

112<sup>TH</sup> CONGRESS  
2<sup>D</sup> SESSION

# H. R. 3847

To amend the Federal Food, Drug, and Cosmetic Act to ensure that a medical device is not marketed based on a determination that the device is substantially equivalent to a predicate device that has been recalled, corrected, or removed from the market because of an intrinsic flaw in technology or design that adversely affects safety, and for other purposes.

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## IN THE HOUSE OF REPRESENTATIVES

JANUARY 31, 2012

Mr. MARKEY (for himself, Mr. WAXMAN, Ms. SCHAKOWSKY, and Ms. DELAURO) introduced the following bill; which was referred to the Committee on Energy and Commerce

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## A BILL

To amend the Federal Food, Drug, and Cosmetic Act to ensure that a medical device is not marketed based on a determination that the device is substantially equivalent to a predicate device that has been recalled, corrected, or removed from the market because of an intrinsic flaw in technology or design that adversely affects safety, 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,*

1 **SECTION 1. SHORT TITLE.**

2 This Act may be cited as the “Safety Of Untested  
3 and New Devices Act of 2012” or the “SOUND Devices  
4 Act of 2012”.

5 **SEC. 2. PREDICATE DEVICES THAT HAVE BEEN RECALLED,**  
6 **CORRECTED, OR REMOVED FROM THE MAR-**  
7 **KET.**

8 (a) SUBMISSION OF INFORMATION BY PERSONS  
9 SEEKING SUBSTANTIAL EQUIVALENCE DETERMINA-  
10 TION.—Section 513(i) of the Federal Food, Drug, and  
11 Cosmetic Act (21 U.S.C. 360c(i)) is amended—

12 (1) by redesignating paragraph (3) as para-  
13 graph (5); and

14 (2) by striking paragraph (2) and inserting the  
15 following:

16 “(2)(A) Any person seeking a determination of sub-  
17 stantial equivalence under subsection (f) or section 520(l)  
18 for a device shall submit to the Secretary information (to  
19 the extent such information is readily available) on the  
20 market status of—

21 “(i) each predicate device; and

22 “(ii) each device in the full device lineage (as  
23 defined in subparagraph (C)).

24 “(B) With respect to each device described in clause  
25 (i) or (ii) of subparagraph (A), the information required  
26 to be submitted under subparagraph (A) shall specify—

1           “(i) whether the device has been corrected or  
2 removed from the market;

3           “(ii) if so, the basis for such correction or re-  
4 moval, including whether such correction or removal  
5 was because of an intrinsic flaw in technology or de-  
6 sign that adversely affects safety; and

7           “(iii) why the device for which a substantial  
8 equivalence determination is sought does not share  
9 any such intrinsic flaw.

10          “(C) In this paragraph, the term ‘device in the full  
11 device lineage’ means a device for which a substantial  
12 equivalence determination was made leading to a substan-  
13 tial equivalence determination for a predicate device re-  
14 ferred to in subparagraph (A)(i).”.

15          (b) REJECTING CLAIMS OF SUBSTANTIAL EQUIVA-  
16 LENCE.—Section 513(i) of the Federal Food, Drug, and  
17 Cosmetic Act (21 U.S.C. 360c(i)), as amended, is further  
18 amended by inserting after paragraph (2) the following:

19          “(3) The Secretary—

20               “(A) shall not find a device to be substantially  
21 equivalent to a predicate device that has been—

22                       “(i) removed from the market at the initia-  
23 tive of the Secretary; or

24                       “(ii) determined to be misbranded or adul-  
25 terated by judicial order;

1           “(B) may reject a claim that a device is sub-  
2           stantially equivalent to a predicate device if—

3                   “(i) the predicate device, or any device in  
4                   a series of one or more devices for which a sub-  
5                   stantial equivalence determination was made  
6                   leading to a substantial equivalence determina-  
7                   tion for the predicate device, has been corrected  
8                   or removed from the market—

9                           “(I) at the initiative of the sponsor; or

10                           “(II) under any other circumstance  
11                           not covered by subparagraph (A); and

12                   “(ii) the correction or removal is due, in  
13                   whole or in part, to an intrinsic flaw in tech-  
14                   nology or design that adversely affects safety;

15           “(C) may reject a claim that a device is sub-  
16           stantially equivalent to a predicate device if—

17                   “(i) the Secretary is in the process of re-  
18                   scinding the clearance granted under section  
19                   510(k), issuing or amending an order under  
20                   section 518(e) (relating to recall authority), or  
21                   taking any other regulatory action because of  
22                   an intrinsic flaw in technology or design that  
23                   adversely affects safety, with respect to—

24                           “(I) the predicate device; or

1                   “(II) any device in the full predicate  
2                   device lineage (meaning any device for  
3                   which a substantial equivalence determina-  
4                   tion was made leading to a substantial  
5                   equivalence determination for the predicate  
6                   device); or

7                   “(ii) the manufacturer or importer of a de-  
8                   vice described in subclause (I) or (II) of clause  
9                   (i) is in the process of correcting or removing  
10                  the device from the market; and

11                  “(D) may reject a claim that a device is sub-  
12                  stantially equivalent to a predicate device if the  
13                  predicate device has been corrected or removed from  
14                  the market and the manufacturer or importer of the  
15                  predicate failed to submit notice of such correction  
16                  or removal in accordance with section 519(g).”.

17                  (c) DATABASE ON ELIGIBLE PREDICATE DEVICES.—  
18                  Section 513(i) of the Federal Food, Drug, and Cosmetic  
19                  Act (21 U.S.C. 360c(i)), as amended, is further amended  
20                  by inserting after paragraph (3) the following:

21                  “(4)(A) The Secretary shall maintain an up-to-date  
22                  database that can be used by the Secretary for purposes  
23                  of determining whether devices are eligible under para-  
24                  graph (3) for use as a predicate device.

1 “(B) The Secretary shall determine whether a device  
2 is eligible under paragraph (3) for use as a predicate de-  
3 vice, and shall make appropriate updates to the database  
4 under this paragraph, whenever—

5 “(i) the Secretary issues, vacates, or amends an  
6 order for a device under section 518(e) (relating to  
7 recall authority);

8 “(ii) the manufacturer or importer of a device  
9 reports a correction or removal of a device under  
10 subsection (g) or (h) of section 519; or

11 “(iii) the Secretary otherwise learns of a correc-  
12 tion or removal of a device (as such terms are used  
13 in subsections (g) and (h) of section 519).

14 “(C) Upon making a determination required by sub-  
15 paragraph (B), the Secretary shall include in the database  
16 under this paragraph information, to the extent such in-  
17 formation is available to the Secretary, about the reason  
18 for the order, correction, or removal.

19 “(D) The Secretary shall publish notice of each deter-  
20 mination under subparagraph (B).”.

21 (d) REPORTS OF CORRECTIONS AND REMOVALS.—

22 (1) IN GENERAL.—Section 519 of the Federal  
23 Food, Drug, and Cosmetic Act (21 U.S.C. 360i) is  
24 amended by adding at the end the following:

1       “(h) INCLUSION OF ROOT CAUSE ANALYSIS IN RE-  
2 PORTS OF REMOVALS AND CORRECTIONS.—

3           “(1) REQUIREMENT.—Whenever a manufac-  
4 turer or importer of a device is required to submit  
5 a report under subsection (g) on a corrective action  
6 or removal of the device, and whenever a manufac-  
7 turer or importer would be so required but for sub-  
8 mitting a report under subsection (a) on a corrective  
9 action or removal of the device, the manufacturer or  
10 importer shall submit, as an addendum to the sub-  
11 mitted report, the root cause assessment of each de-  
12 vice defect leading to the corrective action or re-  
13 moval.

14           “(2) TIMING.—An addendum required by para-  
15 graph (1) shall be submitted to the Secretary  
16 promptly, and not later than 90 days after the cor-  
17 rective action or removal.”.

18           (2) REPORTS FOR DEVICES IN SAME LINEAGE  
19 AS DEVICES SUBJECT TO CORRECTIONS AND REMOV-  
20 ALS.—

21           (A) AUTHORITY TO ORDER REPORTS.—

22           Section 519 of the Federal Food, Drug, and  
23 Cosmetic Act (21 U.S.C. 360i), as amended, is  
24 further amended by adding at the end the fol-  
25 lowing:

1       “(i) REPORTS FOR DEVICES IN SAME LINEAGE AS  
2 DEVICES SUBJECT TO CORRECTIONS AND REMOVALS.—

3           “(1) IN GENERAL.—When a device is corrected  
4 or removed from the market because of an intrinsic  
5 flaw in technology or design that adversely affects  
6 safety—

7           “(A) the Secretary may order the manu-  
8 facturer or importer of each device in the same  
9 lineage which continues to be marketed to sub-  
10 mit a report described in paragraph (2); and

11           “(B) not later than 30 days after receipt  
12 of such an order, the manufacturer or importer  
13 of each such device shall submit the report.

14           “(2) REPORT CONTENTS.—A report described  
15 in this paragraph shall—

16           “(A) state whether the device for which the  
17 report is submitted shares any intrinsic flaw in  
18 technology or design associated with the device  
19 which is corrected or removed from the market;  
20 and

21           “(B) if not, explain why the device for  
22 which the report is submitted does not share  
23 any such intrinsic flaw.

24           “(3) DEFINITION.—In this subsection, the term  
25 ‘device in the same lineage’ refers to a device if—

1           “(A) a substantial equivalence determina-  
2           tion was made for the device corrected or re-  
3           moved from the market; and

4           “(B) such determination leads to a sub-  
5           stantial equivalence determination for the device  
6           involved.”.

7           (B) CONFORMING AMENDMENT.—Section  
8           303(f)(1)(B) of the Federal Food, Drug, and  
9           Cosmetic Act (21 U.S.C. 333(f)(1)(B)) is  
10          amended by striking “or 519(g)” and inserting  
11          “, 519(g), or 519(h)”.

12          (e) REVIEW OF PREVIOUSLY CLEARED LIFE-SUS-  
13          TAINING, LIFE-SUPPORTING, OR IMPLANTABLE DE-  
14          VICES.—

15           (1) REVIEW.—The Secretary shall conduct a re-  
16          view of all covered devices to identify any such de-  
17          vices with respect to which a predicate device, or any  
18          device in the full device lineage, has been corrected  
19          or removed from the market pursuant to a Class I  
20          or Class II recall.

21           (2) PRIORITY.—In conducting the review under  
22          paragraph (1), the Secretary shall prioritize—

23           (A) the review of covered devices that pose  
24          the highest risk to patients; and

1 (B) the identification of covered devices  
2 that share with another device an intrinsic flaw  
3 in technology or design that—

4 (i) adversely affects safety; and

5 (ii) led to the correction or removal  
6 from the market of the other device.

7 (3) REPORT.—Not later than 3 years after the  
8 date of the enactment of this Act, the Secretary  
9 shall submit a report to the Congress on the  
10 progress made by the Secretary in implementing this  
11 subsection.

12 (4) DEFINITIONS.—In this subsection:

13 (A) The terms “Class I”, “Class II”, and  
14 “recall” have the meanings given to such terms  
15 in section 7.3 of title 21, Code of Federal Regu-  
16 lations (or any successor regulations).

17 (B) The term “covered device” means a  
18 device (as defined in section 201 of the Federal  
19 Food, Drug, and Cosmetic Act (21 U.S.C.  
20 321)) that—

21 (i) is cleared under section 510(k) of  
22 such Act (21 U.S.C. 360(k)) before the ef-  
23 fective date of the amendments made by  
24 subsections (a) through (d);

1 (ii) is life-sustaining, life-supporting,  
2 or implantable; and

3 (iii) continues to be marketed.

4 (C) The term “device in the full device lin-  
5 eage” means a device for which a substantial  
6 equivalence determination was made leading to  
7 a substantial equivalence determination for a  
8 predicate device referred to in paragraph (1).

9 (D) The term “Secretary” means the Sec-  
10 retary of Health and Human Services, acting  
11 through the Commissioner of Food and Drugs.

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