

## S 3271

### Fairness in Orphan Drug Exclusivity Act

**Congress:** 116 (2019–2021, Ended)

**Chamber:** Senate

**Policy Area:** Health

**Introduced:** Feb 11, 2020

**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 11, 2020)

**Official Text:** <https://www.congress.gov/bill/116th-congress/senate-bill/3271>

### 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 11, 2020
Sen. Shaheen, Jeanne [D-NH]	D · NH		Feb 11, 2020

### Committee Activity

Committee	Chamber	Activity	Date
Health, Education, Labor, and Pensions Committee	Senate	Referred To	Feb 11, 2020

### Subjects & Policy Tags

#### Policy Area:

Health

### Related Bills

Bill	Relationship	Last Action
116 HR 4712	Related bill	Nov 18, 2020: 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.)

Specifically, when determining whether to grant an exclusivity period to a drug that has orphan status due to low expected sales, the FDA must consider the sales of all drugs from the sponsor that are covered by the same orphan drug designation.

## **Actions Timeline**

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