S 1128

Ensuring Access to Generic Medications Act

Congress: 118 (2023–2025, Ended)
Chamber: Senate
Policy Area: Commerce
Introduced: Mar 30, 2023
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 30, 2023)
Official Text: https://www.congress.gov/bill/118th-congress/senate-bill/1128

Sponsor

Name: Sen. Hassan, Margaret Wood [D-NH]
Party: Democratic • **State:** NH • **Chamber:** Senate

Cosponsors (2 total)

Cosponsor	Party / State	Role	Date Joined
Sen. Braun, Mike [R-IN]	R · IN		Mar 30, 2023
Sen. Paul, Rand [R-KY]	R · KY		Sep 6, 2023

Committee Activity

Committee	Chamber	Activity	Date
Health, Education, Labor, and Pensions Committee	Senate	Referred To	Mar 30, 2023

Subjects & Policy Tags

Policy Area:

Commerce

Related Bills

No related bills are listed.

Summary (as of Mar 30, 2023)

Ensuring Access to Generic Medications Act

This bill authorizes an applicant seeking Food and Drug Administration (FDA) approval for a generic drug (or biosimilar product) to sue to correct or delete patent information provided by the maker of the reference drug (or reference biological product).

Typically, a generic drug is a lower-cost version of a reference drug that gets introduced after the patents covering a reference drug have expired. When the maker of the reference drug first applies for FDA approval to sell the drug, the maker must provide various information to the FDA about the patents that it believes cover the drug, including in the form of *use codes* that describe any methods of using the drug that the reference drug maker believes are covered by a patent.

Use code information is publicly available and is intended to help inform generic drug makers about the patents that may be covering the reference drug. The FDA has stated that overbroad or ambiguous use codes may delay approval of generic drugs.

Under this bill, an applicant seeking FDA approval for a generic drug may sue for an order requiring the applicable reference drug maker to correct or delete use code information that is overly broad or inaccurate, such as a use code that does not correspond to a patent claiming an FDA-approved method of using the reference drug.

Actions Timeline

- **Mar 30, 2023:** Introduced in Senate
- **Mar 30, 2023:** Read twice and referred to the Committee on Health, Education, Labor, and Pensions.