

S 2394

A bill to amend the Federal Food, Drug, and Cosmetic Act to require labeling containing information applicable to pediatric patients.

Congress: 107 (2001–2003, Ended)

Chamber: Senate

Policy Area: Health

Introduced: Apr 29, 2002

Current Status: By Senator Kennedy from Committee on Health, Education, Labor, and Pensions filed written report. Re

Latest Action: By Senator Kennedy from Committee on Health, Education, Labor, and Pensions filed written report.

Report No. 107-300. Additional views filed. (Oct 8, 2002)

Official Text: <https://www.congress.gov/bill/107th-congress/senate-bill/2394>

Sponsor

Name: Sen. Clinton, Hillary Rodham [D-NY]

Party: Democratic • **State:** NY • **Chamber:** Senate

Cosponsors (9 total)

Cosponsor	Party / State	Role	Date Joined
Sen. DeWine, Mike [R-OH]	R · OH		Apr 29, 2002
Sen. Dodd, Christopher J. [D-CT]	D · CT		Apr 29, 2002
Sen. Kennedy, Edward M. [D-MA]	D · MA		Apr 29, 2002
Sen. Murray, Patty [D-WA]	D · WA		Apr 29, 2002
Sen. Bingaman, Jeff [D-NM]	D · NM		Jun 20, 2002
Sen. Kohl, Herb [D-WI]	D · WI		Jun 20, 2002
Sen. Landrieu, Mary L. [D-LA]	D · LA		Jul 9, 2002
Sen. Reed, Jack [D-RI]	D · RI		Jul 9, 2002
Sen. Collins, Susan M. [R-ME]	R · ME		Jul 23, 2002

Committee Activity

Committee	Chamber	Activity	Date
Health, Education, Labor, and Pensions Committee	Senate	Reported By	Aug 1, 2002

Subjects & Policy Tags

Policy Area:

Health

Related Bills

Bill	Relationship	Last Action
107 HR 4730	Identical bill	Jun 3, 2002: Referred to the Subcommittee on Health.

Amends the Federal Food, Drug, and Cosmetic Act to require license applications for new drugs and biological products to assess such drug's or product's safety and effectiveness for relevant pediatric subpopulations, including dosage.

Permits extrapolation from adult studies where the course of the disease and the effects of the drug are sufficiently similar in all populations.

Permits deferral of such assessments if adult studies are completed earlier and the applicant submits a plan for or a description of planned or ongoing pediatric studies.

Authorizes the Secretary of Health and Human Services to specify a date for submission of pediatric assessments if: (1) a drug's or product's use or need in the pediatric populations so dictates; and (2) a written request for related pediatric studies was made and no affirmative response was received. States that drugs or products with delayed assessments will be deemed misbranded and subject to seizure and injunctive proceedings, though not penalties.

Permits full waiver of such assessments if: (1) studies are highly impracticable or impossible and the evidence suggests that the drug or product would be ineffective or unsafe in all pediatric age groups; or (2) there is no meaningful therapeutic advantage or benefit in the pediatric population and little risk if used as labeled.

Permits partial waivers at the request of an applicant for a specific pediatric subpopulation if any of the full waiver grounds apply to that subpopulation or reasonable attempts for a pediatric formulation for that subpopulation have failed. Requires labels of these drugs or products to reflect such waivers.

Actions Timeline

- **Oct 8, 2002:** By Senator Kennedy from Committee on Health, Education, Labor, and Pensions filed written report. Report No. 107-300. Additional views filed.
- **Oct 8, 2002:** By Senator Kennedy from Committee on Health, Education, Labor, and Pensions filed written report. Report No. 107-300. Additional views filed.
- **Aug 1, 2002:** Committee on Health, Education, Labor, and Pensions. Ordered to be reported without amendment favorably.
- **Aug 1, 2002:** Committee on Health, Education, Labor, and Pensions. Reported by Senator Kennedy with an amendment. Without written report.
- **Aug 1, 2002:** Committee on Health, Education, Labor, and Pensions. Reported by Senator Kennedy with an amendment. Without written report.
- **Aug 1, 2002:** Placed on Senate Legislative Calendar under General Orders. Calendar No. 547.
- **Apr 29, 2002:** Introduced in Senate
- **Apr 29, 2002:** Read twice and referred to the Committee on Health, Education, Labor, and Pensions.