HR 4784

Lower Drug Costs through Competition Act

Congress: 114 (2015–2017, Ended)
Chamber: House
Policy Area: Health
Introduced: Mar 17, 2016
Current Status: Referred to the Subcommittee on Health.
Latest Action: Referred to the Subcommittee on Health. (Mar 18, 2016)
Official Text: https://www.congress.gov/bill/114th-congress/house-bill/4784

Sponsor

Name: Rep. Schrader, Kurt [D-OR-5]
Party: Democratic • **State:** OR • **Chamber:** House

Cosponsors (16 total)

Cosponsor	Party / State	Role	Date Joined
Rep. Bilirakis, Gus M. [R-FL-12]	R · FL		Mar 17, 2016
Rep. Peters, Scott H. [D-CA-52]	D · CA		Sep 6, 2016
Rep. Dold, Robert J. [R-IL-10]	R · IL		Sep 7, 2016
Rep. Higgins, Brian [D-NY-26]	D · NY		Sep 12, 2016
Rep. Poliquin, Bruce [R-ME-2]	R · ME		Sep 12, 2016
Rep. Ashford, Brad [D-NE-2]	D · NE		Sep 13, 2016
Rep. Sinema, Kyrsten [D-AZ-9]	D · AZ		Sep 13, 2016
Rep. Cooper, Jim [D-TN-5]	D · TN		Sep 19, 2016
Rep. Moulton, Seth [D-MA-6]	D · MA		Sep 19, 2016
Rep. Costa, Jim [D-CA-16]	D · CA		Sep 21, 2016
Rep. Himes, James A. [D-CT-4]	D · CT		Sep 21, 2016
Rep. Lawrence, Brenda L. [D-MI-14]	D · MI		Sep 21, 2016
Rep. Lee, Barbara [D-CA-13]	D · CA		Sep 21, 2016
Rep. Posey, Bill [R-FL-8]	R · FL		Sep 26, 2016
Rep. Bera, Ami [D-CA-7]	D · CA		Sep 28, 2016
Rep. Lipinski, Daniel [D-IL-3]	D · IL		Dec 8, 2016

Committee Activity

Committee	Chamber	Activity	Date
Energy and Commerce Committee	House	Referred to	Mar 18, 2016

Subjects & Policy Tags

Policy Area:

Health

Related Bills

Bill	Relationship	Last Action
114 S 2615	Related bill	**Mar 1, 2016:** Read twice and referred to the Committee on Health, Education, Labor, and Pensions.

Summary (as of Mar 17, 2016)

Lower Drug Costs through Competition 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 180 days. The FDA may expedite the inspection of a facility proposed to manufacture such a drug.

Beginning FY2018, the FDA must award a transferrable generic drug priority review voucher to the sponsor of such an application once the drug has a sustained market presence. A voucher may be used to have the FDA review and take action upon a generic drug application within 180 days of submission. The FDA must establish an additional user fee for applications subject to a voucher. This voucher program is terminated at the end of FY2021.

The FDA must periodically report on generic drug applications filed before FY2017 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

- **Mar 18, 2016:** Referred to the Subcommittee on Health.
- **Mar 17, 2016:** Introduced in House
- **Mar 17, 2016:** Referred to the House Committee on Energy and Commerce.