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Medical Device Patient Safety Act

Congress: 112 (2011–2013, Ended)
Chamber: Senate
Policy Area: Health
Introduced: Dec 14, 2011
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. (Dec 14, 2011)
Official Text: https://www.congress.gov/bill/112th-congress/senate-bill/1995

Sponsor

Name: Sen. Grassley, Chuck [R-IA]
Party: Republican • **State:** IA • **Chamber:** Senate

Cosponsors (2 total)

Cosponsor	Party / State	Role	Date Joined
Sen. Blumenthal, Richard [D-CT]	D · CT		Dec 14, 2011
Sen. Kohl, Herb [D-WI]	D · WI		Dec 14, 2011

Committee Activity

Committee	Chamber	Activity	Date
Health, Education, Labor, and Pensions Committee	Senate	Referred To	Dec 14, 2011

Subjects & Policy Tags

Policy Area:

Health

Related Bills

Bill	Relationship	Last Action
112 HR 5866	Identical bill	**Jun 1, 2012:** Referred to the Subcommittee on Health.

Summary (as of Dec 14, 2011)

Medical Device Patient Safety Act - Directs the Secretary of Health and Human Services (HHS), acting through the Commissioner of Food and Drugs, to establish a program to enhance the oversight by the Food and Drug Administration (FDA) of medical device recalls.

Requires the program to routinely and systematically assess: (1) information submitted to the Secretary pursuant to a device recall order issued under the Federal Food, Drug, and Cosmetic Act (FDCA); and (2) information required to be reported by a device manufacturer to the Secretary regarding the manufacturer's correction or removal of a device. Requires the Secretary to use such information to proactively identify strategies for mitigating health risks presented by defective or unsafe devices. Requires such program to be designed to identify such things as recall trends, the causes of recalls, and the time to complete a recall.

Requires the Secretary to develop explicit criteria for assessing whether a person subject to a recall order or the manufacturer's reporting requirement has performed an effective correction or removal action.

Requires the Secretary to document and publish specified information concerning termination of a recall.

Permits the Secretary to conditionally clear for introduction into interstate commerce for commercial distribution a medical device intended for human use if such medical device is cleared pursuant to specified FDCA reporting requirements concerning the introduction of devices into interstate commerce. Permits the Secretary, as part of such conditional clearance, to: (1) impose specified restrictions on the sale, distribution, or use of the device; (2) require specified labeling for the device; and (3) require the maintenance of specified records that enable the FDA to track the device and determine the safety and effectiveness of the device.

Actions Timeline

- **Dec 14, 2011:** Introduced in Senate
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