S 650

Pediatric Research Equity Act of 2003

Congress: 108 (2003–2005, Ended)
Chamber: Senate
Policy Area: Health
Introduced: Mar 18, 2003
Current Status: Became Public Law No: 108-155.
Latest Action: Became Public Law No: 108-155. (Dec 3, 2003)
Law: 108-155 (Enacted Dec 3, 2003)
Official Text: https://www.congress.gov/bill/108th-congress/senate-bill/650

Sponsor

Name: Sen. DeWine, Mike [R-OH]
Party: Republican • **State:** OH • **Chamber:** Senate

Cosponsors (6 total)

Cosponsor	Party / State	Role	Date Joined
Sen. Clinton, Hillary Rodham [D-NY]	D · NY		Mar 18, 2003
Sen. Dodd, Christopher J. [D-CT]	D · CT		Mar 18, 2003
Sen. Gregg, Judd [R-NH]	R · NH		Mar 18, 2003
Sen. Kennedy, Edward M. [D-MA]	D · MA		Mar 18, 2003
Sen. Frist, William H. [R-TN]	R · TN		Mar 19, 2003
Sen. Murray, Patty [D-WA]	D · WA		Mar 19, 2003

Committee Activity

Committee	Chamber	Activity	Date
Energy and Commerce Committee	House	Referred to	Aug 8, 2003
Health, Education, Labor, and Pensions Committee	Senate	Reported By	Jun 27, 2003

Subjects & Policy Tags

Policy Area:

Health

Related Bills

Bill	Relationship	Last Action
108 HR 2857	Related bill	**Aug 8, 2003:** Referred to the Subcommittee on Health.

Summary (as of Dec 3, 2003)

(This measure has not been amended since it was passed by the Senate on July 23, 2003. The summary of that version is repeated here.)

Pediatric Research Equity Act of 2003 - (Sec. 2) 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, including if the Secretary of Health and Human Services finds that the drug or biological product is ready for approval for use in adults before pediatric studies are complete.

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 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 substantial 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 relevant enforcement action.

Provides that the new authority under this Act to require pediatric studies shall only remain in effect so long as the pediatric exclusivity provisions under the Federal Food, Drug, and Cosmetic Act also remain in effect (until October 1, 2007).

(Sec. 4) Declares that the provisions of this Act pertaining to research into pediatric uses for new drugs and biological products shall apply to license applications for such drugs and products submitted to the Secretary on or after April 1, 1999. Specifies procedures for the treatment of applications submitted between April 1, 1999, and the date of the enactment of this Act with respect to which waivers or deferrals were granted under previous regulations and with respect

to which no waivers or deferrals were granted.

Actions Timeline

- **Dec 3, 2003:** Signed by President.
- **Dec 3, 2003:** Signed by President.
- **Dec 3, 2003:** Became Public Law No: 108-155.
- **Dec 3, 2003:** Became Public Law No: 108-155.
- **Nov 21, 2003:** Presented to President.
- **Nov 21, 2003:** Presented to President.
- **Nov 19, 2003:** Mr. Bilirakis moved to suspend the rules and pass the bill.
- **Nov 19, 2003:** Considered under suspension of the rules. (consideration: CR H11567-11572)
- **Nov 19, 2003:** DEBATE - The House proceeded with forty minutes of debate on S. 650.
- **Nov 19, 2003:** Passed/agreed to in House: On motion to suspend the rules and pass the bill Agreed to by voice vote.(text: CR H11567-11569)
- **Nov 19, 2003:** On motion to suspend the rules and pass the bill Agreed to by voice vote. (text: CR H11567-11569)
- **Nov 19, 2003:** Motion to reconsider laid on the table Agreed to without objection.
- **Aug 8, 2003:** Referred to the Subcommittee on Health.
- **Jul 24, 2003:** Message on Senate action sent to the House.
- **Jul 24, 2003:** Received in the House.
- **Jul 24, 2003:** Referred to the House Committee on Energy and Commerce.
- **Jul 23, 2003:** Measure laid before Senate by unanimous consent. (consideration: CR S9811-9819; text of measure as reported in Senate: CR S9811-9813)
- **Jul 23, 2003:** Passed/agreed to in Senate: Passed Senate with amendments by Unanimous Consent.(text as passed Senate: CR S9816-9818)
- **Jul 23, 2003:** Passed Senate with amendments by Unanimous Consent. (text as passed Senate: CR S9816-9818)
- **Jun 27, 2003:** Committee on Health, Education, Labor, and Pensions. Reported by Senator Gregg with an amendment. With written report No. 108-84. Additional views filed.
- **Jun 27, 2003:** Committee on Health, Education, Labor, and Pensions. Reported by Senator Gregg with an amendment. With written report No. 108-84. Additional views filed.
- **Jun 27, 2003:** Placed on Senate Legislative Calendar under General Orders. Calendar No. 183.
- **Mar 19, 2003:** Committee on Health, Education, Labor, and Pensions. Ordered to be reported with an amendment favorably.
- **Mar 18, 2003:** Introduced in Senate
- **Mar 18, 2003:** Sponsor introductory remarks on measure. (CR S3897-3898)
- **Mar 18, 2003:** Read twice and referred to the Committee on Health, Education, Labor, and Pensions. (text of measure as introduced: CR S3898-3900)