

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 fol-
lowing 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.

1 *Be it enacted by the Senate and House of Representa-*
2 *tives of the United States of America in Congress assembled,*

3 **SECTION 1. SHORT TITLE.**

4 This Act may be cited as the “Medical Device Safety
5 Monitoring Act”.

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

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

1 “(i) PILOT PROJECTS.—

2 “(1) IN GENERAL.—In order to provide timely
3 and reliable information on the safety and effective-
4 ness of cleared or approved devices, including re-
5 sponses to adverse events and malfunctions, and to
6 advance the objectives of part 803 of title 21, Code
7 of Federal Regulations (or successor regulations),
8 and advance the objectives of, and evaluate innova-
9 tive new methods of compliance with, this section
10 and section 522, the Secretary shall, within one year
11 of the date of enactment of this subsection, initiate
12 one or more pilot projects for voluntary participation
13 by a manufacturer or manufacturers of device or de-
14 vice type, or continue existing projects in accordance
15 with paragraph (3), that meet all of the following re-
16 quirements:

17 “(A) Are designed to efficiently generate
18 reliable and timely safety and active surveil-
19 lance data for use by the Secretary or manufac-
20 turers of the devices that are involved in the
21 pilot project.

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

1 lance activities for devices not included in such
2 project.

3 “(C) Are designed and conducted in co-
4 ordination with a comprehensive system for
5 evaluating medical device technology that oper-
6 ates under a governing board with appropriate
7 representation of stakeholders, including con-
8 sumer groups and device manufacturers.

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

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

14 “(i) Devices and device types for
15 which the collection and analysis of real
16 world evidence regarding a device’s safety
17 and effectiveness is likely to advance public
18 health.

19 “(ii) Devices and device types that are
20 widely used.

21 “(iii) Devices and device types, the
22 failure of which has significant health con-
23 sequences.

24 “(iv) Devices and device types for
25 which the Secretary has received public

1 recommendations in accordance with para-
2 graph (2)(B) and has determined to meet
3 one of the criteria under clauses (i)
4 through (iii) and is appropriate for a
5 project under this subsection.

6 “(2) PARTICIPATION.—The Secretary shall es-
7 tablish the conditions and processes for—

8 “(A) authorizing voluntary participation of
9 a manufacturer of a device in the pilot project
10 described in paragraph (1); and

11 “(B) facilitating public recommendations
12 for devices to be prioritized under the pilot
13 project described in paragraph (1), including re-
14 quirements for the data necessary to support
15 such recommendation.

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

1 “(A) If such public or private entities are
2 a component of another organization, the enti-
3 ties have established appropriate security meas-
4 ures to maintain the confidentiality and privacy
5 of the data described in paragraph (1)(D) and
6 the entity shall not make an unauthorized dis-
7 closure of such data to the other components of
8 the organization in breach of such confiden-
9 tiality and privacy requirements.

10 “(B) In the case of the termination or non-
11 renewal of such contracts, cooperative agree-
12 ments, grants, or other appropriate agreements,
13 the entities shall comply with each of the fol-
14 lowing:

15 “(i) Continue to comply with the con-
16 fidentiality and privacy requirements under
17 this subsection with respect to all data dis-
18 closed to the entity.

19 “(ii) Return any data disclosed to
20 such entity under this subsection to which
21 it would not otherwise have access or, if re-
22 turning the data is not practicable, destroy
23 the data.

24 “(C) Have at least one of the following
25 qualifications:

1 “(i) Research, statistical, epidemio-
2 logic, or clinical capability and expertise to
3 conduct and complete the activities under
4 this subsection, including the capability
5 and expertise to provide the Secretary ac-
6 cess to de-identified data consistent with
7 the requirements of this subsection.

8 “(ii) An information technology infra-
9 structure in place to support electronic
10 data and operational standards to provide
11 security for such data, as appropriate.

12 “(iii) Experience with, and expertise
13 on, the development of device safety and
14 effectiveness research and surveillance
15 using electronic health data.

16 “(iv) Other expertise which the Sec-
17 retary determines necessary to fulfill the
18 activities under this subsection.

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

1 “(5) REPORT TO CONGRESS.—Not later than
2 18 months after the date of enactment of this sub-
3 section, and annually thereafter, the Secretary shall
4 submit to the Committee on Health, Education,
5 Labor, and Pensions of the Senate and the Com-
6 mittee on Energy and Commerce of the House of
7 Representatives a report containing a description of
8 the pilot projects being conducted pursuant to this
9 subsection, including for each pilot project—

10 “(A) how the project is being implemented
11 in accordance with paragraph (3) and the con-
12 tractor or grantee as applicable;

13 “(B) the number of manufacturers that
14 have agreed to participate;

15 “(C) the data sources used;

16 “(D) the devices or device categories in-
17 volved; and

18 “(E) the number of patients involved.

19 “(6) COMPLIANCE WITH REQUIREMENTS FOR
20 RECORDS OR REPORTS ON DEVICES.—The participa-
21 tion of a manufacturer in a pilot project under this
22 subsection shall not affect the eligibility of such
23 manufacturer to participate in any quarterly report-
24 ing program implemented under this Act. The Sec-
25 retary 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

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

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

9 (b) REPORT.—Not later than January 31, 2021, the
10 Secretary of Health and Human Services, acting through
11 the Commissioner of Food and Drugs, shall conduct a re-
12 view through an independent third party to evaluate the
13 strengths, limitations, and appropriate use of evidence col-
14 lected pursuant to real world evidence pilot projects de-
15 scribed in the letters described in section 201(b) of the
16 Medical Device User Fee Amendments of 2017 and sub-
17 section (i) of section 519 of the Federal Food, Drug, and
18 Cosmetic Act (21 U.S.C. 360i), as amended by subsection
19 (a), for informing premarket and postmarket decision-
20 making for multiple device types, and to determine wheth-
21 er the methods, systems, and programs in such pilot
22 projects efficiently generate reliable and timely evidence
23 about the effectiveness or safety surveillance of devices.

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