HR 2455

To amend the Federal Food, Drug, and Cosmetic Act with respect to precision medicine.

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/2455

Sponsor

Name: Rep. Pitts, Joseph R. [R-PA-16]
Party: Republican • **State:** PA • **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 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 amends the Federal Food, Drug, and Cosmetic Act to require the Food and Drug Administration (FDA) to define "precision drug or biological product." (Precision medications are commonly understood to be treatments for those patients who are likely to respond to the medication based on a biomarker, which is a biological characteristic such as a genetic factor.)

The FDA must issue and periodically update guidance that addresses the development and use of biomarkers to identify the subset of patients that are likely to respond to a medication.
The FDA may rely upon data previously submitted for a different approved medication or indication to expedite the clinical development of a precision medication that has been designated for the treatment of a serious or rare condition.

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.