HR 3047

Best Pharmaceuticals for Children Act

Congress: 107 (2001–2003, Ended)
Chamber: House
Policy Area: Health
Introduced: Oct 4, 2001
Current Status: Referred to the Subcommittee on Health.
Latest Action: Referred to the Subcommittee on Health. (Oct 15, 2001)
Official Text: https://www.congress.gov/bill/107th-congress/house-bill/3047

Sponsor

Name: Rep. Waxman, Henry A. [D-CA-29]
Party: Democratic • **State:** CA • **Chamber:** House

Cosponsors (7 total)

Cosponsor	Party / State	Role	Date Joined
Rep. Barrett, Thomas M. [D-WI-5]	D · WI		Oct 4, 2001
Rep. Brown, Sherrod [D-OH-13]	D · OH		Oct 4, 2001
Rep. Deutsch, Peter [D-FL-20]	D · FL		Oct 4, 2001
Rep. Dingell, John D. [D-MI-16]	D · MI		Oct 4, 2001
Rep. Green, Gene [D-TX-29]	D · TX		Oct 4, 2001
Rep. Pallone, Frank, Jr. [D-NJ-6]	D · NJ		Oct 4, 2001
Rep. Stupak, Bart [D-MI-1]	D · MI		Oct 4, 2001

Committee Activity

Committee	Chamber	Activity	Date
Energy and Commerce Committee	House	Referred to	Oct 15, 2001

Subjects & Policy Tags

Policy Area:

Health

Related Bills

No related bills are listed.

Summary (as of Oct 4, 2001)

Best Pharmaceuticals for Children Act - Amends the Federal Food, Drug, and Cosmetic Act to require the Secretary of Health and Human Services to establish a pediatric drug studies program. Directs the Secretary to establish and maintain a list of drugs for which: (1) there is an approved market application and no patent or market exclusivity protection; and (2) additional pediatric safety and effectiveness studies are needed. Authorizes the Secretary to require holders or sponsors of certain drugs to conduct such studies on a contract payment basis. Requires the Secretary to give preference to the holders or sponsors of drugs for which the studies are requested rather than required when awarding test contracts.

Sets forth procedures for making labeling changes for already marketed drugs, if so indicated by such studies.

Eliminates the user fee waiver for pediatric supplements to a human drug application.

Sets forth requirements for the additional six-month exclusivity period for new or already-marketed pediatric drugs.

Amends Title IV of the Public Health Service Act to direct the Secretary to establish the Foundation for Pediatric Research to support research on drugs lacking exclusivity for which pediatric studies are needed.

Directs the Secretary to establish an Office of Pediatric Therapeutics within the Office of the Commissioner of Food and Drugs, which shall coordinate all FDA pediatric activities.

Directs the Secretary to contract with the Institute of Medicine to review Federal regulations, reports, and support for research involving children, with particular attention to issues of compensation, informed consent, and risk/benefits assessments in terms of research versus therapeutic treatment.

Actions Timeline

- **Oct 15, 2001:** Referred to the Subcommittee on Health.
- **Oct 4, 2001:** Introduced in House
- **Oct 4, 2001:** Introduced in House
- **Oct 4, 2001:** Referred to the House Committee on Energy and Commerce.