S 2289

Better Pharmaceuticals and Devices for Children Act of 2012

Congress: 112 (2011–2013, Ended)
Chamber: Senate
Policy Area: Health
Introduced: Apr 17, 2012
Current Status: Read twice and referred to the Committee on Health, Education, Labor, and Pensions.
Latest Action: Read twice and referred to the Committee on Health, Education, Labor, and Pensions. (Apr 17, 2012)
Official Text: https://www.congress.gov/bill/112th-congress/senate-bill/2289

Sponsor

Name: Sen. Reed, Jack [D-RI]
Party: Democratic • **State:** RI • **Chamber:** Senate

Cosponsors (3 total)

Cosponsor	Party / State	Role	Date Joined
Sen. Alexander, Lamar [R-TN]	R · TN		Apr 17, 2012
Sen. Murray, Patty [D-WA]	D · WA		Apr 17, 2012
Sen. Roberts, Pat [R-KS]	R · KS		Apr 17, 2012

Committee Activity

Committee	Chamber	Activity	Date
Health, Education, Labor, and Pensions Committee	Senate	Referred To	Apr 17, 2012

Subjects & Policy Tags

Policy Area:

Health

Related Bills

Bill	Relationship	Last Action
112 S 3187	Related bill	**Jul 9, 2012:** Became Public Law No: 112-144.
112 S 2516	Related bill	**May 7, 2012:** Placed on Senate Legislative Calendar under General Orders. Calendar No. 389.

Summary (as of Apr 17, 2012)

Better Pharmaceuticals and Devices for Children Act of 2012 - Amends the Federal Food, Drug, and Cosmetic Act to make provisions extending market exclusivity for conducting pediatric studies permanent. Applies such provisions only to completed pediatric studies that are the subject of a written request by the Secretary of Health and Human Services (HHS).

Requires the Secretary to issue internal standard operating procedures that provide for review by the Pediatric Review Committee of any significant modifications to pediatric study plans or written requests by the Secretary for pediatric studies.

Directs the Secretary to make publicly available the medical, statistical, and clinical pharmacology reviews of pediatric studies submitted between January 4, 2002, and September 7, 2007, for which six months of market exclusivity was granted and that resulted in a labeling change.

Establishes a process under which the Secretary may grant an extension to a new drug applicant to defer submission of an assessment of a drug's safety and effectiveness in pediatric populations.

Sets forth enforcement provisions if a persons fails to submit a required assessment, meet requirements for a deferral, or submit a request for approval of a pediatric formulation.

Establishes a procedure for the Secretary and applicant to agree on a pediatric study plan prior to submission of an assessment.

Makes the Pediatric Advisory Committee a permanent committee. Extends the Pediatric Subcommittee of the Oncologic Drugs Advisory Committee for the duration of the Oncologic Drugs Advisory Committee.

Extends for five years the program for humanitarian exemptions for pediatric medical devices.

Reauthorizes through FY2017 a demonstration program to promote pediatric device development.

Reauthorizes a National Institutes of Health (NIH) program of research on pediatric therapeutics.

Requires the Comptroller General (GAO) to evaluate the effectiveness of current federal programs in ensuring that medicines used by children are tested in pediatric populations and properly labeled for use in children.

Actions Timeline

- **Apr 17, 2012:** Introduced in Senate
- **Apr 17, 2012:** Sponsor introductory remarks on measure. (CR S2395)
- **Apr 17, 2012:** Read twice and referred to the Committee on Health, Education, Labor, and Pensions.