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Ensuring Timely Access to Generics Act of 2021

Congress: 117 (2021–2023, Ended)

Chamber: Senate

Policy Area: Health

Introduced: Mar 3, 2021

Current Status: Read twice and referred to the Committee on Health, Education, Labor, and Pensions.

Latest Action: Read twice and referred to the Committee on Health, Education, Labor, and Pensions. (Mar 3, 2021)

Official Text: <https://www.congress.gov/bill/117th-congress/senate-bill/562>

Sponsor

Name: Sen. Shaheen, Jeanne [D-NH]

Party: Democratic • **State:** NH • **Chamber:** Senate

Cosponsors (3 total)

Cosponsor	Party / State	Role	Date Joined
Sen. Bennet, Michael F. [D-CO]	D · CO		Mar 3, 2021
Sen. Cassidy, Bill [R-LA]	R · LA		Mar 3, 2021
Sen. Rubio, Marco [R-FL]	R · FL		Mar 3, 2021

Committee Activity

Committee	Chamber	Activity	Date
Health, Education, Labor, and Pensions Committee	Senate	Referred To	Mar 3, 2021

Subjects & Policy Tags

Policy Area:

Health

Related Bills

Bill	Relationship	Last Action
117 HR 8588	Related bill	Nov 1, 2022: Referred to the Subcommittee on Courts, Intellectual Property, and the Internet.

Ensuring Timely Access to Generics Act of 2021

This bill imposes requirements related to third-party petitions concerning an application for Food and Drug Administration (FDA) approval to market a generic drug or biosimilar. (The current statute refers to these petitions as *citizen petitions*, which typically involve requests that the 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 requires the FDA to establish procedures for referring such a delaying petition to the Federal Trade Commission.

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

- **Mar 3, 2021:** Introduced in Senate
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