S 142

Preserve Access to Affordable Generics and Biosimilars Act

Congress: 118 (2023–2025, Ended)
Chamber: Senate
Policy Area: Health
Introduced: Jan 30, 2023
Current Status: Placed on Senate Legislative Calendar under General Orders. Calendar No. 20.
Latest Action: Placed on Senate Legislative Calendar under General Orders. Calendar No. 20. (Mar 1, 2023)
Official Text: https://www.congress.gov/bill/118th-congress/senate-bill/142

Sponsor

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

Cosponsors (10 total)

Cosponsor	Party / State	Role	Date Joined
Sen. Blumenthal, Richard [D-CT]	D · CT		Jan 30, 2023
Sen. Booker, Cory A. [D-NJ]	D · NJ		Jan 30, 2023
Sen. Cramer, Kevin [R-ND]	R · ND		Jan 30, 2023
Sen. Durbin, Richard J. [D-IL]	D · IL		Jan 30, 2023
Sen. Grassley, Chuck [R-IA]	R · IA		Jan 30, 2023
Sen. Kelly, Mark [D-AZ]	D · AZ		Jan 30, 2023
Sen. Van Hollen, Chris [D-MD]	D · MD		Jan 30, 2023
Sen. Ernst, Joni [R-IA]	R · IA		Feb 1, 2023
Sen. Ossoff, Jon [D-GA]	D · GA		Feb 1, 2023
Sen. Welch, Peter [D-VT]	D · VT		Feb 9, 2023

Committee Activity

Committee	Chamber	Activity	Date
Judiciary Committee	Senate	Reported By	Mar 1, 2023

Subjects & Policy Tags

Policy Area:

Health

Related Bills

No related bills are listed.

Summary (as of Mar 1, 2023)

Preserve Access to Affordable Generics and Biosimilars Act

This bill authorizes the Federal Trade Commission (FTC) to initiate proceedings against parties to any agreement resolving or settling a patent infringement claim in connection with the sale of a drug or biological product. Such an agreement is presumed to have anticompetitive effects and is a violation of this bill if the filer of the generic drug or biosimilar application receives anything of value and agrees to limit or forego research, development, manufacturing, marketing, or sales of the generic drug or biosimilar.

An agreement is exempted if the only consideration granted to the generic manufacturer is (1) the right to market and secure final approval for its product prior to the expiration of any statutory exclusivity, (2) a payment for reasonable litigation expenses, or (3) a covenant not to sue on any claim that the generic drug or biosimilar infringes a patent. An agreement is also exempt if the agreement's pro-competitive benefits outweigh the anticompetitive effects.

When a generic or biosimilar drug manufacturer enters into an agreement with another drug manufacturer related to the manufacturing, marketing, or sale of a drug, the manufacturers must certify that the material they have given the FTC concerning the agreement contains the complete agreement and any agreements related to that main agreement, including descriptions of any oral agreements or representations.

The bill imposes penalties for violations of this bill, including the forfeiture of the 180-day marketing exclusivity period for a generic drug.

Actions Timeline

- **Mar 1, 2023:** Committee on the Judiciary. Reported by Senator Durbin with an amendment in the nature of a substitute. Without written report.
- **Mar 1, 2023:** Placed on Senate Legislative Calendar under General Orders. Calendar No. 20.
- **Feb 9, 2023:** Committee on the Judiciary. Ordered to be reported with an amendment in the nature of a substitute favorably.
- **Jan 30, 2023:** Introduced in Senate
- **Jan 30, 2023:** Read twice and referred to the Committee on the Judiciary.