S 1077

Advancing Breakthrough Devices for Patients Act of 2016

Congress: 114 (2015–2017, Ended)
Chamber: Senate
Policy Area: Health
Introduced: Apr 23, 2015
Current Status: Placed on Senate Legislative Calendar under General Orders. Calendar No. 412.
Latest Action: Placed on Senate Legislative Calendar under General Orders. Calendar No. 412. (Apr 5, 2016)
Official Text: https://www.congress.gov/bill/114th-congress/senate-bill/1077

Sponsor

Name: Sen. Burr, Richard [R-NC]
Party: Republican • **State:** NC • **Chamber:** Senate

Cosponsors (3 total)

Cosponsor	Party / State	Role	Date Joined
Sen. Bennet, Michael F. [D-CO]	D · CO		Apr 23, 2015
Sen. Hatch, Orrin G. [R-UT]	R · UT		Apr 23, 2015
Sen. Donnelly, Joe [D-IN]	D · IN		Oct 20, 2015

Committee Activity

Committee	Chamber	Activity	Date
Health, Education, Labor, and Pensions Committee	Senate	Reported By	Apr 5, 2016

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 2337	Related bill	**May 15, 2015:** Referred to the Subcommittee on Health.

Summary (as of Apr 5, 2016)

Advancing Breakthrough Devices for Patients Act of 2016

(Sec. 2) This bill amends the Federal Food, Drug, and Cosmetic Act to revise requirements regarding priority review of breakthrough medical devices.

Upon a sponsor's request, the Food and Drug Administration (FDA) must determine whether a device meets the criteria for designation as a breakthrough device. 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 and timely 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 and flexible as practicable; (3) utilize timely postmarket data collection; and (4) agree to clinical protocols, subject to a decision that a substantial scientific issue essential to determining the safety or effectiveness of the device exists.

The FDA must issue guidance and report on this priority review process.

Actions Timeline

- **Apr 5, 2016:** Committee on Health, Education, Labor, and Pensions. Reported by Senator Alexander with an amendment in the nature of a substitute. Without written report.
- **Apr 5, 2016:** Placed on Senate Legislative Calendar under General Orders. Calendar No. 412.
- **Mar 9, 2016:** Committee on Health, Education, Labor, and Pensions. Ordered to be reported with an amendment in the nature of a substitute favorably.
- **Apr 23, 2015:** Introduced in Senate
- **Apr 23, 2015:** Read twice and referred to the Committee on Health, Education, Labor, and Pensions.