HR 2857

Pediatric Research Equity Act of 2003

Congress: 108 (2003–2005, Ended)
Chamber: House
Policy Area: Health
Introduced: Jul 24, 2003
Current Status: Referred to the Subcommittee on Health.
Latest Action: Referred to the Subcommittee on Health. (Aug 8, 2003)
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Sponsor

Name: Rep. Greenwood, James C. [R-PA-8]
Party: Republican • **State:** PA • **Chamber:** House

Cosponsors (7 total)

Cosponsor	Party / State	Role	Date Joined
Rep. Eshoo, Anna G. [D-CA-14]	D · CA		Jul 24, 2003
Rep. Pryce, Deborah [R-OH-15]	R · OH		Jul 24, 2003
Rep. Baldwin, Tammy [D-WI-2]	D · WI		Oct 1, 2003
Rep. Weldon, Curt [R-PA-7]	R · PA		Oct 1, 2003
Rep. Wilson, Heather [R-NM-1]	R · NM		Oct 1, 2003
Rep. Andrews, Robert E. [D-NJ-1]	D · NJ		Oct 15, 2003
Rep. Johnson, Nancy L. [R-CT-5]	R · CT		Oct 15, 2003

Committee Activity

Committee	Chamber	Activity	Date
Energy and Commerce Committee	House	Referred to	Aug 8, 2003

Subjects & Policy Tags

Policy Area:

Health

Related Bills

Bill	Relationship	Last Action
108 S 650	Related bill	**Dec 3, 2003:** Became Public Law No: 108-155.

Summary (as of Jul 24, 2003)

Pediatric Research Equity Act of 2003 - Amends the Federal Food, Drug, and Cosmetic Act to require license applications for new drugs and biological products to assess such drug's or product's safety and effectiveness for relevant pediatric subpopulations, including dosage.

Permits deferral of such assessments under specified circumstances.

Permits full waiver of such assessments under certain conditions, including if: (1) studies are highly impractical or impossible; or (2) there is no meaningful therapeutic advantage or benefit in the pediatric population and the drug or biological product is not likely to be used in a substantial number of pediatric patients.

Permits partial waivers at the request of an applicant for a specific pediatric subpopulation if any of the full waiver grounds apply to that subpopulation or reasonable attempts for a pediatric formulation for that subpopulation have failed.

Requires labels to provide indication in cases in which a waiver has been granted due to evidence a product would be unsafe or ineffective in pediatric populations.

Authorizes the Secretary of Health and Human Services to specify a date for submission of pediatric assessments if: (1) the drug or biological product would represent a meaningful therapeutic benefit for pediatric patients for one or more claimed indications and the absence of adequate labeling could pose significant risks to pediatric patients; or (2) it is used for a number of pediatric patients for the labeled indications and the absence of adequate labeling could pose significant risks to pediatric patients. Sets forth criteria for full waiver and partial waivers of such requirement. Requires labels to provide indication in cases in which a waiver has been granted due to evidence a product would be unsafe or ineffective in pediatric populations.

Requires the Secretary to issue a written request for related pediatric studies under the Public Health Service Act or under this Act before requiring an assessment for a drug. Directs the Secretary, after determining that there is no agreement to such a written request, to certify whether the Secretary has sufficient funds to conduct the study under the Public Health Service Act, taking into account prioritization of drugs for which pediatric studies are needed.

States that if a person fails to submit an assessment under this Act, or a request for approval of a pediatric formulation, the relevant drug or biological product may be considered misbranded solely because of that failure and subject to enforcement action.

Actions Timeline

- **Aug 8, 2003:** Referred to the Subcommittee on Health.
- **Jul 24, 2003:** Introduced in House
- **Jul 24, 2003:** Introduced in House
- **Jul 24, 2003:** Referred to the House Committee on Energy and Commerce.