

S 316

Preserve Access to Affordable Generics Act

Congress: 110 (2007–2009, Ended)

Chamber: Senate

Policy Area: Commerce

Introduced: Jan 17, 2007

Current Status: Committee on the Judiciary Subcommittee on Antitrust, Competition Policy and Consumer Rights. Hearin

Latest Action: Committee on the Judiciary Subcommittee on Antitrust, Competition Policy and Consumer Rights.

Hearings held. (Mar 7, 2007)

Official Text: https://www.congress.gov/bill/110th-congress/senate-bill/316

Sponsor

Name: Sen. Kohl, Herb [D-WI]

Party: Democratic • State: WI • Chamber: Senate

Cosponsors (10 total)

Cosponsor	Party / State	Role	Date Joined
Sen. Feingold, Russell D. [D-WI]	D · WI		Jan 17, 2007
Sen. Grassley, Chuck [R-IA]	R · IA		Jan 17, 2007
Sen. Leahy, Patrick J. [D-VT]	D · VT		Jan 17, 2007
Sen. Schumer, Charles E. [D-NY]	D · NY		Jan 17, 2007
Sen. Kennedy, Edward M. [D-MA]	D · MA		Feb 14, 2007
Sen. Durbin, Richard J. [D-IL]	D · IL		Feb 27, 2007
Sen. Johnson, Tim [D-SD]	D · SD		Apr 11, 2007
Sen. Obama, Barack [D-IL]	D · IL		Sep 12, 2007
Sen. Brown, Sherrod [D-OH]	D · OH		Dec 18, 2007
Sen. Klobuchar, Amy [D-MN]	D · MN		Sep 8, 2008

Committee Activity

Committee	Chamber	Activity	Date
Judiciary Committee	Senate	Hearings By (subcommittee)	Mar 7, 2007

Subjects & Policy Tags

Policy Area:

Commerce

Related Bills

Bill	Relationship	Last Action
110 HR 1432	Related bill	Mar 12, 2007: Referred to the Subcommittee on Commerce, Trade and Consumer Protection.

**(This measure has not been amended since it was introduced. The summary has been expanded because action occurred on the measure.)**

Preserve Access to Affordable Generics Act - Amends the Clayton Act to make it unlawful for a person, in connection with the sale of a drug product, to be a party to any agreement resolving or settling a patent infringement claim in which: (1) an abbreviated new drug (generic) application filer receives anything of value; and (2) such filer agrees not to research, develop, manufacture, market, or sell the generic product for any period. Excludes a resolution or settlement that includes no more than the right to market the generic product prior to the expiration of the patent.

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 agreements: (1) are complete, final, and exclusive; (2) include any ancillary agreements that are contingent upon, provide a contingent condition for, or are otherwise related to, the agreement; and (3) include written descriptions of any relevant oral agreements, representations, commitments, or promises between the parties that have not been reduced to writing.

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 Federal Trade Commission (FTC) or the court that an agreement has violated this Act.

Requires the FTC to study the prevalence of anticompetitive agreements in the pharmaceutical industry and their impact. Requires the Attorney General or FTC to consider whether any additional enforcement action is necessary.

Authorizes appropriations.

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## Actions Timeline

- **Mar 7, 2007:** Committee on the Judiciary Subcommittee on Antitrust, Competition Policy and Consumer Rights. Hearings held.
- **Feb 27, 2007:** Committee on the Judiciary. Reported by Senator Leahy without amendment. Without written report.
- **Feb 27, 2007:** Placed on Senate Legislative Calendar under General Orders. Calendar No. 59.
- **Feb 15, 2007:** Committee on the Judiciary. Approved for reporting without amendment favorably.
- **Jan 17, 2007:** Introduced in Senate
- **Jan 17, 2007:** Sponsor introductory remarks on measure. (CR S679)
- **Jan 17, 2007:** Read twice and referred to the Committee on the Judiciary. (text of measure as introduced: CR S679-680)
- **Jan 17, 2007:** Committee on the Judiciary. Hearings held.