S 4098

Pediatric Medical Device Safety and Improvement Act of 2006

Congress: 109 (2005–2007, Ended)
Chamber: Senate
Policy Area: Health
Introduced: Dec 6, 2006
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 S11346-11348) (Dec 6, 2006)
Official Text: https://www.congress.gov/bill/109th-congress/senate-bill/4098

Sponsor

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

Cosponsors (2 total)

Cosponsor	Party / State	Role	Date Joined
Sen. DeWine, Mike [R-OH]	R · OH		Dec 6, 2006
Sen. Clinton, Hillary Rodham [D-NY]	D · NY		Dec 7, 2006

Committee Activity

Committee	Chamber	Activity	Date
Health, Education, Labor, and Pensions Committee	Senate	Referred To	Dec 7, 2006

Subjects & Policy Tags

Policy Area:

Health

Related Bills

No related bills are listed.

Summary (as of Dec 6, 2006)

Pediatric Medical Device Safety and Improvement Act of 2006 - Amends the Federal Food, Drug, and Cosmetic Act to require an application for the approval of a medical device or a product development protocol to include: (1) a description of any pediatric subpopulations that suffer from the disease or condition that the device is intended to treat, diagnose, or cure; and (2) the number of affected pediatric patients.

Excludes a medical device distributed pursuant to the humanitarian device exemption from the prohibition that no device be sold for an amount that exceeds the cost of the device if: (1) the device is intended for the treatment or diagnosis of a disease or condition that occurs in pediatric patients; and (2) other specified requirements are met.

Requires the Director of the National Institutes of Health (NIH) to designate a contact point to help innovators and physicians access funding for pediatric medical device development.

Requires the Secretary of Health and Human Services to award grants for demonstration projects to promote pediatric device development.

Includes as a duty of the Office of Pediatric Therapeutics increasing pediatric access to medical devices.

Allows the Secretary to require: (1) postmarket surveillance on certain devices that are expected to have significant use in pediatric populations; and (2) a prospective surveillance period of more than 36 months for such devices, as necessary.

Requires the Secretary, acting through the Commissioner of Food and Drugs, to establish a publicly accessible database of all studies and surveillance of medical devices.

Requires the Secretary to adopt voluntary national standards for medical device coding.

Actions Timeline

- **Dec 6, 2006:** Introduced in Senate
- **Dec 6, 2006:** Sponsor introductory remarks on measure. (CR S11343-11346)
- **Dec 6, 2006:** Read twice and referred to the Committee on Health, Education, Labor, and Pensions. (text of measure as introduced: CR S11346-11348)

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