S 2300

Lower PRICED Drugs Act

Congress: 109 (2005–2007, Ended)
Chamber: Senate
Policy Area: Health
Introduced: Feb 16, 2006
Current Status: Star Print ordered on the bill.
Latest Action: Star Print ordered on the bill. (Feb 27, 2006)
Official Text: https://www.congress.gov/bill/109th-congress/senate-bill/2300

Sponsor

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

Cosponsors (2 total)

Cosponsor	Party / State	Role	Date Joined
Sen. Lott, Trent [R-MS]	R · MS		Feb 16, 2006
Sen. Kohl, Herb [D-WI]	D · WI		Mar 13, 2006

Committee Activity

Committee	Chamber	Activity	Date
Health, Education, Labor, and Pensions Committee	Senate	Referred To	Feb 16, 2006

Subjects & Policy Tags

Policy Area:

Health

Related Bills

Bill	Relationship	Last Action
109 HR 6022	Related bill	**Aug 1, 2006:** Referred to the Subcommittee on Health.

Summary (as of Feb 16, 2006)

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 drugs to only those new drugs for which the Secretary of Health and Human Services approves labeling that contains specific, therapeutically meaningful information about the use of the drug product in pediatric patients.

Prohibits the Secretary from delaying the approval of a new drug application while a petition is reviewed and considered. Requires the Secretary to take final agency action on a petition within six months 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

- **Feb 27, 2006:** Star Print ordered on the bill.
- **Feb 16, 2006:** Introduced in Senate
- **Feb 16, 2006:** Sponsor introductory remarks on measure. (CR S1420-1421)
- **Feb 16, 2006:** Read twice and referred to the Committee on Health, Education, Labor, and Pensions. (text of measure as introduced: CR S1421-1422)