

HR 456

Fairness in Orphan Drug Exclusivity Act

Congress: 118 (2023–2025, Ended)

Chamber: House

Policy Area: Health

Introduced: Jan 24, 2023

Current Status: Referred to the Subcommittee on Health.

Latest Action: Referred to the Subcommittee on Health. (Feb 3, 2023)

Official Text: <https://www.congress.gov/bill/118th-congress/house-bill/456>

Sponsor

Name: Rep. Carter, Earl L. "Buddy" [R-GA-1]

Party: Republican • **State:** GA • **Chamber:** House

Cosponsors

No cosponsors are listed for this bill.

Committee Activity

Committee	Chamber	Activity	Date
Energy and Commerce Committee	House	Referred to	Feb 3, 2023

Subjects & Policy Tags

Policy Area:

Health

Related Bills

No related bills are listed.

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 within its first 12 years of U.S. sales of the drug.

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 3, 2023:** Referred to the Subcommittee on Health.
- **Jan 24, 2023:** Introduced in House
- **Jan 24, 2023:** Referred to the House Committee on Energy and Commerce.