HR 2337

To amend the Federal Food, Drug, and Cosmetic Act to authorize priority review for breakthrough devices.

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/2337

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 S 1077	Related bill	**Apr 5, 2016:** Placed on Senate Legislative Calendar under General Orders. Calendar No. 412.
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 replace the requirement that the Food and Drug Administration (FDA) prioritize review of breakthrough medical devices with a requirement that the FDA establish a program to provide priority review for breakthrough medical devices.

Prior to submitting an application for approval, a medical device sponsor may request that the FDA designate the medical device for priority review. The FDA must provide a summary of the basis for its determination regarding designation.

To expedite the development and review of designated medical devices, the FDA must:

- assign a team of staff for each device,
- adopt an efficient process for dispute resolution,
- provide for interactive communication with the device sponsor,
- expedite review of manufacturing and quality systems compliance,
- disclose to the sponsor in advance the topics of any consultation between the FDA and external experts or an advisory committee and provide the sponsor the opportunity to recommend external experts,
- assign staff to address questions by institutional review committees concerning investigational use of the device.

The FDA may: (1) coordinate with the sponsor regarding early agreement on a data development plan; (2) take steps to ensure that the design of clinical trials is as efficient as practicable; (3) utilize timely postmarket data collection; and (4) agree to clinical protocols, subject to an FDA determination that changes are required to prevent an unreasonable risk to the public health or that a substantial scientific issue is essential to the safety or effectiveness of the device.

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.