

HR 3452

Best Pharmaceuticals for Children Act

Congress: 107 (2001–2003, Ended)

Chamber: House

Policy Area: Health

Introduced: Dec 11, 2001

Current Status: Referred to the Subcommittee on Health.

Latest Action: Referred to the Subcommittee on Health. (Dec 28, 2001)

Official Text: <https://www.congress.gov/bill/107th-congress/house-bill/3452>

Sponsor

Name: Rep. Greenwood, James C. [R-PA-8]

Party: Republican • State: PA • Chamber: House

Cosponsors (1 total)

Cosponsor	Party / State	Role	Date Joined
Rep. Eshoo, Anna G. [D-CA-14]	D · CA		Dec 11, 2001

Committee Activity

Committee	Chamber	Activity	Date
Energy and Commerce Committee	House	Referred to	Dec 28, 2001

Subjects & Policy Tags

Policy Area:

Health

Related Bills

Bill	Relationship	Last Action
107 S 1789	Identical bill	Jan 4, 2002: Became Public Law No: 107-109.

Best Pharmaceuticals for Children Act - Amends the Public Health Service Act to direct the Secretary of Health and Human Services, through the National Institutes of Health, to develop an annual list of approved drugs for which: (1) there is an approved or pending new drug application or no patent or market exclusivity protection; and (2) additional pediatric safety and effectiveness studies are needed. Directs the Secretary to award contracts to entities with appropriate experience for pediatric clinical trials of such drugs.

Establishes a Food and Drug Administration (FDA) contract process for related labeling changes.

Amends the Federal Food, Drug, and Cosmetic Act to: (1) eliminate the user fee waiver for pediatric supplements to a human drug application; (2) provide priority status for pediatric supplements; (3) include neonates within the definition of pediatric studies; (4) provide for dissemination of pediatric supplement information; and (5) set forth requirements for the additional six-month exclusivity period for new or already-marketed pediatric drugs.

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.

Includes within the purposes and activities of the Foundation for the National Institutes of Health the collection of funds for pediatric pharmacological research.

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

- **Dec 28, 2001:** Referred to the Subcommittee on Health.
- **Dec 11, 2001:** Introduced in House
- **Dec 11, 2001:** Introduced in House
- **Dec 11, 2001:** Referred to the House Committee on Energy and Commerce.