S 1622

FDA Device Accountability Act of 2016

Congress: 114 (2015–2017, Ended)
Chamber: Senate
Policy Area: Health
Introduced: Jun 18, 2015
Current Status: Placed on Senate Legislative Calendar under General Orders. Calendar No. 426.
Latest Action: Placed on Senate Legislative Calendar under General Orders. Calendar No. 426. (Apr 18, 2016)
Official Text: https://www.congress.gov/bill/114th-congress/senate-bill/1622

Sponsor

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

Cosponsors (4 total)

Cosponsor	Party / State	Role	Date Joined
Sen. Franken, Al [D-MN]	D · MN		Jun 18, 2015
Sen. Kirk, Mark Steven [R-IL]	R · IL		Oct 5, 2015
Sen. Enzi, Michael B. [R-WY]	R · WY		Feb 8, 2016
Sen. Alexander, Lamar [R-TN]	R · TN		Feb 10, 2016

Committee Activity

Committee	Chamber	Activity	Date
Health, Education, Labor, and Pensions Committee	Senate	Reported By	Apr 18, 2016

Subjects & Policy Tags

Policy Area:

Health

Related Bills

No related bills are listed.

Summary (as of Apr 18, 2016)

FDA Device Accountability Act of 2016

(Sec. 2) This bill amends the Federal Food, Drug, and Cosmetic Act to eliminate the requirement for the Institutional Review Board supervising the clinical testing of an investigational or humanitarian medical device to be local.

(Sec. 3) The Food and Drug Administration (FDA) must revise the guidance entitled "Recommendations for Clinical Laboratory Improvement Amendments of 1988 (CLIA) Waiver Applications for Manufacturers of In Vitro Diagnostic Devices."

(Sec. 4) The FDA must ensure that employees who review premarket submissions of medical devices receive training on least burdensome means requirements. (Currently, the FDA is required to consider the least burdensome appropriate means for a sponsor to demonstrate the effectiveness of a medical device or demonstrate a device's substantial equivalence to an approved medical device.) The FDA must periodically assess the implementation of those requirements. The ombudsman for any applicable unit of the FDA must audit and report on the training.

The FDA must consider the least burdensome appropriate means necessary to demonstrate medical device safety and effectiveness when requesting additional information from a device sponsor to support a premarket approval application, including the role of postmarket information in such a demonstration.
The FDA's documented rationale for a significant decision regarding a medical device must include a statement regarding how the least burdensome requirements were considered and applied.

Actions Timeline

- **Apr 18, 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 18, 2016:** Placed on Senate Legislative Calendar under General Orders. Calendar No. 426.
- **Feb 9, 2016:** Committee on Health, Education, Labor, and Pensions. Ordered to be reported with an amendment in the nature of a substitute favorably.
- **Jun 18, 2015:** Introduced in Senate
- **Jun 18, 2015:** Read twice and referred to the Committee on Health, Education, Labor, and Pensions.