

S 838

Best Pharmaceuticals for Children Act

Congress: 107 (2001–2003, Ended)

Chamber: Senate

Policy Area: Health

Introduced: May 7, 2001

Current Status: Held at the desk.

Latest Action: Held at the desk. (Oct 23, 2001)

Official Text: https://www.congress.gov/bill/107th-congress/senate-bill/838

Sponsor

Name: Sen. Dodd, Christopher J. [D-CT]

Party: Democratic • State: CT • Chamber: Senate

Cosponsors (14 total)

Cosponsor	Party / State	Role	Date Joined
Sen. DeWine, Mike [R-OH]	R · OH		May 7, 2001
Sen. Frist, William H. [R-TN]	R · TN		May 17, 2001
Sen. Jeffords, James M. [R-VT]	R · VT		May 17, 2001
Sen. Mikulski, Barbara A. [D-MD]	D · MD		May 17, 2001
Sen. Bond, Christopher S. [R-MO]	R · MO		May 21, 2001
Sen. Collins, Susan M. [R-ME]	R · ME		Jun 8, 2001
Sen. Landrieu, Mary L. [D-LA]	D · LA		Jun 25, 2001
Sen. Feinstein, Dianne [D-CA]	D · CA		Jul 10, 2001
Sen. Carper, Thomas R. [D-DE]	D · DE		Jul 11, 2001
Sen. Corzine, Jon S. [D-NJ]	D · NJ		Jul 11, 2001
Sen. Murray, Patty [D-WA]	D · WA		Jul 23, 2001
Sen. Reed, Jack [D-RI]	D · RI		Jul 24, 2001
Sen. Bingaman, Jeff [D-NM]	D · NM		Jul 25, 2001
Sen. Roberts, Pat [R-KS]	R · KS		Jul 25, 2001

Committee Activity

Committee	Chamber	Activity	Date
Health, Education, Labor, and Pensions Committee	Senate	Reported By	Oct 4, 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 HR 2887	Related bill	Nov 16, 2001: Received in the Senate. Read twice. Placed on Senate Legislative Calendar under General Orders. Calendar No. 228.

Best Pharmaceuticals for Children Act - Amends the Federal Food, Drug, and Cosmetic Act (Act) to eliminate the requirement that the Secretary of Health and Human Services develop a priority list of drugs for which additional pediatric information may be beneficial. Provides that a drug may qualify for a written request for pediatric studies if the Secretary determines that information relating to the use of an approved drug may produce pediatric health benefits.

(Sec. 3) Amends the Public Health Service Act to direct the Secretary, through the National Institutes of Health, to develop a list of approved drugs for which: (1) there is no patent or market exclusivity protection, and additional pediatric safety and effectiveness studies are needed; or (2) there is an approved or submitted application. Directs the Secretary to award contracts to entities with appropriate pediatric clinical trials experience.

Establishes a Food and Drug Administration (FDA) contract process for the studies and labeling changes of drugs lacking patent and other market exclusivity protections, including authority to declare a drug misbranded for manufacturer failure to make a requested labeling change. Authorizes appropriations through FY 2007.

(Sec. 4) Amends the Act to set forth provisions concerning written requests for studies to holders of approved applications for drugs that have market exclusivity. Requires a holder agreeing to a study to indicate when the study will commence. Provides that if the holder does not agree to a written request within a specified period, and if the Secretary determines that there is a continuing need for information relating to the use of the drug in the pediatric population, the Secretary shall refer the drug to the Foundation for the National Institutes of Health for the conduct of the pediatric studies described in the written request.

(Sec. 5) Amends the 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 the definition of pediatric studies; (4) provide for dissemination of pediatric supplement information; (5) prohibit a drug from receiving the six-month pediatric exclusivity unless on or before October 1, 2007, the Secretary makes a written request for pediatric studies and an approvable application is submitted; (6) set forth rules for situations of overlapping pediatric exclusivity and certain abbreviated new drug approval exclusivity; and (7) provide for prompt approval of certain abbreviated drug applications when specified pediatric information is added to the labeling.

(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. 12) Directs the Secretary to contract with the Institute of Medicine for a study of Federal regulations respecting research involving children, including federally-supported reports and evidence-based research.

(Sec. 13) Amends the Public Health Service Act to permit the Foundation for the National Institutes of Health to collect funds and award grants for pediatric research and studies on drugs.

(Sec. 14) Directs the Secretary to convene and consult an advisory committee on pediatrics.

(Sec. 15) Directs the Secretary to report to Congress concerning the effectiveness and impact of this Act concerning pediatric medicines.

Actions Timeline

- **Oct 23, 2001:** Received in the House.
- **Oct 23, 2001:** Message on Senate action sent to the House.
- **Oct 23, 2001:** Held at the desk.
- **Oct 18, 2001:** Measure laid before Senate by unanimous consent. (consideration: CR S10816-10819; text of measure as reported: CR S10816-10818)
- **Oct 18, 2001:** The committee substitute as amended agreed to by Unanimous Consent.
- **Oct 18, 2001:** Passed/agreed to in Senate: Passed Senate with an amendment by Unanimous Consent.
- **Oct 18, 2001:** Passed Senate with an amendment by Unanimous Consent.
- **Oct 4, 2001:** Committee on Health, Education, Labor, and Pensions. Reported by Senator Kennedy with an amendment in the nature of a substitute. With written report No. 107-79.
- **Oct 4, 2001:** Committee on Health, Education, Labor, and Pensions. Reported by Senator Kennedy with an amendment in the nature of a substitute. With written report No. 107-79.
- **Oct 4, 2001:** Placed on Senate Legislative Calendar under General Orders. Calendar No. 184.
- **Aug 1, 2001:** Committee on Health, Education, Labor, and Pensions. Ordered to be reported with an amendment in the nature of a substitute favorably.
- **May 7, 2001:** Introduced in Senate
- **May 7, 2001:** Sponsor introductory remarks on measure. (CR S4422)
- **May 7, 2001:** Read twice and referred to the Committee on Health, Education, Labor, and Pensions. (text of measure as introduced: CR S4422-4424)