

112TH CONGRESS  
1ST SESSION

# S. 1995

To enhance Food and Drug Administration oversight of medical device recalls, to provide for the conditional clearance of certain medical devices, and for other purposes.

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## IN THE SENATE OF THE UNITED STATES

DECEMBER 14, 2011

Mr. GRASSLEY (for himself, Mr. KOHL, and Mr. BLUMENTHAL) introduced the following bill; which was read twice and referred to the Committee on Health, Education, Labor, and Pensions

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## A BILL

To enhance Food and Drug Administration oversight of medical device recalls, to provide for the conditional clearance of certain medical devices, and for other purposes.

1 *Be it enacted by the Senate and House of Representa-*  
2 *tives of the United States of America in Congress assembled,*

3 **SECTION 1. SHORT TITLE.**

4 This Act may be cited as the “Medical Device Patient  
5 Safety Act”.

6 **SEC. 2. OVERSIGHT OF DEVICE RECALLS BY THE FOOD**  
7 **AND DRUG ADMINISTRATION.**

8 (a) DEFINITIONS.—In this Act:

1           (1) COMMISSIONER.—The term “Commis-  
2           sioner” means the Commissioner of Food and  
3           Drugs.

4           (2) DEVICE.—The term “device” has the mean-  
5           ing given that term in section 201(h) of the Federal  
6           Food, Drug, and Cosmetic Act (21 U.S.C. 321(h)).

7           (3) SECRETARY.—The term “Secretary” means  
8           the Secretary of Health and Human Services.

9           (b) ACTIONS BY SECRETARY.—To enhance the over-  
10          sight by the Food and Drug Administration of device re-  
11          calls, the Secretary of Health and Human Services, acting  
12          through the Commissioner of Food and Drugs, shall carry  
13          out the activities described in this section.

14          (c) ASSESSMENT OF DEVICE RECALL INFORMA-  
15          TION.—

16               (1) IN GENERAL.—

17                   (A) ASSESSMENT PROGRAM.—The Sec-  
18                  retary shall establish a program to routinely  
19                  and systematically assess—

20                           (i) information submitted to the Sec-  
21                          retary pursuant to a device recall order  
22                          under section 518(e) of the Federal Food,  
23                          Drug, and Cosmetic Act (21 U.S.C.  
24                          360h(e)); and

1 (ii) information required to be re-  
2 ported to the Secretary regarding a correc-  
3 tion or removal of a device under section  
4 519(g) of such Act (21 U.S.C. 360i(g)).

5 (B) USE.—The Secretary shall use the as-  
6 sessment of information described under sub-  
7 paragraph (A) to proactively identify strategies  
8 for mitigating health risks presented by defec-  
9 tive or unsafe devices.

10 (2) DESIGN.—The program under paragraph  
11 (1) shall be designed, at a minimum, to identify—

12 (A) trends in the numbers and types of de-  
13 vice recalls;

14 (B) the types of devices in each device  
15 class that are most frequently recalled;

16 (C) the causes of device recalls;

17 (D) the length of time needed for a person  
18 subject to a device recall to complete the recall;

19 (E) the length of time needed for the Sec-  
20 retary to terminate a device recall;

21 (F) whether the Secretary has performed a  
22 device recall audit check;

23 (G) which persons have been subject to the  
24 most device recalls; and

1 (H) any other information as the Secretary  
2 determines appropriate.

3 (d) AUDIT CHECK PROCEDURES.—The Secretary  
4 shall clarify procedures for conducting device recall audit  
5 checks to improve the ability of investigators to perform  
6 these checks in a consistent manner.

7 (e) ASSESSMENT CRITERIA.—The Secretary shall de-  
8 velop explicit criteria for assessing whether a person sub-  
9 ject to a recall order under section 518(e) of the Federal  
10 Food, Drug, and Cosmetic Act (21 U.S.C. 360h(e)) or to  
11 a requirement under section 519(g) of such Act (21  
12 U.S.C. 360i(g)) has performed an effective correction or  
13 removal action under such section 519(g).

14 (f) TERMINATION OF RECALLS.—

15 (1) IN GENERAL.—The Secretary shall docu-  
16 ment the basis for the termination by the Food and  
17 Drug Administration of—

18 (A) an individual device recall ordered  
19 under section 518(e) of the Federal Food,  
20 Drug, and Cosmetic Act (21 U.S.C. 360h(e));  
21 and

22 (B) the requirement on a manufacturer or  
23 importer of a device to report any correction or  
24 removal action for which a report is required to

1 be submitted to the Secretary under section  
2 519(g) of such Act (21 U.S.C. 360i(g)).

3 (2) PUBLICATION.—

4 (A) IN GENERAL.—The Secretary shall,  
5 with respect to each termination described in  
6 paragraph (1), publish the documentation re-  
7 quired under such paragraph not later than 180  
8 days after such termination.

9 (B) PROTECTION OF CONFIDENTIAL IN-  
10 FORMATION OR TRADE SECRETS.—Before pub-  
11 lic disclosure of the documentation under sub-  
12 paragraph (A), the Secretary shall delete from  
13 the documentation the following:

14 (i) Any information that constitutes  
15 trade secret or confidential commercial or  
16 financial information.

17 (ii) Any personnel, medical, or similar  
18 information, including the serial numbers  
19 of implanted devices, which would con-  
20 stitute a clearly unwarranted invasion of  
21 personal privacy.

1 **SEC. 3. CONDITIONAL CLEARANCE OF CERTAIN MEDICAL**  
2 **DEVICES.**

3 (a) IN GENERAL.—Chapter V of the Federal Food,  
4 Drug, and Cosmetic Act (21 U.S.C. 351 et seq.) is amend-  
5 ed by inserting after section 510 the following:

6 **“SEC. 510A. CONDITIONAL CLEARANCE OF CERTAIN MED-**  
7 **ICAL DEVICES.**

8 “(a) IN GENERAL.—Notwithstanding any other pro-  
9 vision of law, the Secretary may conditionally clear for in-  
10 troduction into interstate commerce for commercial dis-  
11 tribution a medical device intended for human use if such  
12 medical device is cleared pursuant to section 510(k).

13 “(b) POSTCLEARANCE REQUIREMENTS.—As part of  
14 the conditional clearance under subsection (a), the Sec-  
15 retary may impose the following:

16 “(1) The Secretary may restrict the sale, dis-  
17 tribution, or use of the device but only to the extent  
18 that the sale, distribution, or use of the device may  
19 be restricted pursuant to section 520(e).

20 “(2) The Secretary—

21 “(A) may require continuing evaluation  
22 and periodic reporting on the safety, effective-  
23 ness, and reliability of the device for its in-  
24 tended use; and

25 “(B) shall, to the extent the Secretary  
26 makes a requirement under subparagraph (A),

1 state in the clearance order the reason or pur-  
2 pose for such a requirement and the number of  
3 patients to be evaluated and the reports re-  
4 quired to be submitted.

5 “(3) The Secretary may require a prominent  
6 display in the labeling of the device and in the ad-  
7 vertising of warnings, hazards, or precautions impor-  
8 tant for the device’s safe and effective use, including  
9 patient information such as information provided to  
10 the patient on alternative modes of therapy and on  
11 risks and benefits associated with the use of the de-  
12 vice.

13 “(4) The Secretary—

14 “(A) may require maintenance of records  
15 that will enable the applicant to submit to the  
16 Food and Drug Administration information  
17 needed to trace patients if such information is  
18 necessary to protect the public health; and

19 “(B) shall, to the extent the Secretary  
20 makes the requirement under subparagraph  
21 (A), require that the identity of any patient be  
22 disclosed in records maintained under the  
23 postclearance reporting requirements only to  
24 the extent required for the medical welfare of  
25 the individual, to determine the safety or effec-

1           tiveness of the device, or to verify a record, re-  
2           port, or information submitted to the agency.

3           “(5) The Secretary may require maintenance of  
4           records for specified periods of time and organiza-  
5           tion and indexing of records into identifiable files to  
6           enable the Food and Drug Administration to deter-  
7           mine whether there is reasonable assurance of the  
8           continued safety and effectiveness of the device.

9           “(6) The Secretary may require submission of  
10          periodic reports, at specified intervals, which reports  
11          shall comply with the following:

12               “(A) Identify any of the following changes:

13                   “(i) New indications for use of the de-  
14                   vice.

15                   “(ii) Labeling changes.

16                   “(iii) The use of a different facility or  
17                   establishment to manufacture, process, or  
18                   package the device.

19                   “(iv) Changes in sterilization proce-  
20                   dures.

21                   “(v) Changes in packaging.

22                   “(vi) Changes in the performance or  
23                   design specifications, circuits, components,  
24                   ingredients, principle of operation, or phys-  
25                   ical layout of the device.



1 “(vii) Extension of the expiration date  
2 of the device based on data obtained under  
3 a new or revised stability or sterility test-  
4 ing protocol.

5 “(viii) A change that does not affect  
6 the device’s safety or effectiveness.

7 “(B) Contain a summary and bibliography  
8 of the following information not previously sub-  
9 mitted:

10 “(i) Unpublished reports of data from  
11 any clinical investigations or nonclinical  
12 laboratory studies involving the device or  
13 related devices and known to or that rea-  
14 sonably should be known to the applicant.

15 “(ii) Reports in the scientific lit-  
16 erature concerning the device and known  
17 to or that reasonably should be known to  
18 the applicant. If, after reviewing the sum-  
19 mary and bibliography, the Food and Drug  
20 Administration concludes that the agency  
21 needs a copy of the unpublished or pub-  
22 lished reports, the Food and Drug Admin-  
23 istration shall notify the applicant that  
24 copies of such reports should be submitted.

1           “(C) Identify changes made pursuant to an  
2           exception or alternative granted under section  
3           801.128 or 809.11 of title 21, Code of Federal  
4           Regulations.

5           “(7) The Secretary may require batch testing of  
6           the device.

7           “(8) The Secretary may provide for any other  
8           requirements determined by the Secretary to be nec-  
9           essary to provide reasonable assurance, or continued  
10          reasonable assurance, of the safety and effectiveness  
11          of the device.

12          “(9) The Secretary may require device tracking  
13          as provided under part 821 of title 21, Code of Fed-  
14          eral Regulations.

15          “(c) RESCISSION OF CONDITIONAL CLEARANCE.—  
16          The Secretary may rescind the conditional clearance of a  
17          medical device under subsection (a) if the Secretary deter-  
18          mines that the conditions imposed on the clearance of the  
19          device described in subsection (b) have not been met.”.

20          (b) CIVIL MONETARY PENALTIES.—Section  
21          303(f)(1)(A) of the Federal Food, Drug, and Cosmetic Act  
22          (21 U.S.C. 333(f)(1)(A)) is amended by inserting “, or  
23          a regulation promulgated or an order issued to carry out  
24          this Act,” after “any person who violates a requirement  
25          of this Act”.

1       (c) PROCESS FOR THE REVIEW OF DEVICE APPLICA-  
2 TIONS.—Section 737(8)(J) of the Federal Food, Drug,  
3 and Cosmetic Act (21 U.S.C. 379i(8)(J)) is amended by  
4 inserting “or required as a condition of clearance of a de-  
5 vice under section 510A” after “Act”.

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