S 1069

Medical Device Safety Monitoring Act

Congress: 115 (2017–2019, Ended)
Chamber: Senate
Policy Area: Health
Introduced: May 8, 2017
Current Status: Read twice and referred to the Committee on Health, Education, Labor, and Pensions.
Latest Action: Read twice and referred to the Committee on Health, Education, Labor, and Pensions. (May 8, 2017)
Official Text: https://www.congress.gov/bill/115th-congress/senate-bill/1069

Sponsor

Name: Sen. Casey, Robert P., Jr. [D-PA]
Party: Democratic • **State:** PA • **Chamber:** Senate

Cosponsors (2 total)

Cosponsor	Party / State	Role	Date Joined
Sen. Franken, Al [D-MN]	D · MN		May 8, 2017
Sen. Warren, Elizabeth [D-MA]	D · MA		May 8, 2017

Committee Activity

Committee	Chamber	Activity	Date
Health, Education, Labor, and Pensions Committee	Senate	Referred To	May 8, 2017

Subjects & Policy Tags

Policy Area:

Health

Related Bills

Bill	Relationship	Last Action
115 HR 2430	Related bill	**Aug 18, 2017:** Became Public Law No: 115-52.
115 S 934	Related bill	**May 11, 2017:** Placed on Senate Legislative Calendar under General Orders. Calendar No. 76.

Summary (as of May 8, 2017)

Medical Device Safety Monitoring Act

This bill amends the Federal Food, Drug, and Cosmetic Act to require the Food and Drug Administration (FDA) to support pilot projects in order to provide timely and reliable information on the safety and effectiveness of marketed medical devices. The projects must: (1) be designed to generate safety and active surveillance data, (2) inform support for safety and active surveillance activities, (3) be coordinated with a system for evaluating medical device technology that operates under a board with representation from consumer groups and device manufacturers, and (4) use electronic health data.

The FDA may determine that a manufacturer's participation in a pilot project satisfies requirements regarding reporting or postmarket surveillance if the project captures adverse event information and the FDA has established procedures to publish safety information from the project.

Not later than January 31, 2021, the FDA must evaluate real world evidence pilot projects, such as the ones supported by this bill, for their ability to inform decision-making and efficiently generate evidence about the safety or effectiveness of medical devices.

Actions Timeline

- **May 8, 2017:** Introduced in Senate
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