S 993

Pediatric Research Improvement Act

Congress: 110 (2007–2009, Ended)
Chamber: Senate
Policy Area: Health
Introduced: Mar 27, 2007
Current Status: Read twice and referred to the Committee on Health, Education, Labor, and Pensions.
Latest Action: Read twice and referred to the Committee on Health, Education, Labor, and Pensions. (Mar 27, 2007)
Official Text: https://www.congress.gov/bill/110th-congress/senate-bill/993

Sponsor

Name: Sen. Clinton, Hillary Rodham [D-NY]
Party: Democratic • **State:** NY • **Chamber:** Senate

Cosponsors (1 total)

Cosponsor	Party / State	Role	Date Joined
Sen. Dodd, Christopher J. [D-CT]	D · CT		Mar 27, 2007

Committee Activity

Committee	Chamber	Activity	Date
Health, Education, Labor, and Pensions Committee	Senate	Referred To	Mar 27, 2007

Subjects & Policy Tags

Policy Area:

Health

Related Bills

No related bills are listed.

Summary (as of Mar 27, 2007)

Pediatric Research Improvement Act - Amends the Federal Food, Drug, and Cosmetic Act (FFDCA) to direct an applicant seeking to waive submission requirements related to pediatric assessments of the safety and effectiveness of a drug or biological product to submit to the Secretary of Health and Human Services documentation detailing why a pediatric formulation cannot be developed.

Requires an applicant seeking to defer submission of some or all of such assessments to submit to the Secretary a timeline for the completion of pediatric studies.

Requires the Secretary to create an internal committee to review pediatric assessment requests issued, pediatric assessments conducted, and deferral and waiver requests.

Considers a supplement to a new drug or biological license application proposing a labeling change as a result of any pediatric assessments to be a priority supplement. Sets forth dispute resolution procedures for labeling changes for pediatric drugs.

Requires the Commissioner of the Food and Drug Administration (FDA) to make available to the public the medical, statistical, and clinical pharmacology reviews of pediatric assessments.

Requires the Secretary to: (1) require sponsors of the assessments that result in labeling changes to distribute such information to physicians and other health care providers; (2) ensure that all adverse event reports that have been received for such a drug are referred to the Office of Pediatric Therapeutics for one year after a labeling change; and (3) contract with the Institute of Medicine to study and report to Congress regarding the pediatric studies conducted pursuant to FFDCA since 1997.

Requires the Comptroller General to report to Congress on the effectiveness of FFDCA provisions relating to pediatric studies in ensuring that medicines used by children are tested and properly labeled.

Actions Timeline

- **Mar 27, 2007:** Introduced in Senate
- **Mar 27, 2007:** Sponsor introductory remarks on measure. (CR S3842)
- **Mar 27, 2007:** Read twice and referred to the Committee on Health, Education, Labor, and Pensions.