HR 2589

Improving Pharmaceuticals for Children Act of 2007

Congress: 110 (2007–2009, Ended)
Chamber: House
Policy Area: Health
Introduced: Jun 6, 2007
Current Status: Referred to the Subcommittee on Health.
Latest Action: Referred to the Subcommittee on Health. (Jun 6, 2007)
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Sponsor

Name: Rep. Eshoo, Anna G. [D-CA-14]
Party: Democratic • **State:** CA • **Chamber:** House

Cosponsors

No cosponsors are listed for this bill.

Committee Activity

Committee	Chamber	Activity	Date
Energy and Commerce Committee	House	Referred to	Jun 6, 2007

Subjects & Policy Tags

Policy Area:

Health

Related Bills

No related bills are listed.

Summary (as of Jun 6, 2007)

Improving Pharmaceuticals for Children Act of 2007 - Amends the Federal Food, Drug, and Cosmetic Act to revise provisions relating to market exclusivity for pediatric drug studies on new or already approved drugs to: (1) require that appropriate labeling changes are timely made; and (2) prohibit the Secretary of Health and Human Services from extending the period of market exclusivity later than one year prior to the expiration of such period.

Directs the Secretary to: (1) publish a notice identifying any drug for which a pediatric formulation was developed, studied, and found to be safe and effective in the pediatric population if such formulation is not introduced onto the market within one year; and (2) order the labeling of a drug to include information about the results of a pediatric study.

Requires the Secretary, acting through the Director of the National Institutes of Heath (NIH), to develop, publish, and revise a priority list of needs in pediatric therapeutics.

Revises requirements for the submission of pediatric assessments of the safety and effectiveness of a drug or biological product with a new drug or supplemental application to require an applicant seeking: (1) a deferral of such requirements to submit a timeline for the completion of such studies; and (2) a waiver of such requirements to submit documentation detailing why a pediatric formulation cannot be developed.

Considers a supplement to any new drug or biological license application proposing a labeling change as a result of any pediatric assessment to be a priority application or supplement.

Requires the Comptroller General to study the effectiveness of federal law in ensuring that medicines used by children are tested and properly labeled.

Actions Timeline

- **Jun 6, 2007:** Introduced in House
- **Jun 6, 2007:** Referred to the House Committee on Energy and Commerce.
- **Jun 6, 2007:** Referred to the Subcommittee on Health.