II

114TH CONGRESS
2D SESSION

S. 2737

To improve medical device innovation.

IN THE SENATE OF THE UNITED STATES

MARCH 17, 2016

Ms. KLOBUCHAR (for herself and Mr. ROBERTS) 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 improve medical device innovation.

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 ''Improving Medical Device Innovation Act''.

SEC. 2. RECOGNITION OF STANDARDS.

(a) IN GENERAL.—Section 514(c) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360d(c)) is amended—

(1) in paragraph (1), by inserting after subparagraph (B) the following new subparagraphs:

''(C)(i) Any person may submit a request for recognition under subparagraph (A) of all or part of an appropriate standard established by a nationally or internationally recognized standard organization.

''(ii) Not later than 60 calendar days after the Secretary receives such a request, the Secretary shall—

''(I) make a determination to recognize all, part, or none of the standard that is the subject of the request; and

''(II) issue to the person who submitted such request a response in writing that states the Secretary's rationale for that determination, including the scientific, technical, regulatory, or other basis for such determination.

''(iii) The Secretary shall take such actions as may be necessary to implement all or part of a standard recognized under subclause (I) of clause (ii), in accordance with subparagraph (A).

''(D) The Secretary shall make publicly available, in such manner as the Secretary determines appropriate, the rationale for recogni-

tion of all, part, or none of a standard, including the scientific, technical, regulatory, or other basis for the decision regarding such recognition.''; and

(2) by adding at the end the following:

''(4) TRAINING ON USE OF STANDARDS.—The Secretary shall provide to all employees of the Food and Drug Administration who review premarket submissions for devices periodic training on the concept and use of recognized standards for purposes of meeting a premarket submission requirement or other applicable requirement under this Act, including standards relevant to an employee's area of device review.''.

(b) GUIDANCE.—The Secretary of Health and Human Services, acting through the Commissioner of Food and Drugs, shall review and update, if necessary, previously published guidance and standard operating procedures identifying the principles for recognizing standards, and for withdrawing the recognition of standards, under section 514(c) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360d(c)), taking into account the experience with and reliance on a standard by foreign regulatory authorities and the device industry, and whether

recognition of a standard will promote harmonization among regulatory authorities in the regulation of devices.

SEC. 3. CERTAIN CLASS I AND CLASS II DEVICES.

(a) CLASS I DEVICES.—Section 510(l) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360(l)) is amended—

(1) by striking ''A report under subsection (k)'' and inserting ''(1) A report under subsection (k)''; and

(2) by adding at the end the following new paragraph:

''(2) Not later than 120 calendar days after the date of enactment of the Improving Medical Device Innovation Act and at least once every 5 years thereafter, as the Secretary determines appropriate, the Secretary shall identify, through publication in the Federal Register, any type of class I device that the Secretary determines no longer requires a report under subsection (k) to provide reasonable assurance of safety and effectiveness. Upon such publication—

''(A) each type of class I device so identified shall be exempt from the requirement for a report under subsection (k); and

"(B) the classification regulation applicable to each such type of device shall be deemed amended to incorporate such exemption.".

(b) CLASS II DEVICES.—Section 510(m) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360(m)) is amended—

(1) by striking paragraph (1) and inserting the following new paragraph:

"(1) The Secretary shall—

"(A) not later than 90 days after the date of enactment of the Improving Medical Device Innovation Act and at least once every 5 years thereafter, as the Secretary determines appropriate—

"(i) publish in the Federal Register a notice that contains a list of each type of class II device that the Secretary determines no longer requires a report under subsection (k) to provide reasonable assurance of safety and effectiveness; and

"(ii) provide for a period of not less than 60 calendar days for public comment beginning on the date of the publication of such notice; and

''(B) not later than 210 calendar days after the date of enactment of the Improving Medical Device Innovation Act, publish in the Federal Register a list representing the Secretary's final determination with respect to the devices contained in the list published under subparagraph (A).''; and

(2) in paragraph (2)—

(A) by striking ''1 day after the date of publication of a list under this subsection,'' and inserting ''1 calendar day after the date of publication of the final list under paragraph (1)(B),''; and

(B) by striking ''30-day period'' and inserting ''60-calendar-day period''; and

(C) by adding at the end the following new paragraph:

''(3) Upon the publication of the final list under paragraph (1)(B)—

''(A) each type of class II device so listed shall be exempt from the requirement for a report under subsection (k); and

''(B) the classification regulation applicable to each such type of device shall be deemed amended to incorporate such exemption.''.

SEC. 4. CLASSIFICATION PANELS.

(a) CLASSIFICATION PANELS.—Paragraph (5) of section 513(b) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360c(b)) is amended—

(1) by striking ''(5)'' and inserting ''(5)(A)''; and

(2) by adding at the end the following:

''(B) When a device is specifically the subject of review by a classification panel, the Secretary shall—

''(i) ensure that adequate expertise is represented on the classification panel to assess—

''(I) the disease or condition which the device is intended to cure, treat, mitigate, prevent, or diagnose; and

''(II) the technology of the device; and

''(ii) provide an opportunity for the person whose device is specifically the subject of panel review to provide recommendations on the expertise needed among the voting members of the panel.

''(C) For purposes of subparagraph (B)(i), the term 'adequate expertise' means that the

membership of the classification panel includes—

"(i) two or more voting members, with a specialty or other expertise clinically relevant to the device under review; and

"(ii) at least one voting member who is knowledgeable about the technology of the device.

"(D) The Secretary shall provide an annual opportunity for patients, representatives of patients, and sponsors of medical device submissions to provide recommendations for individuals with appropriate expertise to fill voting member positions on classification panels.".

(b) PANEL REVIEW PROCESS.—Section 513(b)(6) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360c(b)(6)) is amended—

(1) in subparagraph (A)(iii), by inserting before the period at the end ", including by designating a representative who will be provided a time during the panel meeting to address the panel individually (or accompanied by experts selected by such representative) for the purpose of correcting misstatements of fact or providing clarifying information,

subject to the discretion of the panel chairperson''; and

(2) by striking subparagraph (B) and inserting the following new subparagraph:

''(B)(i) Any meeting of a classification panel with respect to the review of a device shall—

''(I) provide adequate time for initial presentations by the person whose device is specifically the subject of such review and by the Secretary; and

''(II) provide adequate time for and encourage free and open participation by all interested persons.

''(ii) Following the initial presentations described in clause (i), the panel may—

''(I) pose questions to the designated representative described in subparagraph (A)(iii); and

''(II) consider the responses to such questions in the panel's review of the device.''.

SEC. 5. POSTMARKET PILOT TO IMPROVE MEDICAL DEVICE REPORTING.

(a) PILOT PROJECTS.—

(1) IN GENERAL.—In order to improve the value and efficiency of reporting so as to advance the objectives of section 519(a) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360i(a)), within one year of the date of enactment of this Act, the Secretary of Health and Human Services shall establish one or more pilot projects, in coordination with device manufacturers, to explore and evaluate the use of alternative methods of compliance with such subsection for manufacturers of devices described in section 513(a)(1)(C) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360c(a)(1)(C)).

(2) VOLUNTARY PARTICIPATION.—Participation in such pilot projects shall be voluntary for device manufacturers. The Secretary may establish the conditions for such voluntary participation and may establish a process for authorizing participation.

(3) PURPOSES.—The pilot projects established under paragraph (1) shall be designed to—

(A) test methods of reporting for one or more device types, with priority given to devices for which device manufacturers submit a relatively high volume of reports under the regulations implementing section 519(a) of the Fed-

eral Food, Drug, and Cosmetic Act (21 U.S.C. 360i(a));

(B) evaluate forms of data monitoring and reporting that improve the usability of report data by focusing on events and information that are most relevant to reasonably assuring the safety and effectiveness of the device;

(C) identify methods of reporting that will be least burdensome for device manufacturers; and

(D) evaluate methods that are alternative to, and do not duplicate, compliance with requirements of part 803 of title 21, Code of Federal Regulations (or successor regulations).

(4) NOTIFICATION TO CONGRESS.—The Secretary of Health and Human Services shall notify the Committee on Health, Education, Labor, and Pensions of the Senate and the Committee on Energy and Commerce of the House of Representatives not later than 18 months after the date of enactment of this Act of the number of manufacturers that have agreed to participate in a pilot project under this subsection with the Secretary of Health and Human Services.

(5) RULE OF CONSTRUCTION.—Nothing in this subsection shall limit the authority of the Secretary of Health and Human Services to provide for alternative methods of medical device reporting under part 803 of title 21, Code of Federal Regulations (or successor regulations), including such methods described in this subsection.

(6) COMPLIANCE WITH REQUIREMENTS FOR RECORDS OR REPORTS ON DEVICES.—

(A) IN GENERAL.—A device manufacturer that participates in a pilot project under this subsection shall be required to comply with all applicable provisions of section 519 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360i), and implementing regulations, except as described in subparagraph (B).

(B) CONDITIONAL EXEMPTION.—The Secretary may determine that, for a specified time period to be determined by the Secretary, a manufacturer participating in a pilot project under this subsection is exempt from certain provisions of section 519(a) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360i(a)), and implementing regulations, if such

manufacturer complies with the conditions set forth in a pilot project under this subsection.

(b) GAO REVIEW.—

(1) REVIEW OF PILOT PROJECTS.—The Comptroller General of the United States shall conduct a review of the pilot projects established under subsection (a), and of the reporting system under part 803 of title 21, Code of Federal Regulations (or successor regulations).

(2) REPORT.—Not later than January 31, 2021, the Comptroller General of the United States shall submit to Congress a report containing the results of the review described in paragraph (1). Such report shall analyze the value, efficiency, and effectiveness of reporting methods under subsections (a) and (b) of section 519 of Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360i) and identify any recommendations for statutory amendments that would enhance the objectives of section 519(a) of such Act.

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