S 369

Preserve Access to Affordable Generics Act

Congress: 111 (2009–2011, Ended)
Chamber: Senate
Policy Area: Commerce
Introduced: Feb 3, 2009
Current Status: By Senator Leahy from Committee on the Judiciary filed written report. Report No. 111-123. Minority
Latest Action: By Senator Leahy from Committee on the Judiciary filed written report. Report No. 111-123. Minority views filed. (Feb 2, 2010)
Official Text: https://www.congress.gov/bill/111th-congress/senate-bill/369

Sponsor

Name: Sen. Kohl, Herb [D-WI]
Party: Democratic • **State:** WI • **Chamber:** Senate

Cosponsors (11 total)

Cosponsor	Party / State	Role	Date Joined
Sen. Brown, Sherrod [D-OH]	D · OH		Feb 3, 2009
Sen. Durbin, Richard J. [D-IL]	D · IL		Feb 3, 2009
Sen. Feingold, Russell D. [D-WI]	D · WI		Feb 3, 2009
Sen. Grassley, Chuck [R-IA]	R · IA		Feb 3, 2009
Sen. Collins, Susan M. [R-ME]	R · ME		May 12, 2009
Sen. Klobuchar, Amy [D-MN]	D · MN		Jun 1, 2009
Sen. Nelson, Bill [D-FL]	D · FL		Jun 23, 2009
Sen. Franken, Al [D-MN]	D · MN		Sep 9, 2009
Sen. Dorgan, Byron L. [D-ND]	D · ND		Feb 24, 2010
Sen. Johnson, Tim [D-SD]	D · SD		Jul 26, 2010
Sen. Sanders, Bernard [I-VT]	I · VT		Aug 2, 2010

Committee Activity

Committee	Chamber	Activity	Date
Judiciary Committee	Senate	Reported By	Oct 15, 2009

Subjects & Policy Tags

Policy Area:

Commerce

Related Bills

No related bills are listed.

Summary (as of Oct 15, 2009)

Preserve Access to Affordable Generics Act - Declares as the purposes of this Act to: (1) enhance competition in the pharmaceutical market by stopping anticompetitive agreements between brand name and generic drug manufacturers; and (2) support the purpose and intent of antitrust laws by prohibiting anticompetitive practices in the pharmaceutical industry that harm consumers.

Amends the Federal Trade Commission Act to authorize the Federal Trade Commission (FTC) to initiate a proceeding against parties to any agreement resolving or settling, on a final or interim basis, a patent infringement claim, in connection with the sale of a drug product. Establishes a presumption that any such agreement has anticompetitive effects and is unlawful if the filer of an abbreviated new drug application receives anything of value and agrees to limit or forego research, development, manufacturing, marketing, or sales of the drug product for any period of time. Allows an exception to such presumption if the parties to the agreement demonstrate by clear and convincing evidence, based on specified competitive factors, that the procompetitive benefits of the agreement outweigh the anticompetitive effects.

Exempts from the restrictions of this Act a resolution or settlement of a patent infringement claim if the only consideration granted by a new drug application holder to a filer of an abbreviated new drug application is the right to market the drug product in the United States prior to the expiration of any patent that is the basis for the patent infringement claim or any patent right that would prevent the marketing of such drug, a payment for reasonable litigation expenses not exceeding $7.5 million, and a covenant not to sue on any claim that the filer infringes a U.S. patent.

Allows review of FTC enforcement orders under this Act in federal court. Imposes civil penalties for violations of this Act.

Amends the Medicare Prescription Drug, Improvement, and Modernization Act of 2003 to set forth additional filing requirements related to agreements between a brand name drug company and a generic drug applicant. Requires the Chief Executive Officer or the company official responsible for negotiating any agreement to file a certification that materials filed with respect to such agreement are complete, final, and exclusive.

Amends the Federal Food, Drug, and Cosmetic Act to provide that forfeiture of the 180-day exclusivity period for the marketing of a generic drug occurs if there is a final decision of the FTC or a court that an agreement has violated this Act.

Grants the FTC exclusive authority to litigate matters relating to anticompetitive practices in connection with the sale of generic brand drugs. Establishes a three-year limitation period for bringing FTC enforcement actions (other than cease and desist requests) under this Act.

Actions Timeline

- **Feb 2, 2010:** By Senator Leahy from Committee on the Judiciary filed written report. Report No. 111-123. Minority views filed.
- **Oct 15, 2009:** Committee on the Judiciary. Ordered to be reported with an amendment in the nature of a substitute favorably.
- **Oct 15, 2009:** Committee on the Judiciary. Reported by Senator Leahy with an amendment in the nature of a substitute. Without written report.
- **Oct 15, 2009:** Placed on Senate Legislative Calendar under General Orders. Calendar No. 183.
- **Feb 3, 2009:** Introduced in Senate
- **Feb 3, 2009:** Sponsor introductory remarks on measure. (CR S1433)
- **Feb 3, 2009:** Read twice and referred to the Committee on the Judiciary. (text of measure as introduced: CR S1433-1434)