II

115TH CONGRESS
1ST SESSION

# S. 1069

To establish pilot projects in order to provide timely and reliable information on the safety and effectiveness of cleared or approved devices.

---

IN THE SENATE OF THE UNITED STATES

MAY 8, 2017

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

---

# A BILL

To establish pilot projects in order to provide timely and reliable information on the safety and effectiveness of cleared or approved devices.

*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 Safety Monitoring Act''.

**SEC. 2. DEVICE PILOT PROJECTS.**

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

''(i) PILOT PROJECTS.—

''(1) IN GENERAL.—In order to provide timely and reliable information on the safety and effectiveness of cleared or approved devices, including responses to adverse events and malfunctions, and to advance the objectives of part 803 of title 21, Code of Federal Regulations (or successor regulations), and advance the objectives of, and evaluate innovative new methods of compliance with, this section and section 522, the Secretary shall, within one year of the date of enactment of this subsection, initiate one or more pilot projects for voluntary participation by a manufacturer or manufacturers of device or device type, or continue existing projects in accordance with paragraph (3), that meet all of the following requirements:

''(A) Are designed to efficiently generate reliable and timely safety and active surveillance data for use by the Secretary or manufacturers of the devices that are involved in the pilot project.

''(B) Inform the development of methods, systems, data criteria, and programs that could be used to support safety and active surveil-

lance activities for devices not included in such project.

"(C) Are designed and conducted in coordination with a comprehensive system for evaluating medical device technology that operates under a governing board with appropriate representation of stakeholders, including consumer groups and device manufacturers.

"(D) Use electronic health data including claims data, patient survey data, and any other data, as the Secretary determines appropriate.

"(E) Prioritize devices and device types that meet one or more of the following criteria:

"(i) Devices and device types for which the collection and analysis of real world evidence regarding a device's safety and effectiveness is likely to advance public health.

"(ii) Devices and device types that are widely used.

"(iii) Devices and device types, the failure of which has significant health consequences.

"(iv) Devices and device types for which the Secretary has received public

recommendations in accordance with paragraph (2)(B) and has determined to meet one of the criteria under clauses (i) through (iii) and is appropriate for a project under this subsection.

''(2) PARTICIPATION.—The Secretary shall establish the conditions and processes for—

''(A) authorizing voluntary participation of a manufacturer of a device in the pilot project described in paragraph (1); and

''(B) facilitating public recommendations for devices to be prioritized under the pilot project described in paragraph (1), including requirements for the data necessary to support such recommendation.

''(3) IMPLEMENTATION.—The Secretary may satisfy the requirements of paragraphs (1) and (2) by continuing or expanding existing projects, or by beginning new projects, that meet the criteria of subparagraphs (A) through (E) of paragraph (1) or by entering into contracts, cooperative agreements, grants, or other appropriate agreements with public or private entities that have a significant presence in the United States, and meet the following additional conditions:

''(A) If such public or private entities are a component of another organization, the entities have established appropriate security measures to maintain the confidentiality and privacy of the data described in paragraph (1)(D) and the entity shall not make an unauthorized disclosure of such data to the other components of the organization in breach of such confidentiality and privacy requirements.

''(B) In the case of the termination or nonrenewal of such contracts, cooperative agreements, grants, or other appropriate agreements, the entities shall comply with each of the following:

''(i) Continue to comply with the confidentiality and privacy requirements under this subsection with respect to all data disclosed to the entity.

''(ii) Return any data disclosed to such entity under this subsection to which it would not otherwise have access or, if returning the data is not practicable, destroy the data.

''(C) Have at least one of the following qualifications:

''(i) Research, statistical, epidemiologic, or clinical capability and expertise to conduct and complete the activities under this subsection, including the capability and expertise to provide the Secretary access to de-identified data consistent with the requirements of this subsection.

''(ii) An information technology infrastructure in place to support electronic data and operational standards to provide security for such data, as appropriate.

''(iii) Experience with, and expertise on, the development of device safety and effectiveness research and surveillance using electronic health data.

''(iv) Other expertise which the Secretary determines necessary to fulfill the activities under this subsection.

''(4) REVIEW OF CONTRACT IN THE EVENT OF A MERGER OR ACQUISITION.—The Secretary shall review a contract with a qualified entity under this subsection in the event of a merger or acquisition of the entity in order to ensure that the requirements under this subsection will continue to be met.

''(5) REPORT TO CONGRESS.—Not later than 18 months after the date of enactment of this subsection, and annually thereafter, the Secretary shall submit to the Committee on Health, Education, Labor, and Pensions of the Senate and the Committee on Energy and Commerce of the House of Representatives a report containing a description of the pilot projects being conducted pursuant to this subsection, including for each pilot project—

''(A) how the project is being implemented in accordance with paragraph (3) and the contractor or grantee as applicable;

''(B) the number of manufacturers that have agreed to participate;

''(C) the data sources used;

''(D) the devices or device categories involved; and

''(E) the number of patients involved.

''(6) COMPLIANCE WITH REQUIREMENTS FOR RECORDS OR REPORTS ON DEVICES.—The participation of a manufacturer in a pilot project under this subsection shall not affect the eligibility of such manufacturer to participate in any quarterly reporting program implemented under this Act. The Secretary may determine that, for the specified time pe-

riod to be determined by the Secretary, a manufacturer's participation in a pilot project under this subsection may meet certain other requirements of this section or section 522 if—

''(A) the project has demonstrated success in capturing relevant adverse event information; and

''(B) the Secretary has established procedures for making adverse event and safety information collected from the pilot public, to the extent possible, if collected pursuant to this section or section 522.

''(7) PRIVACY REQUIREMENTS.—With respect to the pilot projects conducted pursuant to this subsection—

''(A) individual identifiable health information shall not be disclosed when presenting any information from such project; and

''(B) such projects shall comply with section 264(c) of the Health Insurance Portability and Accountability Act of 1996 (42 U.S.C. 1320d–2 note) and sections 552 and 552a of title 5, United States Code.

''(8) OTHER COMPLIANCE.—Any pilot program undertaken in coordination with the comprehensive

system described in paragraph (1)(C), including pilot projects under this subsection, that relates to the use of real world evidence for devices shall comply with paragraph (1)(B), the conditions listed in subparagraphs (A) and (B) of paragraph (3), and paragraphs (4), (5), (6), and (7).

''(9) SUNSET.—This subsection shall cease to have force or effect on October 1, 2022.''.

(b) REPORT.—Not later than January 31, 2021, the Secretary of Health and Human Services, acting through the Commissioner of Food and Drugs, shall conduct a review through an independent third party to evaluate the strengths, limitations, and appropriate use of evidence collected pursuant to real world evidence pilot projects described in the letters described in section 201(b) of the Medical Device User Fee Amendments of 2017 and subsection (i) of section 519 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360i), as amended by subsection (a), for informing premarket and postmarket decision-making for multiple device types, and to determine whether the methods, systems, and programs in such pilot projects efficiently generate reliable and timely evidence about the effectiveness or safety surveillance of devices.

○