

## HR 749

### Lower Drug Costs through Competition Act

**Congress:** 115 (2017–2019, Ended)

**Chamber:** House

**Policy Area:** Health

**Introduced:** Jan 30, 2017

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

**Latest Action:** Referred to the Subcommittee on Health. (Feb 3, 2017)

**Official Text:** <https://www.congress.gov/bill/115th-congress/house-bill/749>

## Sponsor

**Name:** Rep. Schrader, Kurt [D-OR-5]

**Party:** Democratic • **State:** OR • **Chamber:** House

## Cosponsors (24 total)

| Cosponsor   | Party / State | Role | Date Joined  |
|---|---------------|------|--------------|
| Rep. Bera, Ami [D-CA-7]   | D · CA        |      | Jan 30, 2017 |
| Rep. Bilirakis, Gus M. [R-FL-12]                                | R · FL        |      | Jan 30, 2017 |
| Rep. Cooper, Jim [D-TN-5]                                       | D · TN        |      | Jan 30, 2017 |
| Rep. Costa, Jim [D-CA-16]                                       | D · CA        |      | Jan 30, 2017 |
| Rep. Lipinski, Daniel [D-IL-3]                                  | D · IL        |      | Jan 30, 2017 |
| Rep. Moulton, Seth [D-MA-6]                                     | D · MA        |      | Jan 30, 2017 |
| Rep. Peters, Scott H. [D-CA-52]                                 | D · CA        |      | Jan 30, 2017 |
| Rep. Posey, Bill [R-FL-8]                                       | R · FL        |      | Jan 30, 2017 |
| Rep. Sinema, Kyrsten [D-AZ-9]                                   | D · AZ        |      | Jan 30, 2017 |
| Rep. Peterson, Collin C. [D-MN-7]                               | D · MN        |      | Feb 1, 2017  |
| Rep. O'Halleran, Tom [D-AZ-1]                                   | D · AZ        |      | Feb 2, 2017  |
| Rep. Guthrie, Brett [R-KY-2]                                    | R · KY        |      | Feb 3, 2017  |
| Rep. Bishop, Sanford D., Jr. [D-GA-2]                           | D · GA        |      | Feb 9, 2017  |
| Rep. Cuellar, Henry [D-TX-28]                                   | D · TX        |      | Feb 9, 2017  |
| Rep. Soto, Darren [D-FL-9]                                      | D · FL        |      | Feb 9, 2017  |
| Rep. Walz, Timothy J. [D-MN-1]                                  | D · MN        |      | Feb 9, 2017  |
| Rep. Crist, Charlie [D-FL-13]                                   | D · FL        |      | Mar 7, 2017  |
| Rep. Schneider, Bradley Scott [D-IL-10]                         | D · IL        |      | Mar 24, 2017 |
| Rep. Bacon, Don [R-NE-2]  | R · NE        |      | Apr 27, 2017 |
| Rep. Fortenberry, Jeff [R-NE-1]                                 | R · NE        |      | May 1, 2017  |
| Resident Commissioner González-Colón, Jenniffer [R-PR-At Large] | R · PR        |      | May 24, 2017 |
| Rep. Gottheimer, Josh [D-NJ-5]                                  | D · NJ        |      | Jun 2, 2017  |
| Rep. Gianforte, Greg [R-MT-At Large]                            | R · MT        |      | Feb 6, 2018  |
| Rep. Knight, Stephen [R-CA-25]                                  | R · CA        |      | Feb 6, 2018  |

## Committee Activity

| Committee                     | Chamber | Activity    | Date        |
|-------------------------------|---------|-------------|-------------|
| Energy and Commerce Committee | House   | Referred to | Feb 3, 2017 |

## Subjects & Policy Tags

### Policy Area:

Health

## Related Bills

| Bill      | Relationship | Last Action  |
|-----------|--------------|--|
| 115 S 297 | Related bill | Feb 2, 2017: Read twice and referred to the Committee on Health, Education, Labor, and Pensions. |

## Summary (as of Jan 30, 2017)

### 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 FY2019, 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 start of FY2024.

The FDA must periodically report on generic drug applications filed before FY2018 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 3, 2017:** Referred to the Subcommittee on Health.
- **Jan 30, 2017:** Introduced in House
- **Jan 30, 2017:** Referred to the House Committee on Energy and Commerce.