S 1096

Preserve Access to Affordable Generics and Biosimilars Act

Congress: 119 (2025–2027, Current)
Chamber: Senate
Policy Area: Health
Introduced: Mar 24, 2025
Current Status: Placed on Senate Legislative Calendar under General Orders. Calendar No. 46.
Latest Action: Placed on Senate Legislative Calendar under General Orders. Calendar No. 46. (Apr 10, 2025)
Official Text: https://www.congress.gov/bill/119th-congress/senate-bill/1096

Sponsor

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

Cosponsors (8 total)

Cosponsor	Party / State	Role	Date Joined
Sen. Blumenthal, Richard [D-CT]	D · CT		Mar 24, 2025
Sen. Booker, Cory A. [D-NJ]	D · NJ		Mar 24, 2025
Sen. Cramer, Kevin [R-ND]	R · ND		Mar 24, 2025
Sen. Durbin, Richard J. [D-IL]	D · IL		Mar 24, 2025
Sen. Ernst, Joni [R-IA]	R · IA		Mar 24, 2025
Sen. Grassley, Chuck [R-IA]	R · IA		Mar 24, 2025
Sen. Kelly, Mark [D-AZ]	D · AZ		Mar 24, 2025
Sen. Welch, Peter [D-VT]	D · VT		Mar 24, 2025

Committee Activity

Committee	Chamber	Activity	Date
Judiciary Committee	Senate	Reported By	Apr 10, 2025

Subjects & Policy Tags

Policy Area:

Health

Related Bills

No related bills are listed.

Summary (as of Mar 24, 2025)

Preserve Access to Affordable Generics and Biosimilars Act

This bill prohibits parties from entering into any agreement that resolves or settles a patent claim related to the sale of a drug or biological product and that has anticompetitive effects. Such an agreement is presumed to have anticompetitive effects if the filer of a 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 exempt 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 U.S. patent. An agreement is also exempt if the agreement's pro-competitive benefits outweigh the anticompetitive effects.

The bill provides for enforcement by the Federal Trade Commission (FTC). Violators are subject to penalties including the forfeiture of the 180-day marketing exclusivity period for a generic drug.

Additionally, 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 and the Department of Justice concerning the agreement contains the complete agreement and any related agreements, including descriptions of any oral agreements or representations.

Actions Timeline

- **Apr 10, 2025:** Committee on the Judiciary. Reported by Senator Grassley with an amendment in the nature of a substitute. Without written report.
- **Apr 10, 2025:** Placed on Senate Legislative Calendar under General Orders. Calendar No. 46.
- **Apr 3, 2025:** Committee on the Judiciary. Ordered to be reported with an amendment in the nature of a substitute favorably.
- **Mar 24, 2025:** Introduced in Senate
- **Mar 24, 2025:** Read twice and referred to the Committee on the Judiciary.

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