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Preserve Access to Affordable Generics Act

Congress: 114 (2015–2017, Ended)
Chamber: Senate
Policy Area: Commerce
Introduced: Sep 9, 2015
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. (Sep 22, 2015)
Official Text: https://www.congress.gov/bill/114th-congress/senate-bill/2019

Sponsor

Name: Sen. Klobuchar, Amy [D-MN]
Party: Democratic • **State:** MN • **Chamber:** Senate

Cosponsors (1 total)

Cosponsor	Party / State	Role	Date Joined
Sen. Grassley, Chuck [R-IA]	R · IA		Sep 9, 2015

Committee Activity

Committee	Chamber	Activity	Date
Judiciary Committee	Senate	Hearings By (subcommittee)	Sep 22, 2015

Subjects & Policy Tags

Policy Area:

Commerce

Related Bills

No related bills are listed.

Summary (as of Sep 9, 2015)

Preserve Access to Affordable Generics Act

This bill 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 a patent infringement claim in connection with the sale of a drug. Such an agreement, with specified exceptions, is presumed to have anticompetitive effects and is a violation of this Act if the filer of an abbreviated new drug (generic) application receives anything of value and agrees to limit or forego research, development, manufacturing, marketing, or sales of the generic drug.

An agreement is exempted if the only consideration granted to the generic manufacturer is: (1) the right to market the generic drug prior to the expiration of any statutory exclusivity, (2) a payment for reasonable litigation expenses, and (3) a covenant not to sue on any claim that the generic drug infringes a patent.

An entity subject to an FTC enforcement order may petition for the order be reviewed in federal court. Civil penalties are imposed for violations of this Act.

This bill amends the Medicare Prescription Drug, Improvement, and Modernization Act of 2003 to require a brand name manufacturer and generic manufacturer to submit to the FTC any other agreements the parties enter into within 30 days of entering into an agreement related to the manufacturing, marketing, sale, or exclusivity period of a drug.

This bill amends the Federal Food, Drug, and Cosmetic Act to forfeit the 180-day exclusivity period for a generic drug if the FTC or a court decides that an agreement violated this Act.

The FTC is granted exclusive authority to litigate matters relating to anticompetitive practices in connection with the sale of generic drugs. The FTC may not commence enforcement actions (other than cease and desist requests) more than six years after the FTC is notified of an agreement.

Actions Timeline

- **Sep 22, 2015:** Committee on the Judiciary Subcommittee on Antitrust, Competition Policy and Consumer Rights. Hearings held.
- **Sep 9, 2015:** Introduced in Senate
- **Sep 9, 2015:** Read twice and referred to the Committee on the Judiciary.