S 705

Innovation in Pediatric Drugs Act of 2025

Congress: 119 (2025–2027, Current)
Chamber: Senate
Policy Area: Health
Introduced: Feb 25, 2025
Current Status: Read twice and referred to the Committee on Health, Education, Labor, and Pensions. (Sponsor introdu
Latest Action: Read twice and referred to the Committee on Health, Education, Labor, and Pensions. (Sponsor introductory remarks on measure: CR S1347) (Feb 25, 2025)
Official Text: https://www.congress.gov/bill/119th-congress/senate-bill/705

Sponsor

Name: Sen. Reed, Jack [D-RI]
Party: Democratic • **State:** RI • **Chamber:** Senate

Cosponsors (1 total)

Cosponsor	Party / State	Role	Date Joined
Sen. Capito, Shelley Moore [R-WV]	R · WV		Feb 25, 2025

Committee Activity

Committee	Chamber	Activity	Date
Health, Education, Labor, and Pensions Committee	Senate	Referred To	Feb 25, 2025

Subjects & Policy Tags

Policy Area:

Health

Related Bills

No related bills are listed.

Summary (as of Feb 25, 2025)

Innovation in Pediatric Drugs Act of 2025

This bill expands the Food and Drug Administration's (FDA's) authority with respect to research on rare pediatric diseases, including by permitting the FDA to require pediatric studies on certain orphan drugs and to take enforcement action against drug sponsors that fail to satisfy pediatric study requirements.

Specifically, the bill would impose pediatric study requirements on drugs for rare diseases or conditions (i.e., orphan drugs) if the FDA determines that (1) the drug could improve the treatment, diagnosis, or prevention of a disease compared with currently available products for the relevant pediatric population; or (2) there is a need for additional options within the drug's class or indication. (Under current law, pediatric study requirements generally do not apply to orphan drugs.) The FDA must issue guidance describing how these changes will be implemented, including information on how waivers will be granted.

The bill also permits the FDA to take enforcement action against drug sponsors that fail to comply with pediatric study requirements, if such sponsors demonstrated a lack of due diligence in satisfying the requirements.

Additionally, the bill authorizes the National Institutes of Health to allot a certain amount of funds for priority pediatric research, including research on drugs with no remaining patents on which pediatric studies are needed.

Finally, the Government Accountability Office must report on the bill's impact on rare disease drug development and on the availability of pediatric information on orphan drugs.

Actions Timeline

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