S 1789

Best Pharmaceuticals for Children Act

Congress: 107 (2001–2003, Ended)
Chamber: Senate
Policy Area: Health
Introduced: Dec 8, 2001
Current Status: Became Public Law No: 107-109.
Latest Action: Became Public Law No: 107-109. (Jan 4, 2002)
Law: 107-109 (Enacted Jan 4, 2002)
Official Text: https://www.congress.gov/bill/107th-congress/senate-bill/1789

Sponsor

Name: Sen. Dodd, Christopher J. [D-CT]
Party: Democratic • **State:** CT • **Chamber:** Senate

Cosponsors (1 total)

Cosponsor	Party / State	Role	Date Joined
Sen. DeWine, Mike [R-OH]	R · OH		Dec 8, 2001

Committee Activity

No committee referrals or activity are recorded for this bill.

Subjects & Policy Tags

Policy Area:

Health

Related Bills

Bill	Relationship	Last Action
107 HR 3452	Identical bill	**Dec 28, 2001:** Referred to the Subcommittee on Health.
107 HR 2887	Related bill	**Nov 16, 2001:** Received in the Senate. Read twice. Placed on Senate Legislative Calendar under General Orders. Calendar No. 228.
107 S 838	Related bill	**Oct 23, 2001:** Held at the desk.

Summary (as of Dec 12, 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.

(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 the National Institutes of Health 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) 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. 13) Includes within the purposes and activities of the Foundation for the National Institutes of Health the collection of funds for pediatric pharmacologic research.

(Sec. 14) Directs the Secretary to convene and consult an advisory committee on pediatric pharmacology to advise and make recommendations to the Secretary on matters relating to pediatric pharmacology.

(Sec. 15) Sets forth the duties of the Pediatric Subcommittee of the Oncologic Drugs Advisory Committee in carrying out its mission of reviewing and evaluating data concerning the safety and effectiveness of marketed and investigational human drug products for use in the treatment of pediatric cancers.

Requires the Director of the National Cancer Institute to expand, intensify, and coordinate the activities of the Institute with respect to research and the development of preclinical models to evaluate which therapies are likely to be effective for treating pediatric cancer.

(Sec. 16) Directs the Comptroller General of the United States, in consultation with the Secretary, to submit to Congress

a report concerning the effectiveness and economic impact of pediatric drug studies, the nature and type of studies in children for each drug granted exclusivity, recommendations, and other matters.

(Sec. 17) 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. 18) Requires pediatric studies to take into account adequate representation of children of ethnic and racial minorities and directs the Comptroller General to study and report on the representation of ethnic and racial minority children in such studies.

Actions Timeline

- **Jan 4, 2002:** Signed by President.
- **Jan 4, 2002:** Signed by President.
- **Jan 4, 2002:** Became Public Law No: 107-109.
- **Jan 4, 2002:** Became Public Law No: 107-109.
- **Jan 3, 2002:** Presented to President.
- **Jan 3, 2002:** Presented to President.
- **Dec 18, 2001:** Mr. Tauzin moved to suspend the rules and pass the bill.
- **Dec 18, 2001:** Considered under suspension of the rules. (consideration: CR H10200-10212)
- **Dec 18, 2001:** DEBATE - The House proceeded with forty minutes of debate on S. 1789.
- **Dec 18, 2001:** Passed/agreed to in House: On motion to suspend the rules and pass the bill Agreed to by voice vote.(text: CR H10200-10204)
- **Dec 18, 2001:** On motion to suspend the rules and pass the bill Agreed to by voice vote. (text: CR H10200-10204)
- **Dec 18, 2001:** Motion to reconsider laid on the table Agreed to without objection.
- **Dec 12, 2001:** Passed/agreed to in Senate: Passed Senate without amendment by Unanimous Consent.(consideration: CR S13070-13076; text: CR S13071-13076)
- **Dec 12, 2001:** Passed Senate without amendment by Unanimous Consent. (consideration: CR S13070-13076; text: CR S13071-13076)
- **Dec 12, 2001:** Received in the House.
- **Dec 12, 2001:** Message on Senate action sent to the House.
- **Dec 12, 2001:** Held at the desk.
- **Dec 10, 2001:** Read the second time. Placed on Senate Legislative Calendar under General Orders. Calendar No. 271.
- **Dec 8, 2001:** Introduced in Senate
- **Dec 8, 2001:** Introduced in the Senate. Read the first time. Placed on Senate Legislative Calendar under Read the First Time.