# S 64

Preserve Access to Affordable Generics and Biosimilars Act

**Congress:** 116 (2019–2021, Ended)
**Chamber:** Senate
**Policy Area:** Health
**Introduced:** Jan 9, 2019
**Current Status:** Read twice and referred to the Committee on the Judiciary.
**Latest Action:** Read twice and referred to the Committee on the Judiciary. (Jan 9, 2019)
**Official Text:** https://www.congress.gov/bill/116th-congress/senate-bill/64

## Sponsor

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

## Cosponsors (7 total)

| Cosponsor | Party / State | Role | Date Joined |
|---|---|---|---|
| Sen. Grassley, Chuck [R-IA] | R · IA | | Jan 9, 2019 |
| Sen. Ernst, Joni [R-IA] | R · IA | | Jan 28, 2019 |
| Sen. Leahy, Patrick J. [D-VT] | D · VT | | Jan 28, 2019 |
| Sen. Cramer, Kevin [R-ND] | R · ND | | Mar 28, 2019 |
| Sen. Durbin, Richard J. [D-IL] | D · IL | | Apr 10, 2019 |
| Sen. Collins, Susan M. [R-ME] | R · ME | | Jun 5, 2019 |
| Sen. Van Hollen, Chris [D-MD] | D · MD | | Jun 5, 2019 |

## Committee Activity

| Committee | Chamber | Activity | Date |
|---|---|---|---|
| Judiciary Committee | Senate | Referred To | Jan 9, 2019 |

## Subjects & Policy Tags

**Policy Area:**

Health

## Related Bills

| Bill | Relationship | Last Action |
|---|---|---|
| 116 HR 2375 | Related bill | **Dec 24, 2020:** Placed on the Union Calendar, Calendar No. 576. |
| 116 S 3384 | Related bill | **Mar 3, 2020:** Read twice and referred to the Committee on Finance. |
| 116 S 1801 | Related bill | **Jun 12, 2019:** Read twice and referred to the Committee on Finance. |
| 116 HR 1344 | Related bill | **Mar 25, 2019:** Referred to the Subcommittee on Antitrust, Commercial, and Administrative Law. |

## Summary (as of Jan 9, 2019)

### 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 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

- **Jan 9, 2019:** Introduced in Senate
- **Jan 9, 2019:** Read twice and referred to the Committee on the Judiciary.