HR 2887

Best Pharmaceuticals for Children Act

Congress: 107 (2001–2003, Ended)
Chamber: House
Policy Area: Health
Introduced: Sep 13, 2001
Current Status: Received in the Senate. Read twice. Placed on Senate Legislative Calendar under General Orders. Cale
Latest Action: Received in the Senate. Read twice. Placed on Senate Legislative Calendar under General Orders. Calendar No. 228. (Nov 16, 2001)
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Sponsor

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

Cosponsors (22 total)

Cosponsor	Party / State	Role	Date Joined
Rep. Brady, Robert A. [D-PA-1]	D · PA		Sep 13, 2001
Rep. Buyer, Steve [R-IN-5]	R · IN		Sep 13, 2001
Rep. Eshoo, Anna G. [D-CA-14]	D · CA		Sep 13, 2001
Rep. Lofgren, Zoe [D-CA-16]	D · CA		Sep 13, 2001
Rep. Roybal-Allard, Lucille [D-CA-33]	D · CA		Sep 13, 2001
Rep. Rush, Bobby L. [D-IL-1]	D · IL		Sep 13, 2001
Rep. Upton, Fred [R-MI-6]	R · MI		Sep 13, 2001
Rep. Wynn, Albert Russell [D-MD-4]	D · MD		Sep 13, 2001
Rep. Roukema, Marge [R-NJ-5]	R · NJ		Sep 20, 2001
Rep. Rangel, Charles B. [D-NY-15]	D · NY		Sep 24, 2001
Rep. Smith, Christopher H. [R-NJ-4]	R · NJ		Sep 24, 2001
Rep. Frank, Barney [D-MA-4]	D · MA		Sep 25, 2001
Rep. Fattah, Chaka [D-PA-2]	D · PA		Oct 4, 2001
Rep. Whitfield, Ed [R-KY-1]	R · KY		Oct 4, 2001
Rep. Woolsey, Lynn C. [D-CA-6]	D · CA		Oct 4, 2001
Rep. Morella, Constance A. [R-MD-8]	R · MD		Oct 10, 2001
Rep. Owens, Major R. [D-NY-11]	D · NY		Oct 10, 2001
Rep. Dooley, Calvin M. [D-CA-20]	D · CA		Oct 17, 2001
Rep. McGovern, James P. [D-MA-3]	D · MA		Oct 17, 2001
Rep. Lantos, Tom [D-CA-12]	D · CA		Nov 1, 2001
Rep. Capuano, Michael E. [D-MA-8]	D · MA		Nov 7, 2001
Rep. Kind, Ron [D-WI-3]	D · WI		Nov 8, 2001

Committee Activity

Committee	Chamber	Activity	Date
Energy and Commerce Committee	House	Reported by	Oct 5, 2001

Subjects & Policy Tags

Policy Area:

Health

Related Bills

Bill	Relationship	Last Action
107 S 1789	Related bill	**Jan 4, 2002:** Became Public Law No: 107-109.
107 S 838	Related bill	**Oct 23, 2001:** Held at the desk.
107 S 828	Related bill	**May 3, 2001:** Read twice and referred to the Committee on Finance.

Summary (as of Nov 15, 2001)

Best Pharmaceuticals for Children Act - Amends the Public Health Service Act to direct the Secretary of Health and Human Services, through the National Institutes of Health (NIH), to develop an annual list of approved drugs for which: (1) there is a referral, an approved or pending new drug application, or no patent or market exclusivity protection; and (2) additional pediatric safety and effectiveness studies are needed. Directs the Secretary to award contracts to entities with appropriate experience for pediatric clinical trials of such drugs. Requires the results of such trials to be reported to the Commissioner of Food and Drugs who shall then determine and request any necessary labeling changes. Authorizes the Commissioner to deem a drug misbranded if the holder of an approved application refuses to make the requested change. Requires the Secretary to send a nonbinding letter of recommendation to an approved application holder if such studies indicate a reformulation is necessary. Sets forth reporting, label change, and dispute resolution requirements. Maintains the confidentiality of commercial information or trade secrets. Authorizes appropriations.

(Sec. 4) Amends the Federal Food, Drug, and Cosmetic Act to set forth procedures for written requests for pediatric studies to holders of approved applications for drugs that have market exclusivity. Requires the Secretary to refer such drugs to the Foundation for Pediatric Research for pediatric studies if the need for more information continues and the holder refuses. Directs the Secretary to refer such drug onward to the Public Health Service list if the Foundation has insufficient funds to conduct the study.

(Sec. 6) Directs the Secretary to establish an Office of Pediatric Therapeutics within the Office of the Commissioner of Food and Drugs, which shall coordinate all FDA pediatric activities.

(Sec. 7) Amends the Federal Food, Drug, and Cosmetic Act to: (1) eliminate the user fee waiver for pediatric supplements to a human drug application; (2) provide priority status for pediatric supplements; (3) include neonates within age groups for pediatric studies; (4) provide for dissemination of pediatric supplement information; and (5) set forth requirements for the additional six-month exclusivity period for new or already-marketed pediatric drugs.

(Sec. 11) Requires only an abbreviated application for new drug approval for generic drugs with added pediatric information.

(Sec. 12) Establishes an adverse reaction toll-free number which must appear on the labels of drugs approved under new drug application procedures. Requires that adverse effects from drugs with pediatric market exclusivity be reported to and reviewed by the Office of Pediatric Therapeutics.

(Sec. 13) Amends Title IV of the Public Health Service Act to direct the Secretary to establish the Foundation for Pediatric Research to collect funds and award grants for research on drugs lacking exclusivity for which pediatric studies are needed. Requires that the result of such studies be submitted to the Director of NIH and the Commissioner.

(Sec. 14) Directs the Secretary to contract with the Institute of Medicine to review Federal regulations, reports, and support for research involving children, with particular attention to issues of compensation, informed consent, and risk/benefits assessments in terms of research versus therapeutic treatment.

(Sec. 15) Requires the Comptroller General to report to Congress and the Secretary on the effectiveness of this Act in ensuring that all drugs used by children are tested and properly labeled. Requires such report to also include an assessment of: (1) this Act's economic impact; (2) the complexity of the pediatric drug studies; and (3) increased pediatric research ability.

(Sec. 16) Directs the Comptroller General to study and report on the representation of ethnic and racial minority children

in such studies.

Actions Timeline

- **Nov 16, 2001:** Received in the Senate. Read twice. Placed on Senate Legislative Calendar under General Orders. Calendar No. 228.
- **Nov 15, 2001:** Considered as unfinished business. (consideration: CR H8216)
- **Nov 15, 2001:** Passed/agreed to in House: On motion to suspend the rules and pass the bill, as amended Agreed to by the Yeas and Nays: (2/3 required): 338 - 86 (Roll no. 444).(text: CR 11/13/2001 H8094-8098)
- **Nov 15, 2001:** On motion to suspend the rules and pass the bill, as amended Agreed to by the Yeas and Nays: (2/3 required): 338 - 86 (Roll no. 444). (text: CR 11/13/2001 H8094-8098)
- **Nov 15, 2001:** Motion to reconsider laid on the table Agreed to without objection.
- **Nov 13, 2001:** Mr. Tauzin moved to suspend the rules and pass the bill, as amended.
- **Nov 13, 2001:** Considered under suspension of the rules. (consideration: CR H8094-8107)
- **Nov 13, 2001:** DEBATE - The House proceeded with forty minutes of debate on H.R. 2887.
- **Nov 13, 2001:** At the conclusion of debate, the Yeas and Nays were demanded and ordered. Pursuant to the provisions of clause 8, rule XX, the Chair announced that further proceedings on the motion would be postponed.
- **Nov 9, 2001:** Reported (Amended) by the Committee on Energy and Commerce. H. Rept. 107-277.
- **Nov 9, 2001:** Reported (Amended) by the Committee on Energy and Commerce. H. Rept. 107-277.
- **Nov 9, 2001:** Placed on the Union Calendar, Calendar No. 167.
- **Oct 11, 2001:** Committee Consideration and Mark-up Session Held.
- **Oct 11, 2001:** Ordered to be Reported (Amended) by the Yeas and Nays: 41 - 6.
- **Oct 5, 2001:** Subcommittee Consideration and Mark-up Session Held.
- **Oct 5, 2001:** Forwarded by Subcommittee to Full Committee (Amended) by the Yeas and Nays: 24 - 5.
- **Sep 27, 2001:** Referred to the Subcommittee on Health.
- **Sep 13, 2001:** Introduced in House
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- **Sep 13, 2001:** Referred to the House Committee on Energy and Commerce.