HR 5594

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

Congress: 107 (2001–2003, Ended)
Chamber: House
Policy Area: Health
Introduced: Oct 9, 2002
Current Status: Referred to the Subcommittee on Health.
Latest Action: Referred to the Subcommittee on Health. (Oct 28, 2002)
Official Text: https://www.congress.gov/bill/107th-congress/house-bill/5594

Sponsor

Name: Rep. Morella, Constance A. [R-MD-8]
Party: Republican • **State:** MD • **Chamber:** House

Cosponsors (1 total)

Cosponsor	Party / State	Role	Date Joined
Rep. Pryce, Deborah [R-OH-15]	R · OH		Oct 9, 2002

Committee Activity

Committee	Chamber	Activity	Date
Energy and Commerce Committee	House	Referred to	Oct 28, 2002

Subjects & Policy Tags

Policy Area:

Health

Related Bills

No related bills are listed.

Summary (as of Oct 9, 2002)

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.

Permits full waiver of such assessments if: (1) studies are highly impractical or impossible; (2) the evidence strongly suggests that the drug or product would be ineffective or unsafe in all pediatric age groups; (3) there is no meaningful therapeutic advantage or benefit in the pediatric population; or (4) the drug or product is not likely to be used in a substantial number of pediatric patients.

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 to provide indication in cases in which a waiver has been granted due to evidence a product would be unsafe or ineffective in pediatric populations.

Authorizes the Secretary of Health and Human Services to specify a date for submission of pediatric assessments if: (1) the drug or biological product would represent a meaningful therapeutic benefit for pediatric patients for one or more claimed indications and the absence of adequate labeling could pose significant risks to pediatric patients; or (2) it is used for a number of pediatric patients for the labeled indications and the absence of adequate labeling could pose significant risks to pediatric patients. Sets forth criteria for full waiver and partial waivers of such requirement. Requires labels to provide indication in cases in which a waiver has been granted due to evidence a product would be unsafe or ineffective in pediatric populations.

Requires the Secretary to issue a written request for related pediatric studies under the Public Health Service Act before requiring an assessment for a drug.

States that drugs or products with delayed assessments may be deemed misbranded and subject to seizure and injunctive proceedings, though not penalties.

Actions Timeline

- **Oct 28, 2002:** Referred to the Subcommittee on Health.
- **Oct 9, 2002:** Introduced in House
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- **Oct 9, 2002:** Referred to the House Committee on Energy and Commerce.