S 1088

Lower PRICED Drugs Act

Congress: 110 (2007–2009, Ended)
Chamber: Senate
Policy Area: Health
Introduced: Apr 11, 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. (Apr 11, 2007)
Official Text: https://www.congress.gov/bill/110th-congress/senate-bill/1088

Sponsor

Name: Sen. Stabenow, Debbie [D-MI]
Party: Democratic • **State:** MI • **Chamber:** Senate

Cosponsors (3 total)

Cosponsor	Party / State	Role	Date Joined
Sen. Lott, Trent [R-MS]	R · MS		Apr 11, 2007
Sen. Kohl, Herb [D-WI]	D · WI		Apr 12, 2007
Sen. Levin, Carl [D-MI]	D · MI		Apr 16, 2007

Committee Activity

Committee	Chamber	Activity	Date
Health, Education, Labor, and Pensions Committee	Senate	Referred To	Apr 11, 2007

Subjects & Policy Tags

Policy Area:

Health

Related Bills

No related bills are listed.

Summary (as of Apr 11, 2007)

Lower Prices Reduced with Increased Competition and Efficient Development of Drugs Act or the Lower PRICED Drugs Act - Amends the Federal Food, Drug, and Cosmetic Act to require an abbreviated application for a new drug containing certain antibiotics, the approved labeling for which includes a method of use that is claimed by a patent, to include a statement: (1) that identifies the relevant patent and the approved use covered by the patent; and (2) that the applicant is not seeking approval of such use.

Requires the court to consider the totality of circumstances and the public interest in deciding whether to shorten the 30-month period that delays the approval of an abbreviated drug application when a patent infringement case is filed against the applicant.

Limits market exclusivity provided for conducting pediatric studies of new or already approved drugs to only those drugs for which the Secretary of Health and Human Services approves labeling that provides specific, therapeutically meaningful information about the use of the drug in pediatric patients. Reduces market exclusivity for such studies for drugs with sales revenue that is $1 billion or more.

Prohibits the Secretary from delaying approval of a new drug application while a petition seeking any action relating to such an application is being reviewed or considered. Requires the Secretary to take final agency action on a petition within 180 days of receipt, with no extensions allowed.

Extends the 30-month period that the Secretary has to approve or disapprove an abbreviated application for a new drug by the amount of time that lapses from the date the Secretary receives a petition and the date of the final agency action on the petition, without regard to whether the Secretary grants or denies the petition.

Actions Timeline

- **Apr 11, 2007:** Introduced in Senate
- **Apr 11, 2007:** Read twice and referred to the Committee on Health, Education, Labor, and Pensions.