HR 2443

To amend the Federal Food, Drug, and Cosmetic Act with respect to CLIA waiver study design guidance for in vitro diagnostics.

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/2443

Sponsor

Name: Rep. Guthrie, Brett [R-KY-2]
Party: Republican • **State:** KY • **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	**Dec 13, 2016:** Became Public Law No: 114-255.
114 HR 6	Related bill	**Jul 13, 2015:** Received in the Senate and Read twice and referred to the Committee on Health, Education, Labor, and Pensions.

Summary (as of May 19, 2015)

This bill requires the Department of Health and Human Services to publish guidance that revises “Recommendations for Clinical Laboratory Improvement Amendments of 1988 (CLIA) Waiver Applications for Manufacturers of In Vitro Diagnostic Devices” and includes guidance on using comparable performance between types of users to demonstrate the accuracy of a medical device.

Actions Timeline

- **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.