S 1067

Ensuring Timely Access to Generics Act of 2023

Congress: 118 (2023–2025, Ended)
Chamber: Senate
Policy Area: Health
Introduced: Mar 29, 2023
Current Status: Placed on Senate Legislative Calendar under General Orders. Calendar No. 107.
Latest Action: Placed on Senate Legislative Calendar under General Orders. Calendar No. 107. (Jun 22, 2023)
Official Text: https://www.congress.gov/bill/118th-congress/senate-bill/1067

Sponsor

Name: Sen. Shaheen, Jeanne [D-NH]
Party: Democratic • **State:** NH • **Chamber:** Senate

Cosponsors (5 total)

Cosponsor	Party / State	Role	Date Joined
Sen. Baldwin, Tammy [D-WI]	D · WI		Mar 29, 2023
Sen. Bennet, Michael F. [D-CO]	D · CO		Mar 29, 2023
Sen. Braun, Mike [R-IN]	R · IN		Mar 29, 2023
Sen. Collins, Susan M. [R-ME]	R · ME		Mar 29, 2023
Sen. Rubio, Marco [R-FL]	R · FL		Mar 29, 2023

Committee Activity

Committee	Chamber	Activity	Date
Health, Education, Labor, and Pensions Committee	Senate	Reported By	Jun 22, 2023

Subjects & Policy Tags

Policy Area:

Health

Related Bills

Bill	Relationship	Last Action
118 S 2226	Related bill	**Jul 27, 2023:** Senate ordered measure printed as passed.
118 S 1269	Related bill	**Apr 25, 2023:** Read twice and referred to the Committee on Health, Education, Labor, and Pensions.

Summary (as of Jun 22, 2023)

Ensuring Timely Access to Generics Act of 2023

This bill establishes additional requirements related to citizen petitions concerning applications for generic drug or biosimilar market approval. (Citizen petitions are petitions submitted by third parties requesting that the Food and Drug Administration (FDA) take certain actions, such as requiring additional warnings on a drug.)

Under the bill, the FDA may deny a citizen petition that (1) was submitted primarily to delay the approval of the relevant application, or (2) does not on its face raise valid scientific or regulatory issues. Currently, the FDA may deny a petition as an attempt at delay only if the petition meets both of these requirements.

The bill also expressly requires a third party, before filing a lawsuit to force the FDA to set aside or prevent market approval of a generic drug or biosimilar, to first file a citizen petition with the information and arguments that form the basis of the lawsuit. A citizen petition must be filed within 60 days of when the filer knew or reasonably should have known the information that forms the basis of the petition.

Actions Timeline

- **Jun 22, 2023:** Committee on Health, Education, Labor, and Pensions. Reported by Senator Sanders with an amendment in the nature of a substitute. Without written report.
- **Jun 22, 2023:** Placed on Senate Legislative Calendar under General Orders. Calendar No. 107.
- **May 11, 2023:** Committee on Health, Education, Labor, and Pensions. Ordered to be reported with an amendment in the nature of a substitute favorably.
- **Mar 29, 2023:** Introduced in Senate
- **Mar 29, 2023:** Read twice and referred to the Committee on Health, Education, Labor, and Pensions.