S 4918

Increasing Prescription Drug Competition Act

Congress: 117 (2021–2023, Ended)
Chamber: Senate
Policy Area: Health
Introduced: Sep 22, 2022
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. (Sep 22, 2022)
Official Text: https://www.congress.gov/bill/117th-congress/senate-bill/4918

Sponsor

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

Cosponsors (1 total)

Cosponsor	Party / State	Role	Date Joined
Sen. Braun, Mike [R-IN]	R · IN		Sep 22, 2022

Committee Activity

Committee	Chamber	Activity	Date
Health, Education, Labor, and Pensions Committee	Senate	Referred To	Sep 22, 2022

Subjects & Policy Tags

Policy Area:

Health

Related Bills

No related bills are listed.

Summary (as of Sep 22, 2022)

Increasing Prescription Drug Competition Act

This bill provides that certifications in generic drug applications of certain patents involved in Risk Evaluation and Mitigation Strategy (REMS) programs have no effect upon the drug's approval. (The Food and Drug Administration sometimes requires a REMS program for certain drugs with safety risks, which may include restrictions on a drug's distribution through elements to ensure safe use (ETASU), such as special requirements for pharmacies that dispense the drug.)

Specifically, certifications in generic drug applications with respect to patents that involve an ETASU for REMS requirements have no effect on the effective date of the drug's approval, notwithstanding any other provisions that allow for a stay of approval pending litigation outcomes (i.e., 30-month stay).

The bill also specifies that in a civil action alleging patent infringement with respect to REMS requirements, the sponsor of the approved brand-name drug may only seek damages from (rather than an injunction against) the generic drug applicant.

Actions Timeline

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