

HR 1629

Fairness in Orphan Drug Exclusivity Act

Congress: 117 (2021–2023, Ended)

Chamber: House

Policy Area: Health

Introduced: Mar 8, 2021

Current Status: Received in the Senate and Read twice and referred to the Committee on Health, Education, Labor, and

Latest Action: Received in the Senate and Read twice and referred to the Committee on Health, Education, Labor, and Pensions. (May 20, 2021)

Official Text: <https://www.congress.gov/bill/117th-congress/house-bill/1629>

Sponsor

Name: Rep. Dean, Madeleine [D-PA-4]

Party: Democratic • **State:** PA • **Chamber:** House

Cosponsors (2 total)

Cosponsor	Party / State	Role	Date Joined
Rep. Veasey, Marc A. [D-TX-33]	D · TX		Mar 8, 2021
Rep. Fitzpatrick, Brian K. [R-PA-1]	R · PA		May 11, 2021

Committee Activity

Committee	Chamber	Activity	Date
Budget Committee	House	Referred To	Mar 8, 2021
Energy and Commerce Committee	House	Referred to	Mar 9, 2021
Health, Education, Labor, and Pensions Committee	Senate	Referred To	May 20, 2021

Subjects & Policy Tags

Policy Area:

Health

Related Bills

Bill	Relationship	Last Action
117 HRES 403	Related bill	May 18, 2021: Motion to reconsider laid on the table Agreed to without objection.
117 S 250	Related bill	Feb 4, 2021: 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

- **May 20, 2021:** Received in the Senate and Read twice and referred to the Committee on Health, Education, Labor, and Pensions.
- **May 19, 2021:** Considered under the provisions of rule H. Res. 403. (consideration: CR H2560-2563)
- **May 19, 2021:** Rule provides for consideration of H.R. 1629 and H. Res. 275. The resolution provides for consideration of H.R. 1629 under a closed rule and H. Res. 275 under a closed rule. The resolution provides for one hour of debate on both the bill and resolution. The rule provides that H. Res. 398 is hereby adopted. The rule provides at any time through the legislative day of Thursday, May 20, 2021, the Speaker may entertain motions offered by the Majority Leader or designee with respect to multiple measures that were object of motions to suspend the rules on the legislative days of May 17 or 18, 2021.
- **May 19, 2021:** DEBATE - The House proceeded with one hour of debate on H.R. 1629.
- **May 19, 2021:** The previous question was ordered pursuant to the rule.
- **May 19, 2021:** POSTPONED PROCEEDINGS - At the conclusion of debate on H.R. 1629, the Chair put the question on passage and by voice vote, announced that the ayes had prevailed. Mrs. Greene (GA) demanded the yeas and nays and the Chair postponed further proceedings on the question of passage until a time to be announced.
- **May 19, 2021:** Considered as unfinished business. (consideration: CR H2572-2573)
- **May 19, 2021:** Passed/agreed to in House: On passage Passed by the Yeas and Nays: 402 - 23 (Roll no. 150).(text: CR H2561)
- **May 19, 2021:** On passage Passed by the Yeas and Nays: 402 - 23 (Roll no. 150). (text: CR H2561)
- **May 19, 2021:** Motion to reconsider laid on the table Agreed to without objection.
- **May 17, 2021:** Rules Committee Resolution H. Res. 403 Reported to House. Rule provides for consideration of H.R. 1629 and H. Res. 275. The resolution provides for consideration of H.R. 1629 under a closed rule and H. Res. 275 under a closed rule. The resolution provides for one hour of debate on both the bill and resolution. The rule provides that H. Res. 398 is hereby adopted. The rule provides at any time through the legislative day of Thursday, May 20, 2021, the Speaker may entertain motions offered by the Majority Leader or designee with respect to multiple measures that were object of motions to suspend the rules on the legislative days of May 17 or 18, 2021.
- **May 11, 2021:** Mr. Pallone moved to suspend the rules and pass the bill.
- **May 11, 2021:** Considered under suspension of the rules. (consideration: CR H2181-2183; text: CR H2181-2182)
- **May 11, 2021:** DEBATE - The House proceeded with forty minutes of debate on H.R. 1629.
- **May 11, 2021:** At the conclusion of debate, the Yeas and Nays were demanded and ordered. Pursuant to the provisions of clause 8, rule XX, the Chair announced that further proceedings on the motion would be postponed.
- **May 11, 2021:** Considered as unfinished business. (consideration: CR H2184-2185)
- **May 11, 2021:** Failed of passage/not agreed to in House: On motion to suspend the rules and pass the bill Failed by the Yeas and Nays: (2/3 required): 250 - 168 (Roll no. 134).
- **May 11, 2021:** On motion to suspend the rules and pass the bill Failed by the Yeas and Nays: (2/3 required): 250 - 168 (Roll no. 134).
- **Mar 9, 2021:** Referred to the Subcommittee on Health.
- **Mar 8, 2021:** Introduced in House
- **Mar 8, 2021:** Referred to the Committee on Energy and Commerce, and in addition to the Committee on the Budget, 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.