

## HR 4692

### Increasing Prescription Drug Competition Act

**Congress:** 118 (2023–2025, Ended)

**Chamber:** House

**Policy Area:** Health

**Introduced:** Jul 17, 2023

**Current Status:** Referred to the Subcommittee on Health.

**Latest Action:** Referred to the Subcommittee on Health. (Jul 21, 2023)

**Official Text:** <https://www.congress.gov/bill/118th-congress/house-bill/4692>

## Sponsor

**Name:** Rep. Slotkin, Elissa [D-MI-7]

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

## Cosponsors

No cosponsors are listed for this bill.

## Committee Activity

Committee	Chamber	Activity	Date
Energy and Commerce Committee	House	Referred to	Jul 21, 2023

## Subjects & Policy Tags

### Policy Area:

Health

## Related Bills

Bill	Relationship	Last Action
118 S 574	Related bill	Mar 1, 2023: Read twice and referred to the Committee on Health, Education, Labor, and Pensions.

## **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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- **Jul 21, 2023:** Referred to the Subcommittee on Health.
- **Jul 17, 2023:** Introduced in House
- **Jul 17, 2023:** Referred to the House Committee on Energy and Commerce.