

*Patty Murray*AMENDMENT NO. 1

Calendar No. _____

Purpose: To establish a medical device postmarket surveillance system.

IN THE SENATE OF THE UNITED STATES—114th Cong., 2d Sess.

S. 1878(title) _____

_____Referred to the Committee on _____ and
ordered to be printed

Ordered to lie on the table and to be printed

AMENDMENT intended to be proposed by Mrs. MURRAY (for herself, Ms. MIKULSKI, Mr. SANDERS, Mr. CASEY, Mr. FRANKEN, Mr. BENNET, Mr. WHITEHOUSE, Ms. BALDWIN, Mr. MURPHY, and Ms. WARREN)

Viz:

1 At the appropriate place, insert the following:

2 SEC. _____. MEDICAL DEVICE POSTMARKET SURVEIL-
3 LANCE SYSTEM.4 Section 519 of the Federal Food, Drug, and Cosmetic
5 Act (21 U.S.C. 360i) is amended by striking subsection
6 (h) and inserting the following:7 “(h) MEDICAL DEVICE POSTMARKET SURVEILLANCE
8 SYSTEM.—

9 “(1) DEFINITIONS.—In this subsection:

1 “(A) ELECTRONIC HEALTH DATA.—The
2 term ‘electronic health data’ means electronic
3 medical records, medical claims, medical admin-
4 istrative data, and clinical registries.

5 “(B) APPLICABLE SOURCES.—The term
6 ‘applicable sources’ includes—

7 “(i) Federal electronic health data
8 from the Centers for Medicare & Medicaid
9 Services, the Veterans Administration, and
10 other Federal health programs;

11 “(ii) the Food and Drug Administra-
12 tion’s Global Unique Device Identification
13 Database (GUDID);

14 “(iii) private-sector electronic health
15 data; and

16 “(iv) any other sources determined
17 appropriate and selected by the Secretary
18 to help create a robust system to identify
19 adverse events and potential medical device
20 safety signals.

21 “(2) IN GENERAL.—The Secretary shall estab-
22 lish and implement a medical device postmarket sur-
23 veillance system (hereafter referred to in this sub-
24 section as ‘the device surveillance system’) that shall
25 utilize electronic health data from applicable sources

1 to provide timely and reliable information on medical
2 device safety and effectiveness.

3 “(3) DEVELOPMENT AND IMPLEMENTATION.—

4 “(A) DEVICE SURVEILLANCE SYSTEM
5 PLAN.—Not later than 6 months after the date
6 of enactment of this subsection, the Secretary,
7 in collaboration with public, academic, and pri-
8 vate entities, including device manufacturers,
9 and other stakeholders determined appropriate
10 by the Secretary, shall initiate the development
11 of a plan to implement the device surveillance
12 system within 5 years of the date of enactment
13 of this subsection.

14 “(B) PLAN ELEMENTS.—The plan de-
15 scribed in subparagraph (A) shall include—

16 “(i) recommendations to the Secretary
17 on—

18 “(I) the operational and govern-
19 ance structure for a multi-stakeholder
20 entity that shall facilitate the Sec-
21 retary’s administration of the device
22 surveillance system;

23 “(II) technical approaches to uti-
24 lizing electronic health data from all
25 applicable sources to accomplish the

1 goal of the device surveillance system,
2 as described in paragraph (2);

3 “(III) mechanisms to ensure ap-
4 propriate patient and data privacy
5 protections in the device surveillance
6 system;

7 “(IV) additional mechanisms that
8 may support a robust device surveil-
9 lance system, including whether stra-
10 tegic linkages with systems in place
11 before the development of the plan
12 may be appropriate and create effi-
13 ciencies; and

14 “(V) methods, standards, and ac-
15 cess for the analysis and communica-
16 tion of post-marketing data derived
17 from the device surveillance system,
18 and an evaluation of whether
19 postmarket surveillance procedures
20 that were in place before the develop-
21 ment of the plan should be updated to
22 create efficiencies; and

23 “(ii) estimated costs for the device
24 surveillance system.

25 “(C) REPORT.—

1 “(i) DRAFT REPORT.—Not later than
2 24 months after the date of enactment of
3 this subsection, the Secretary shall publish
4 a draft report in the Federal Register de-
5 scribing the implementation plan of the de-
6 vice surveillance system described in sub-
7 paragraph (B) and provide an opportunity
8 for the public to comment on such draft
9 report.

10 “(ii) FINAL REPORT.—Not later than
11 48 months after the date of enactment of
12 this subsection, the Secretary shall publish
13 a final report describing the implementa-
14 tion plan of the device surveillance system
15 in the Federal Register.

16 “(4) ESTABLISHMENT.—

17 “(A) IN GENERAL.—Not later than 6
18 months after the publication of, and in accord-
19 ance with, the final report described in para-
20 graph (3)(C)(ii), the Secretary, in collaboration
21 with public, academic, and private entities, in-
22 cluding device manufacturers, and other stake-
23 holders determined appropriate by the Sec-
24 retary, and through a public-private partnership
25 or other means, shall—

1 “(i) establish the governing board of
2 the device surveillance system; and

3 “(ii) establish the multi-stakeholder
4 entity described in paragraph (3)(B)(i)(I),
5 as described in the Secretary’s final report
6 under paragraph (3)(C)(ii), in consultation
7 with such governing board.

8 “(B) PROCEDURES.—

9 “(i) IN GENERAL.—Not later than 12
10 months after the publication of the final
11 report described in paragraph (3)(C)(ii),
12 the Secretary, taking into consideration the
13 recommendations of the governing board of
14 the device surveillance system, shall estab-
15 lish and maintain procedures to carry out
16 each of the following:

17 “(I) Utilize the device surveil-
18 lance system to conduct active adverse
19 event surveillance using electronic
20 health data from applicable sources.

21 “(II) Query the device surveil-
22 lance system for information about
23 safety and other outcomes selected at
24 the discretion of the Secretary.

1 “(III) Query the device surveil-
2 lance system for information about
3 patient outcomes linked to devices
4 through Unique Device Identifiers for
5 purposes of assessing medical device
6 safety and other outcomes selected at
7 the discretion of the Secretary.

8 “(IV) Enable the device surveil-
9 lance system to export data in a form
10 appropriate for further aggregation,
11 statistical analysis, and reporting.

12 “(ii) QUERIES WITHIN THE FIRST
13 YEAR OF SYSTEM OPERATION.—Within the
14 first year of operation of the device surveil-
15 lance system, the Secretary shall—

16 “(I) conduct a query described in
17 clause (i)(II) for not less than 6 high-
18 risk implantable devices that, in the
19 aggregate, account for 100,000 proce-
20 dures per year; and

21 “(II) conduct a query described
22 in clause (i)(III) for not less than 1
23 high-risk implantable device.

24 “(iii) PRIVACY AND SECURITY.—Ac-
25 tivities under this subparagraph shall be

1 carried out in compliance with the health
2 privacy and security regulations promul-
3 gated under section 264(c) of the Health
4 Insurance Portability and Accountability
5 Act of 1996 (42 U.S.C. 1320d-2 note).

6 “(C) AUTHORITY FOR AGREEMENTS.—The
7 Secretary may enter into contracts, cooperative
8 agreements, grants, and other appropriate
9 mechanisms, with public and private entities to
10 fulfill the requirements of this paragraph.

11 “(5) FUNDING.—Beginning for fiscal year
12 2017, of the amounts distributed by the Secretary of
13 the Treasury to the Food and Drug Administration
14 from the Biomedical Innovation Fund in accordance
15 with the National Biomedical Research Act, an
16 amount of \$25,000,000 shall be used to carry out
17 this subsection, including the implementation and
18 maintenance of the device surveillance system. Be-
19 ginning for fiscal year 2019, such amount shall in-
20 crease to \$35,000,000.”.