Labor, and Pensions.

Fairness in Orphan Drug Exclusivity Act

This bill limits which orphan drugs may be granted a market exclusivity period by the Food and Drug Administration (FDA). (Generally, an orphan drug is one that is not economically viable because of the rarity of the disease that it treats; the sponsor of an FDA-designated orphan drug may be granted various incentives, such as a seven-year period in which the FDA may not grant market approval to a different sponsor for the same drug to treat the same disease.)

Under this bill, if a drug is designated as an orphan drug on the basis that there is no reasonable expectation that the sponsor will recover the costs of developing and distributing the drug from U.S. sales, the drug shall be granted the seven-year exclusivity period only if the sponsor demonstrates that there is no reasonable expectation that it will recover such costs specifically within its first 12 years of U.S. sales of the drug. This requirement shall also apply retroactively to an orphan drug that was granted such an exclusivity period before this bill's enactment.

When deciding whether an orphan drug meets this requirement, the FDA shall consider the sales of all drugs from the sponsor that are covered by the same orphan drug designation.

Actions Timeline

- **Feb 4, 2021:** Introduced in Senate
- **Feb 4, 2021:** Read twice and referred to the Committee on Health, Education, Labor, and Pensions.