AMENDMENT TO THE COMMITTEE PRINT OF H.R. 2430

OFFERED BY MS. Schakowsky #1

At the end of title VI of the bill, add the following:

SEC. 614. DEVICE PILOT PROJECTS TO GENERATE RELIABLE AND TIMELY SAFETY AND ACTIVE SURVEILLANCE DATA.

(a) IN GENERAL.—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 TO GENERATE RELIABLE AND TIMELY SAFETY AND ACTIVE SURVEILLANCE DATA.—

"(1) IN GENERAL.—The Secretary shall, not later than one year after the date of the enactment of the FDA Reauthorization Act of 2017, initiate one or more pilot projects relating to providing timely and reliable information on the safety and effectiveness of devices approved under section 515, cleared under section 510(k), or classified under section 513(f)(2), in which a manufacturer or manufacturers of a device or device type voluntarily participate. Any such project shall meet each of the following criteria:

"(A) The project is 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) The project informs, to the extent applicable, the development of methods, systems, data criteria, and programs that could be used to support safety and active surveillance activities for any device.

"(C) The project shall be designed and conducted in coordination with a comprehensive system for evaluating device technology that operates under a governing board with appropriate representation of stakeholders, including patient groups and device manufacturers.

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

"(E) The project prioritizes 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—

"(I) has received public recommendations in accordance with paragraph (2)(B); and

"(II) has determined to meet one of the criteria under clause (i), (ii), or (iii) and is appropriate for such a pilot project.

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

"(A) under which a manufacturer of a device may voluntarily participate in a pilot project described in paragraph (1); and

"(B) for facilitating public recommendations for devices to be prioritized under such a pilot project, including requirements for the

data necessary to support such a recommendation.

"(3) CONTINUATION OF ONGOING PROJECTS.—The Secretary may continue or expand projects, with respect to providing timely and reliable information on the safety and effectiveness of devices approved under section 515, cleared under section 510(k), or classified under section 513(f)(2), that are being carried out as of the date of the enactment of the FDA Reauthorization Act of 2017. The Secretary shall, beginning on such date of enactment, take such steps as may be necessary —

"(A) to ensure such projects meet the requirements of subparagraphs (A) through (E) of paragraph (1); and

"(B) to increase the voluntary participation in such projects of manufacturers of devices and facilitate public recommendations for any devices prioritized under such a project.

"(4) IMPLEMENTATION.—

"(A) CONTRACTING AUTHORITY.—The Secretary may carry out a pilot project meeting the criteria specified in subparagraphs (A) through (E) of paragraph (1) or a project continued or expanded under paragraph (3) by en-

tering 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 conditions:

"(i) If such an entity is a component of another organization, the entity and the organization have established an agreement under which appropriate security measures are implemented to maintain the confidentiality and privacy of the data described in paragraph (1)(D) and such agreement ensures that the entity will not make an unauthorized disclosure of such data to the other components of the organization in breach of requirements with respect to confidentiality and privacy of such data established under such security measures.

"(ii) In the case of the termination or nonrenewal of such a contract, cooperative agreement, grant, or other appropriate agreement, the entity or entities involved shall comply with each of the following:

"(I) The entity or entities shall continue to comply with the requirements with respect to confidentiality and privacy referred to in clause (i) under this subparagraph with respect to all data disclosed to the entity under such an agreement.

"(II) The entity or entities shall return any data disclosed to such entity pursuant to this subsection and to which it would not otherwise have access or, if returning such data is not practicable, destroy the data.

"(iii) The entity or entities shall have one or more qualifications with respect to—

"(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 to support electronic data and operational standards to provide security for such data, as appropriate;

"(III) experience with, and expertise on, the development of research on, and surveillance of, device safety and effectiveness using electronic health data; or

"(IV) such other expertise which the Secretary determines necessary to carry out such a project.

"(B) REVIEW OF CONTRACT IN THE EVENT OF A MERGER OR ACQUISITION.—The Secretary shall review any contract, cooperative agreement, grant, or other appropriate agreement entered into under this paragraph with an entity meeting the conditions specified in subparagraph (A) in the event of a merger or acquisition of the entity in order to ensure that the requirements specified in this subsection will continue to be met.

"(5) COMPLIANCE WITH REQUIREMENTS FOR RECORDS OR REPORTS ON DEVICES.—The participa-

tion of a manufacturer in pilot projects under this subsection shall not affect the eligibility of such manufacturer to participate in any quarterly reporting program with respect to devices carried out under section 519 or 522. The Secretary may determine that, for a specified time period to be determined by the Secretary, a manufacturer's participation in a pilot project under this subsection or a project continued or expanded under paragraph (3) may meet the applicable requirements of section 519 or 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 such project public, to the extent possible.

"(6) PRIVACY REQUIREMENTS.— With respect to the disclosure of any health information collected through a project conducted under this subsection—

"(A) individually identifiable health information so collected shall not be disclosed when presenting any information from such project; and

"(B) any such disclosure shall be made in compliance with regulations issued pursuant to 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.

"(7) LIMITATIONS.—

"(A) IN GENERAL.—No pilot project under this subsection undertaken in coordination with the comprehensive system described in paragraph (1)(C), shall allow for an entity participating in such program, other than the Secretary or the Secretary's designee, to make determinations of safety or effectiveness, or substantial equivalence, for purposes of the Act.

"(B) NO USE OF FEES.—Pilot projects initiated under this subsection may not primarily utilize funds collected pursuant to the Medical Device User Fee Amendments of 2017.

"(8) OTHER PROJECTS REQUIRED TO COMPLY.—Paragraphs (1)(B), (4)(A)(i), (4)(A)(ii), (5), and (6) shall apply with respect to any pilot program undertaken in coordination with the comprehensive system described in paragraph (1)(C) that relates to the use of real world evidence for de-

vices in the same manner and to the same extent as such paragraphs apply with respect to pilot projects conducted under this subsection.

"(9) REPORT TO CONGRESS.—Not later than 18 months after the date of enactment of this Act, and annually thereafter, the Secretary shall submit to the Committee on Energy and Commerce of the House of Representatives and the Committee on Health, Education, Labor and Pensions of the Senate a report containing a description of the pilot projects being conducted under this subsection and projects continued or expanded pursuant to paragraph (3), including for each such project—

"(A) how the project is being implemented in accordance with paragraph (4), including how such project is being implemented through a contract, cooperative agreement, grant, or other appropriate agreement, if applicable;

"(B) the number of manufacturers that have agreed to participate in such project;

"(C) the data sources used to conduct such project;

"(D) the devices or device categories involved in such project;

"(E) the number of patients involved in such project; and

"(F) the findings of the project in relation to device safety, including adverse events, malfunctions, and other safety information.

"(10) SUNSET.—The Secretary may not carry out a pilot project initiated by the Secretary under this subsection after 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, may 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 added by subsection (a)—

(1) for purposes of informing premarket and postmarket decisionmaking for multiple device types; and

(2) to determine whether the methods, systems, and programs carried out through such pilot projects efficiently generate reliable and timely evi-

dence about the effectiveness of the surveillance of devices with respect to safety.

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