HR 4712

Fairness in Orphan Drug Exclusivity Act

Congress: 116 (2019–2021, Ended)
Chamber: House
Policy Area: Health
Introduced: Oct 17, 2019
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. (Nov 18, 2020)
Official Text: https://www.congress.gov/bill/116th-congress/house-bill/4712

Sponsor

Name: Rep. Dean, Madeleine [D-PA-4]
Party: Democratic • **State:** PA • **Chamber:** House

Cosponsors (7 total)

Cosponsor	Party / State	Role	Date Joined
Rep. Carter, Earl L. "Buddy" [R-GA-1]	R · GA		Oct 17, 2019
Rep. McKinley, David B. [R-WV-1]	R · WV		Oct 17, 2019
Rep. Veasey, Marc A. [D-TX-33]	D · TX		Oct 17, 2019
Rep. Tonko, Paul [D-NY-20]	D · NY		Dec 5, 2019
Rep. Kim, Andy [D-NJ-3]	D · NJ		Jul 16, 2020
Rep. Soto, Darren [D-FL-9]	D · FL		Aug 4, 2020
Rep. Taylor, Van [R-TX-3]	R · TX		Nov 16, 2020

Committee Activity

Committee	Chamber	Activity	Date
Energy and Commerce Committee	House	Reported by	Mar 11, 2020
Health, Education, Labor, and Pensions Committee	Senate	Referred To	Nov 18, 2020

Subjects & Policy Tags

Policy Area:

Health

Related Bills

Bill	Relationship	Last Action
116 S 3271	Related bill	**Feb 11, 2020:** Read twice and referred to the Committee on Health, Education, Labor, and Pensions.

Summary (as of Nov 17, 2020)

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

- **Nov 18, 2020:** Received in the Senate and Read twice and referred to the Committee on Health, Education, Labor, and Pensions.
- **Nov 17, 2020:** Mr. Pallone moved to suspend the rules and pass the bill, as amended.
- **Nov 17, 2020:** Considered under suspension of the rules. (consideration: CR H5807-5809)
- **Nov 17, 2020:** DEBATE - The House proceeded with forty minutes of debate on H.R. 4712.
- **Nov 17, 2020:** Passed/agreed to in House: On motion to suspend the rules and pass the bill, as amended Agreed to by voice vote.(text: CR H5807)
- **Nov 17, 2020:** On motion to suspend the rules and pass the bill, as amended Agreed to by voice vote. (text: CR H5807)
- **Nov 17, 2020:** Motion to reconsider laid on the table Agreed to without objection.
- **Nov 16, 2020:** Reported (Amended) by the Committee on Energy and Commerce. H. Rept. 116-572.
- **Nov 16, 2020:** Placed on the Union Calendar, Calendar No. 470.
- **Jul 15, 2020:** Committee Consideration and Mark-up Session Held.
- **Jul 15, 2020:** Ordered to be Reported (Amended) by Voice Vote.
- **Mar 11, 2020:** Subcommittee Consideration and Mark-up Session Held.
- **Mar 11, 2020:** Forwarded by Subcommittee to Full Committee (Amended) by Voice Vote .
- **Oct 18, 2019:** Referred to the Subcommittee on Health.
- **Oct 17, 2019:** Introduced in House
- **Oct 17, 2019:** Referred to the House Committee on Energy and Commerce.

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