

Bill Fact Sheet – December 5, 2025 https://legilist.com Bill page: https://legilist.com/bill/107/hr/386

HR 386

Orphan Drug Program Improvement Act of 2001

Congress: 107 (2001–2003, Ended)

Chamber: House
Policy Area: Health
Introduced: Jan 31, 2001

Current Status: Referred to the Subcommittee on Health.

Latest Action: Referred to the Subcommittee on Health. (Feb 14, 2001) **Official Text:** https://www.congress.gov/bill/107th-congress/house-bill/386

Sponsor

Name: Rep. Thornberry, Mac [R-TX-13]

Party: Republican • State: TX • Chamber: House

Cosponsors (3 total)

Cosponsor	Party / State	Role	Date Joined
Rep. Schaffer, Bob [R-CO-4]	$R \cdot CO$		Feb 27, 2001
Rep. Deal, Nathan [R-GA-9]	$R \cdot GA$		Feb 28, 2001
Rep. Tancredo, Thomas G. [R-CO-6]	R · CO		Mar 6, 2001

Committee Activity

Committee	Chamber	Activity	Date
Energy and Commerce Committee	House	Referred to	Feb 14, 2001

Subjects & Policy Tags

Policy Area:

Health

Related Bills

No related bills are listed.

Summary (as of Jan 31, 2001)

Orphan Drug Program Improvement Act of 2001 - Amends the Federal Food, Drug, and Cosmetic Act to require the Secretary of Health and Human Services, respecting application approval or licensing, to conform the designation of a drug for a rare disease or condition (orphan drug) to reflect such drug's approved labeling.

Exempts clinically superior subsequent orphan drugs from the seven-year prohibition of approval respecting a previously approved or licensed drug.

Actions Timeline

- Feb 14, 2001: Referred to the Subcommittee on Health.
- Jan 31, 2001: Introduced in House
- Jan 31, 2001: Introduced in House
- Jan 31, 2001: Referred to the House Committee on Energy and Commerce.