

S 2910

Expanding Access to Low-Cost Generics Act of 2021

Congress: 117 (2021–2023, Ended)

Chamber: Senate

Policy Area: Health

Introduced: Sep 30, 2021

Current Status: Star Print ordered on the bill.

Latest Action: Star Print ordered on the bill. (Oct 20, 2021)

Official Text: <https://www.congress.gov/bill/117th-congress/senate-bill/2910>

Sponsor

Name: Sen. Smith, Tina [D-MN]

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

Cosponsors (1 total)

Cosponsor	Party / State	Role	Date Joined
Sen. Braun, Mike [R-IN]	R · IN		Sep 30, 2021

Committee Activity

Committee	Chamber	Activity	Date
Health, Education, Labor, and Pensions Committee	Senate	Referred To	Sep 30, 2021

Subjects & Policy Tags

Policy Area:

Health

Related Bills

No related bills are listed.

Expanding Access to Low-Cost Generics Act of 2021

This bill modifies provisions related to market exclusivity for a generic drug.

Currently, the Food and Drug Administration (FDA) awards 180 days of exclusivity on the market to a first applicant to file a qualifying application for market approval of a generic drug. Generally, this exclusivity period begins upon a first applicant's commercial marketing of the drug.

The bill authorizes the FDA to approve a subsequent generic drug application prior to a first applicant's first date of commercial marketing if (1) the subsequent application is ready for full approval, (2) a first applicant's application has been pending for at least 30 months, (3) the approval of a first applicant's application is not precluded by patent infringement claims asserted against that first applicant, and (4) no first applicant's application has been effectively approved on the date that all such conditions are met.

Actions Timeline

- **Oct 20, 2021:** Star Print ordered on the bill.
- **Sep 30, 2021:** Introduced in Senate
- **Sep 30, 2021:** Read twice and referred to the Committee on Health, Education, Labor, and Pensions.