

S 1156

Best Pharmaceuticals for Children Amendments of 2007

Congress: 110 (2007–2009, Ended)

Chamber: Senate

Policy Area: Health

Introduced: Apr 18, 2007

Current Status: Read twice and referred to the Committee on Health, Education, Labor, and Pensions. (text of measure

Latest Action: Read twice and referred to the Committee on Health, Education, Labor, and Pensions. (text of measure as introduced: CR S4695-4699) (Apr 18, 2007)

Official Text: <https://www.congress.gov/bill/110th-congress/senate-bill/1156>

Sponsor

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

Party: Democratic • State: CT • Chamber: Senate

Cosponsors (7 total)

Cosponsor	Party / State	Role	Date Joined
Sen. Bingaman, Jeff [D-NM]	D · NM		Apr 18, 2007
Sen. Brown, Sherrod [D-OH]	D · OH		Apr 18, 2007
Sen. Clinton, Hillary Rodham [D-NY]	D · NY		Apr 18, 2007
Sen. Harkin, Tom [D-IA]	D · IA		Apr 18, 2007
Sen. Kennedy, Edward M. [D-MA]	D · MA		Apr 18, 2007
Sen. Murray, Patty [D-WA]	D · WA		Apr 18, 2007
Sen. Reed, Jack [D-RI]	D · RI		Apr 20, 2007

Committee Activity

Committee	Chamber	Activity	Date
Health, Education, Labor, and Pensions Committee	Senate	Referred To	Apr 18, 2007

Subjects & Policy Tags

Policy Area:

Health

Related Bills

No related bills are listed.

Best Pharmaceuticals for Children Amendments of 2007 - Amends the Federal Food, Drug, and Cosmetic Act to make changes to provisions in regard to market exclusivity for pediatric drug studies on new drugs or already approved drugs, including to: (1) require that appropriate labeling changes are timely made; and (2) prohibit the Secretary of Health and Human Services from extending the period of market exclusivity later than nine months prior to the expiration of such period.

Requires an applicant or holder who does not agree with a request to conduct pediatric studies to submit to the Secretary the reasons such pediatric formulation cannot be developed.

Directs the Secretary to: (1) publish a notice identifying any drug for which a pediatric formulation was developed, studied, and found to be safe and effective that is not introduced onto the market within one year; and (2) create an internal review committee to review all written requests issued and all reports submitted.

Reduces market exclusivity for pediatric studies from six months to three months for drugs for which combined annual gross sales exceed \$1 billion.

Requires the Secretary to order the labeling of a drug to include information about the result of a pediatric study whether such study does or does not demonstrate that the drug is safe and effective.

Requires the Comptroller General to submit a report to Congress that addresses the effectiveness of providing market exclusivity for pediatric studies in ensuring that medicines used by children are tested and properly labeled.

Includes pediatric pharmacological research within the pediatric research loan repayment program.

Actions Timeline

- **Apr 18, 2007:** Introduced in Senate
- **Apr 18, 2007:** Sponsor introductory remarks on measure. (CR S4694-4695)
- **Apr 18, 2007:** Read twice and referred to the Committee on Health, Education, Labor, and Pensions. (text of measure as introduced: CR S4695-4699)