

## HR 2416

To amend the Federal Food, Drug, and Cosmetic Act to evaluate the potential use of evidence from clinical experience to help support the approval of new indications for approved drugs, and for other purposes.

**Congress:** 114 (2015–2017, Ended)

**Chamber:** House

**Policy Area:** Health

**Introduced:** May 19, 2015

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

**Latest Action:** Referred to the Subcommittee on Health. (May 22, 2015)

**Official Text:** <https://www.congress.gov/bill/114th-congress/house-bill/2416>

### Sponsor

**Name:** Rep. Burgess, Michael C. [R-TX-26]

**Party:** Republican • **State:** TX • **Chamber:** House

### Cosponsors

*No cosponsors are listed for this bill.*

### Committee Activity

Committee	Chamber	Activity	Date
Energy and Commerce Committee	House	Referred to	May 22, 2015

### Subjects & Policy Tags

**Policy Area:**

Health

### Related Bills

Bill	Relationship	Last Action
114 HR 34	Related bill	<b>Dec 13, 2016:</b> Became Public Law No: 114-255.

This bill amends the Federal Food, Drug, and Cosmetic Act to require the Food and Drug Administration (FDA) to establish a program to evaluate the potential use of evidence from clinical experience to support the approval of a new indication for an approved drug and to support post-approval study requirements.

"Evidence from clinical experience" means data from sources other than randomized clinical trials, including from observational studies, registries, and therapeutic use.

Before implementing the program, the FDA must establish a draft framework for the program that describes current sources of data from clinical experience, gaps in current data collection activities, standards and methodologies for collection and analysis of data from clinical experience, and priority areas, remaining challenges, and potential pilot opportunities that the program will address.

The FDA must use the program to inform guidance to industry on the collection and use of evidence from clinical experience.

### **Actions Timeline**

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- **May 22, 2015:** Referred to the Subcommittee on Health.
- **May 19, 2015:** Introduced in House
- **May 19, 2015:** Referred to the House Committee on Energy and Commerce.