112TH CONGRESS
2D SESSION

S. 2067

To amend the Federal Food, Drug, and Cosmetic Act with respect to medical device regulation, and for other purposes.

IN THE SENATE OF THE UNITED STATES

FEBRUARY 2, 2012

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

---

A BILL

To amend the Federal Food, Drug, and Cosmetic Act with respect to medical device regulation, 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; TABLE OF CONTENTS.

(a) SHORT TITLE.—This Act may be cited as the ''Safe, Efficient, and Transparent Medical Device Approval Act'' or the ''SET Device Act''.

(b) TABLE OF CONTENTS.—The table of contents for this Act is as follows:

SEC. 2. FINDINGS.

Congress finds as follows:

(1) Under the Safe Medical Devices Act of 1990 (Public Law 101–629), Congress amended section 515 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360e) to require the Food and Drug Administration to reclassify preamendment class III devices to a lower class or to require them to go through the premarket approval process.

(2) The Food and Drug Administration has not yet complied with the mandate of Congress under such Act.

(3) The de novo process, created by the Food and Drug Administration Modernization Act of 1997 (Public Law 105–115), is an approval mechanism by which the Food and Drug Administration may down-classify, to class I or class II, devices that have no predicates and thus are designated class III, but are deemed to be of low to moderate risk. The process avoids having novel, low- to moderate-risk devices go through the premarket approval process. Under the current de novo process, the manufacturer must first make a submission under section 510(k) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360), even if no known predicate device exists. A 2011 Institute of Medicine report

found that, between 2005 and 2009, review times for novel therapeutic devices through the de novo process nearly tripled. The report concluded that the current de novo process has not met its potential as an alternative regulatory pathway, and recommended the establishment of a modified de novo process.

SEC. 3. ESTABLISHMENT OF SCHEDULE AND PROMULGATION OF REGULATION.

(a) ESTABLISHMENT OF SCHEDULE.—Not later than 120 days after the date of enactment of this Act, the Secretary of Health and Human Services (referred to in this section as the ''Secretary''), shall establish the schedule referred to in section 515(i)(3) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360e(i)(3)) for each device that the Secretary requires to remain in class III through a determination under section 515(i)(2) of such Act.

(b) ACTION REGARDING CLASS II AND III.—Not later than 18 months after the date of enactment of this Act, the Secretary shall—

(1) issue a final regulation under section 515(b) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360e(b)) for each device that the Secretary requires to remain in class III through a determination under section 515(i)(2) of such Act; and

(2) establish the special controls required by section 513(a)(1)(B) of such Act (21 U.S.C. 360c(a)(1)(B)) for each device that is classified into class II pursuant to a determination revising the classification of the device under section 515(i)(2) of such Act.

SEC. 4. MODIFICATION OF DE NOVO APPLICATION PROCESS.

(a) IN GENERAL.—Section 513(f)(2) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360c(f)(2)) is amended—

(1) by redesignating subparagraphs (B) and (C) as subparagraphs (C) and (D), respectively;

(2) by amending subparagraph (A) to read as follows:

''(A) In the case of a type of device that has not previously been classified under this Act, a person may do one of the following:

''(i) Submit a report under section 510(k), and, if the device is classified into class III under paragraph (1), such person may request, not later than 30 days after receiving written notice of such a classification, the Secretary to classify the device under the criteria set forth in subparagraphs (A) through (C) of subsection (a)(1). The person may, in the re-

quest, recommend to the Secretary a classification for the device. Any such request shall describe the device and provide detailed information and reasons for the recommended classification.

''(ii) Submit a request for initial classification of the device under this subparagraph, if the person declares that there is no legally marketed device upon which to base a substantial equivalence determination as that term is defined in section 513(i). Subject to subparagraph (B), the Secretary shall classify the device under the criteria set forth in subparagraphs (A) through (C) of subsection (a)(1). The person submitting the request for classification under this subparagraph may recommend to the Secretary a classification for the device and shall include in the request an initial draft proposal for applicable special controls, as described in subsection (a)(1)(B), that are necessary, in conjunction with general controls, to provide reasonable assurance of safety and effectiveness and a description of how the special controls provide such assurance.'';

(3) by inserting after subparagraph (A) the following:

''(B) The Secretary may decline to undertake a classification request submitted under clause (2)(A)(ii) if the

Secretary identifies a legally marketed device that could provide a reasonable basis for review of substantial equivalence under paragraph (1), or when the Secretary determines that the device submitted is not of low-moderate risk.''; and

(4) in subparagraph (C), as so redesignated—

(A) in clause (i), by striking ''Not later than 60 days after the date of the submission of the request under subparagraph (A),'' and inserting ''Not later than 90 days after the date of the submission of the request under subparagraph (A)(i) or 120 days after the date of the submission of the request under subparagraph (A)(ii),''; and

(B) in clause (ii), by inserting ''or is classified in'' after ''remains in''.

(b) GAO REPORT.—Not later than 2 years after the date of enactment of this Act, the Comptroller General of the United States shall complete a study and submit to Congress a report on the effectiveness of the review pathway under section 513(f)(2)(A) of the Federal Food, Drug, and Cosmetic Act, as amended by this Act.

(c) CONFORMING AMENDMENT.—Section 513(f)(1)(B) of the Federal Food, Drug, and Cosmetic

Act (21 U.S.C. 360c(f)(1)(B)) is amended by inserting ''a request under paragraph (2) or'' after ''response to''.

○