I

112TH CONGRESS
2D 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.

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

---

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.

Be it enacted by the Senate and House of Representatives of the United States of America in Congress assembled,

SECTION 1. SHORT TITLE.

This Act may be cited as the ''Safety Of Untested and New Devices Act of 2012'' or the ''SOUND Devices Act of 2012''.

SEC. 2. PREDICATE DEVICES THAT HAVE BEEN RECALLED, CORRECTED, OR REMOVED FROM THE MARKET.

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

(1) by redesignating paragraph (3) as paragraph (5); and

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

''(2)(A) Any person seeking a determination of substantial equivalence under subsection (f) or section 520(l) for a device shall submit to the Secretary information (to the extent such information is readily available) on the market status of—

''(i) each predicate device; and

''(ii) each device in the full device lineage (as defined in subparagraph (C)).

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

''(i) whether the device has been corrected or removed from the market;

''(ii) if so, the basis for such correction or removal, including whether such correction or removal was because of an intrinsic flaw in technology or design that adversely affects safety; and

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

''(C) In this paragraph, the term 'device in the full device lineage' means a device for which a substantial equivalence determination was made leading to a substantial equivalence determination for a predicate device referred to in subparagraph (A)(i).''.

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

''(3) The Secretary—

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

''(i) removed from the market at the initiative of the Secretary; or

''(ii) determined to be misbranded or adulterated by judicial order;

''(B) may reject a claim that a device is substantially equivalent to a predicate device if—

''(i) the predicate device, or any device in a series of one or more devices for which a substantial equivalence determination was made leading to a substantial equivalence determination for the predicate device, has been corrected or removed from the market—

''(I) at the initiative of the sponsor; or

''(II) under any other circumstance not covered by subparagraph (A); and

''(ii) the correction or removal is due, in whole or in part, to an intrinsic flaw in technology or design that adversely affects safety;

''(C) may reject a claim that a device is substantially equivalent to a predicate device if—

''(i) the Secretary is in the process of rescinding the clearance granted under section 510(k), issuing or amending an order under section 518(e) (relating to recall authority), or taking any other regulatory action because of an intrinsic flaw in technology or design that adversely affects safety, with respect to—

''(I) the predicate device; or

''(II) any device in the full predicate device lineage (meaning any device for which a substantial equivalence determination was made leading to a substantial equivalence determination for the predicate device); or

''(ii) the manufacturer or importer of a device described in subclause (I) or (II) of clause (i) is in the process of correcting or removing the device from the market; and

''(D) may reject a claim that a device is substantially equivalent to a predicate device if the predicate device has been corrected or removed from the market and the manufacturer or importer of the predicate failed to submit notice of such correction or removal in accordance with section 519(g).''.

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

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

''(B) The Secretary shall determine whether a device is eligible under paragraph (3) for use as a predicate device, and shall make appropriate updates to the database under this paragraph, whenever—

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

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

''(iii) the Secretary otherwise learns of a correction or removal of a device (as such terms are used in subsections (g) and (h) of section 519).

''(C) Upon making a determination required by subparagraph (B), the Secretary shall include in the database under this paragraph information, to the extent such information is available to the Secretary, about the reason for the order, correction, or removal.

''(D) The Secretary shall publish notice of each determination under subparagraph (B).''.

(d) REPORTS OF CORRECTIONS AND REMOVALS.—

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

''(h) INCLUSION OF ROOT CAUSE ANALYSIS IN REPORTS OF REMOVALS AND CORRECTIONS.—

''(1) REQUIREMENT.—Whenever a manufacturer or importer of a device is required to submit a report under subsection (g) on a corrective action or removal of the device, and whenever a manufacturer or importer would be so required but for submitting a report under subsection (a) on a corrective action or removal of the device, the manufacturer or importer shall submit, as an addendum to the submitted report, the root cause assessment of each device defect leading to the corrective action or removal.

''(2) TIMING.—An addendum required by paragraph (1) shall be submitted to the Secretary promptly, and not later than 90 days after the corrective action or removal.''.

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

(A) AUTHORITY TO ORDER REPORTS.—Section 519 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360i), as amended, is further amended by adding at the end the following:

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

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

''(A) the Secretary may order the manufacturer or importer of each device in the same lineage which continues to be marketed to submit a report described in paragraph (2); and

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

''(2) REPORT CONTENTS.—A report described in this paragraph shall—

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

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

''(3) DEFINITION.—In this subsection, the term 'device in the same lineage' refers to a device if—

"(A) a substantial equivalence determination was made for the device corrected or removed from the market; and

"(B) such determination leads to a substantial equivalence determination for the device involved.".

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

(e) REVIEW OF PREVIOUSLY CLEARED LIFE-SUSTAINING, LIFE-SUPPORTING, OR IMPLANTABLE DEVICES.—

(1) REVIEW.—The Secretary shall conduct a review of all covered devices to identify any such devices with respect to which a predicate device, or any device in the full device lineage, has been corrected or removed from the market pursuant to a Class I or Class II recall.

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

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

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

(i) adversely affects safety; and

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

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

(4) DEFINITIONS.—In this subsection:

(A) The terms ''Class I'', ''Class II'', and ''recall'' have the meanings given to such terms in section 7.3 of title 21, Code of Federal Regulations (or any successor regulations).

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

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

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

(iii) continues to be marketed.

(C) The term ''device in the full device lineage'' means a device for which a substantial equivalence determination was made leading to a substantial equivalence determination for a predicate device referred to in paragraph (1).

(D) The term ''Secretary'' means the Secretary of Health and Human Services, acting through the Commissioner of Food and Drugs.

○