Patty Murray

BOM16246 S.L.C.

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) _____

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_____

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:

At the appropriate place, insert the following:

SEC. _____. MEDICAL DEVICE POSTMARKET SURVEILLANCE SYSTEM.

Section 519 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360i) is amended by striking subsection (h) and inserting the following:

"(h) MEDICAL DEVICE POSTMARKET SURVEILLANCE SYSTEM.—

"(1) DEFINITIONS.—In this subsection:

"(A) ELECTRONIC HEALTH DATA.—The term 'electronic health data' means electronic medical records, medical claims, medical administrative data, and clinical registries.

"(B) APPLICABLE SOURCES.—The term 'applicable sources' includes—

"(i) Federal electronic health data from the Centers for Medicare & Medicaid Services, the Veterans Administration, and other Federal health programs;

"(ii) the Food and Drug Administration's Global Unique Device Identification Database (GUDID);

"(iii) private-sector electronic health data; and

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

"(2) IN GENERAL.—The Secretary shall establish and implement a medical device postmarket surveillance system (hereafter referred to in this subsection as 'the device surveillance system') that shall utilize electronic health data from applicable sources

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

"(3) DEVELOPMENT AND IMPLEMENTATION.—

"(A) DEVICE SURVEILLANCE SYSTEM PLAN.—Not later than 6 months after the date of enactment of this subsection, the Secretary, in collaboration with public, academic, and private entities, including device manufacturers, and other stakeholders determined appropriate by the Secretary, shall initiate the development of a plan to implement the device surveillance system within 5 years of the date of enactment of this subsection.

"(B) PLAN ELEMENTS.—The plan described in subparagraph (A) shall include—

"(i) recommendations to the Secretary on—

"(I) the operational and governance structure for a multi-stakeholder entity that shall facilitate the Secretary's administration of the device surveillance system;

"(II) technical approaches to utilizing electronic health data from all applicable sources to accomplish the

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

"(III) mechanisms to ensure appropriate patient and data privacy protections in the device surveillance system;

"(IV) additional mechanisms that may support a robust device surveillance system, including whether strategic linkages with systems in place before the development of the plan may be appropriate and create efficiencies; and

"(V) methods, standards, and access for the analysis and communication of post-marketing data derived from the device surveillance system, and an evaluation of whether postmarket surveillance procedures that were in place before the development of the plan should be updated to create efficiencies; and

"(ii) estimated costs for the device surveillance system.

"(C) REPORT.—

"(i) DRAFT REPORT.—Not later than 24 months after the date of enactment of this subsection, the Secretary shall publish a draft report in the Federal Register describing the implementation plan of the device surveillance system described in subparagraph (B) and provide an opportunity for the public to comment on such draft report.

"(ii) FINAL REPORT.—Not later than 48 months after the date of enactment of this subsection, the Secretary shall publish a final report describing the implementation plan of the device surveillance system in the Federal Register.

"(4) ESTABLISHMENT.—

"(A) IN GENERAL.—Not later than 6 months after the publication of, and in accordance with, the final report described in paragraph (3)(C)(ii), the Secretary, in collaboration with public, academic, and private entities, including device manufacturers, and other stakeholders determined appropriate by the Secretary, and through a public-private partnership or other means, shall—

"(i) establish the governing board of the device surveillance system; and

"(ii) establish the multi-stakeholder entity described in paragraph (3)(B)(i)(I), as described in the Secretary's final report under paragraph (3)(C)(ii), in consultation with such governing board.

"(B) PROCEDURES.—

"(i) IN GENERAL.—Not later than 12 months after the publication of the final report described in paragraph (3)(C)(ii), the Secretary, taking into consideration the recommendations of the governing board of the device surveillance system, shall establish and maintain procedures to carry out each of the following:

"(I) Utilize the device surveillance system to conduct active adverse event surveillance using electronic health data from applicable sources.

"(II) Query the device surveillance system for information about safety and other outcomes selected at the discretion of the Secretary.

"(III) Query the device surveillance system for information about patient outcomes linked to devices through Unique Device Identifiers for purposes of assessing medical device safety and other outcomes selected at the discretion of the Secretary.

"(IV) Enable the device surveillance system to export data in a form appropriate for further aggregation, statistical analysis, and reporting.

"(ii) QUERIES WITHIN THE FIRST YEAR OF SYSTEM OPERATION.—Within the first year of operation of the device surveillance system, the Secretary shall—

"(I) conduct a query described in clause (i)(II) for not less than 6 high-risk implantable devices that, in the aggregate, account for 100,000 procedures per year; and

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

"(iii) PRIVACY AND SECURITY.—Activities under this subparagraph shall be

carried out in compliance with the health privacy and security regulations promulgated under section 264(c) of the Health Insurance Portability and Accountability Act of 1996 (42 U.S.C. 1320d–2 note).

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

"(5) FUNDING.—Beginning for fiscal year 2017, of the amounts distributed by the Secretary of the Treasury to the Food and Drug Administration from the Biomedical Innovation Fund in accordance with the National Biomedical Research Act, an amount of $25,000,000 shall be used to carry out this subsection, including the implementation and maintenance of the device surveillance system. Beginning for fiscal year 2019, such amount shall increase to $35,000,000.".