AUTHENTICATED
U.S. GOVERNMENT
INFORMATION
GPO

I

112TH CONGRESS
2D SESSION

H. R. 5866

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.

IN THE HOUSE OF REPRESENTATIVES

MAY 30, 2012

Mr. BRALEY of Iowa introduced the following bill; which was referred to the Committee on Energy and Commerce

---

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.

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 ''Medical Device Patient Safety Act''.

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

(a) DEFINITIONS.—In this Act:

(1) COMMISSIONER.—The term ''Commissioner'' means the Commissioner of Food and Drugs.

(2) DEVICE.—The term ''device'' has the meaning given that term in section 201(h) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 321(h)).

(3) SECRETARY.—The term ''Secretary'' means the Secretary of Health and Human Services.

(b) ACTIONS BY SECRETARY.—To enhance the oversight by the Food and Drug Administration of device recalls, the Secretary of Health and Human Services, acting through the Commissioner of Food and Drugs, shall carry out the activities described in this section.

(c) ASSESSMENT OF DEVICE RECALL INFORMATION.—

(1) IN GENERAL.—

(A) ASSESSMENT PROGRAM.—The Secretary shall establish a program to routinely and systematically assess—

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

(ii) information required to be reported to the Secretary regarding a correction or removal of a device under section 519(g) of such Act (21 U.S.C. 360i(g)).

(B) USE.—The Secretary shall use the assessment of information described under subparagraph (A) to proactively identify strategies for mitigating health risks presented by defective or unsafe devices.

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

(A) trends in the numbers and types of device recalls;

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

(C) the causes of device recalls;

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

(E) the length of time needed for the Secretary to terminate a device recall;

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

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

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

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

(e) ASSESSMENT CRITERIA.—The Secretary shall develop explicit criteria for assessing whether a person subject to a recall order under section 518(e) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360h(e)) or to a requirement under section 519(g) of such Act (21 U.S.C. 360i(g)) has performed an effective correction or removal action under such section 519(g).

(f) TERMINATION OF RECALLS.—

(1) IN GENERAL.—The Secretary shall document the basis for the termination by the Food and Drug Administration of—

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

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

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

(2) PUBLICATION.—

(A) IN GENERAL.—The Secretary shall, with respect to each termination described in paragraph (1), publish the documentation required under such paragraph not later than 180 days after such termination.

(B) PROTECTION OF CONFIDENTIAL INFORMATION OR TRADE SECRETS.—Before public disclosure of the documentation under subparagraph (A), the Secretary shall delete from the documentation the following:

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

(ii) Any personnel, medical, or similar information, including the serial numbers of implanted devices, which would constitute a clearly unwarranted invasion of personal privacy.

SEC. 3. CONDITIONAL CLEARANCE OF CERTAIN MEDICAL DEVICES.

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

"SEC. 510A. CONDITIONAL CLEARANCE OF CERTAIN MEDICAL DEVICES.

"(a) IN GENERAL.—Notwithstanding any other provision of law, the Secretary may 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 section 510(k).

"(b) POSTCLEARANCE REQUIREMENTS.—As part of the conditional clearance under subsection (a), the Secretary may impose the following:

"(1) The Secretary may restrict the sale, distribution, or use of the device but only to the extent that the sale, distribution, or use of the device may be restricted pursuant to section 520(e).

"(2) The Secretary—

"(A) may require continuing evaluation and periodic reporting on the safety, effectiveness, and reliability of the device for its intended use; and

"(B) shall, to the extent the Secretary makes a requirement under subparagraph (A),

state in the clearance order the reason or purpose for such a requirement and the number of patients to be evaluated and the reports required to be submitted.

"(3) The Secretary may require a prominent display in the labeling of the device and in the advertising of warnings, hazards, or precautions important for the device's safe and effective use, including patient information such as information provided to the patient on alternative modes of therapy and on risks and benefits associated with the use of the device.

"(4) The Secretary—

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

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

tiveness of the device, or to verify a record, report, or information submitted to the agency.

"(5) The Secretary may require maintenance of records for specified periods of time and organization and indexing of records into identifiable files to enable the Food and Drug Administration to determine whether there is reasonable assurance of the continued safety and effectiveness of the device.

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

"(A) Identify any of the following changes:

"(i) New indications for use of the device.

"(ii) Labeling changes.

"(iii) The use of a different facility or establishment to manufacture, process, or package the device.

"(iv) Changes in sterilization procedures.

"(v) Changes in packaging.

"(vi) Changes in the performance or design specifications, circuits, components, ingredients, principle of operation, or physical layout of the device.

"(vii) Extension of the expiration date of the device based on data obtained under a new or revised stability or sterility testing protocol.

"(viii) A change that does not affect the device's safety or effectiveness.

"(B) Contain a summary and bibliography of the following information not previously submitted:

"(i) Unpublished reports of data from any clinical investigations or nonclinical laboratory studies involving the device or related devices and known to or that reasonably should be known to the applicant.

"(ii) Reports in the scientific literature concerning the device and known to or that reasonably should be known to the applicant. If, after reviewing the summary and bibliography, the Food and Drug Administration concludes that the agency needs a copy of the unpublished or published reports, the Food and Drug Administration shall notify the applicant that copies of such reports should be submitted.

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

"(7) The Secretary may require batch testing of the device.

"(8) The Secretary may provide for any other requirements determined by the Secretary to be necessary to provide reasonable assurance, or continued reasonable assurance, of the safety and effectiveness of the device.

"(9) The Secretary may require device tracking as provided under part 821 of title 21, Code of Federal Regulations.

"(c) RESCISSION OF CONDITIONAL CLEARANCE.—The Secretary may rescind the conditional clearance of a medical device under subsection (a) if the Secretary determines that the conditions imposed on the clearance of the device described in subsection (b) have not been met.".

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

(c) PROCESS FOR THE REVIEW OF DEVICE APPLICATIONS.—Section 737(8)(J) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 379i(8)(J)) is amended by inserting ''or required as a condition of clearance of a device under section 510A'' after ''Act''.

○