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Increasing Competition in Pharmaceuticals Act

Congress: 115 (2017–2019, Ended)
Chamber: Senate
Policy Area: Health
Introduced: Feb 2, 2017
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. (Feb 2, 2017)
Official Text: https://www.congress.gov/bill/115th-congress/senate-bill/297

Sponsor

Name: Sen. Collins, Susan M. [R-ME]
Party: Republican • **State:** ME • **Chamber:** Senate

Cosponsors (2 total)

Cosponsor	Party / State	Role	Date Joined
Sen. McCaskill, Claire [D-MO]	D · MO		Feb 2, 2017
Sen. Tester, Jon [D-MT]	D · MT		Mar 6, 2017

Committee Activity

Committee	Chamber	Activity	Date
Health, Education, Labor, and Pensions Committee	Senate	Referred To	Feb 3, 2017

Subjects & Policy Tags

Policy Area:

Health

Related Bills

Bill	Relationship	Last Action
115 HR 749	Related bill	**Feb 3, 2017:** Referred to the Subcommittee on Health.

Summary (as of Feb 2, 2017)

Increasing Competition in Pharmaceuticals Act

This bill amends the Federal Food, Drug, and Cosmetic Act to revise provisions regarding review and approval of generic drug applications or supplements to generic drug applications for drugs: (1) for which there is a shortage, or (2) that have not been recently introduced to the market by more than one manufacturer and for which tentative approval has not been granted to more than two applications.

The Food and Drug Administration (FDA) must prioritize the review of such submissions and act on them within 150 days. User fees are waived for such an application unless the drug is under patent. The FDA may expedite the inspection of a facility proposed to manufacture such a drug.

The FDA must award a transferrable generic drug priority review voucher to the sponsor of such an application upon approval. A voucher may be used to have the FDA review and take action upon a generic drug application within 150 days of submission. The FDA may revoke a voucher awarded for a drug that is not marketed within one year of approval. This voucher program is terminated at the end of FY2022.

The FDA must periodically report on generic drug applications filed before FY2016 that are still pending.

For a new drug application to be eligible for a priority review voucher as a tropical disease product application, the application must include new, essential clinical investigations.
The Government Accountability Office must study the FDA's program for drug risk evaluation and mitigation strategies.

Actions Timeline

- **Feb 2, 2017:** Introduced in Senate
- **Feb 2, 2017:** Read twice and referred to the Committee on Health, Education, Labor, and Pensions.

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