HR 2338

To amend the Federal Food, Drug, and Cosmetic Act to provide for the development and use of patient experience data to enhance the structured risk-benefit assessment framework, and for other purposes.

Congress: 114 (2015–2017, Ended)
Chamber: House
Policy Area: Health
Introduced: May 14, 2015
Current Status: Referred to the Subcommittee on Health.
Latest Action: Referred to the Subcommittee on Health. (May 15, 2015)
Official Text: https://www.congress.gov/bill/114th-congress/house-bill/2338

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 15, 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 14, 2015)

This bill amends the Federal Food, Drug, and Cosmetic Act to require the Food and Drug Administration (FDA) to establish processes under which: (1) an entity seeking to develop patient experience data may submit initial research concepts for feedback; (2) the FDA may request or receive from such an entity draft guidance documents, data, and summaries and analyses of data; and (3) patient experience data may be considered in the risk-benefit assessment of a new drug.

"Patient experience data" is data collected by patients or others that is intended to facilitate the FDA's risk-benefit assessments, including information about the impact of a disease or a therapy on patients' lives.
The FDA must convene workshops and publish guidance on the patient experience data processes described above.

Actions Timeline

- **May 15, 2015:** Referred to the Subcommittee on Health.
- **May 14, 2015:** Introduced in House
- **May 14, 2015:** Referred to the House Committee on Energy and Commerce.