HR 2891

Preserve Access to Affordable Generics and Biosimilars Act

Congress: 117 (2021–2023, Ended)
Chamber: House
Policy Area: Health
Introduced: Apr 28, 2021
Current Status: Ordered to be Reported in the Nature of a Substitute by the Yeas and Nays: 28 - 13.
Latest Action: Ordered to be Reported in the Nature of a Substitute by the Yeas and Nays: 28 - 13. (Sep 29, 2021)
Official Text: https://www.congress.gov/bill/117th-congress/house-bill/2891

Sponsor

Name: Rep. Nadler, Jerrold [D-NY-10]
Party: Democratic • **State:** NY • **Chamber:** House

Cosponsors (7 total)

Cosponsor	Party / State	Role	Date Joined
Rep. Buck, Ken [R-CO-4]	R · CO		Apr 28, 2021
Rep. Cicilline, David N. [D-RI-1]	D · RI		Apr 28, 2021
Rep. Maloney, Carolyn B. [D-NY-12]	D · NY		Apr 28, 2021
Rep. Owens, Burgess [R-UT-4]	R · UT		May 28, 2021
Del. Norton, Eleanor Holmes [D-DC-At Large]	D · DC		Jul 20, 2021
Rep. Budd, Ted [R-NC-13]	R · NC		Sep 24, 2021
Rep. Jackson Lee, Sheila [D-TX-18]	D · TX		Sep 28, 2021

Committee Activity

Committee	Chamber	Activity	Date
Energy and Commerce Committee	House	Referred to	Apr 29, 2021
Judiciary Committee	House	Markup By	Sep 29, 2021

Subjects & Policy Tags

Policy Area:

Health

Related Bills

Bill	Relationship	Last Action
117 HR 5237	Related bill	**Nov 1, 2022:** Referred to the Subcommittee on Courts, Intellectual Property, and the Internet.
117 HR 5260	Related bill	**Nov 1, 2022:** Referred to the Subcommittee on Courts, Intellectual Property, and the Internet.
117 S 1428	Related bill	**Dec 9, 2021:** Placed on Senate Legislative Calendar under General Orders. Calendar No. 180.

Summary (as of Apr 28, 2021)

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

- **Sep 29, 2021:** Committee Consideration and Mark-up Session Held.
- **Sep 29, 2021:** Ordered to be Reported in the Nature of a Substitute by the Yeas and Nays: 28 - 13.
- **Apr 29, 2021:** Referred to the Subcommittee on Health.
- **Apr 28, 2021:** Introduced in House
- **Apr 28, 2021:** Referred to the Committee on the Judiciary, and in addition to the Committee on Energy and Commerce, for a period to be subsequently determined by the Speaker, in each case for consideration of such provisions as fall within the jurisdiction of the committee concerned.