

S 845

Short on Competition Act

Congress: 118 (2023–2025, Ended)

Chamber: Senate

Policy Area: Health

Introduced: Mar 16, 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 16, 2023)

Official Text: https://www.congress.gov/bill/118th-congress/senate-bill/845

Sponsor

Name: Sen. Klobuchar, Amy [D-MN]

Party: Democratic • State: MN • Chamber: Senate

Cosponsors (3 total)

Cosponsor	Party / State	Role	Date Joined
Sen. Durbin, Richard J. [D-IL]	D · IL		Mar 16, 2023
Sen. Grassley, Chuck [R-IA]	R · IA		Mar 16, 2023
Sen. Lee, Mike [R-UT]	R · UT		Mar 16, 2023

Committee Activity

Committee	Chamber	Activity	Date
Health, Education, Labor, and Pensions Committee	Senate	Referred To	Mar 16, 2023

Subjects & Policy Tags

Policy Area:

Health

Related Bills

No related bills are listed.

Short on Competition Act

This bill requires the Food and Drug Administration (FDA) to provide temporary authorization to import certain prescription drugs facing shortages or in a marginally competitive drug market.

Specifically, the FDA shall authorize importation of an eligible drug that is lifesaving, life-sustaining, or intended to treat or prevent a debilitating condition. To be eligible, a drug must (1) be facing a shortage, (2) require a prescription, (3) have received market authorization in certain foreign countries, and (4) have the same active ingredient as the drug for which there is a shortage in the United States. The drug's manufacturer must also seek FDA approval for the drug as a generic drug.

The import authorization shall be for three years or until the shortage no longer applies, whichever occurs first. Importation shall begin within 60 days of the FDA receiving an application that meets all of the applicable requirements. The FDA may deny importation of a drug for reasons related to safety or effectiveness.

Drugs in marginally competitive markets must be treated as being in a shortage for the purposes of this bill and for the purposes of expedited inspections and review. A drug is in a marginally competitive market if (1) there are fewer than five holders of approved applications for commercially available brand-name or generic versions of the drug, (2) the drug has been approved for at least 10 years, and (3) the patents on the drug's active ingredients have expired.

Actions Timeline

- **Mar 16, 2023:** Introduced in Senate
- **Mar 16, 2023:** Read twice and referred to the Committee on Health, Education, Labor, and Pensions.