

**AMENDMENT TO THE COMMITTEE PRINT OF H.R.**

**2430**

**OFFERED BY M.S. Schakowsky**

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

1 **SEC. 614. DEVICE PILOT PROJECTS TO GENERATE RELI-**  
2 **ABLE AND TIMELY SAFETY AND ACTIVE SUR-**  
3 **VEILLANCE DATA.**

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

7 “(i) PILOT PROJECTS TO GENERATE RELIABLE AND  
8 TIMELY SAFETY AND ACTIVE SURVEILLANCE DATA.—

9 “(1) IN GENERAL.—The Secretary shall, not  
10 later than one year after the date of the enactment  
11 of the FDA Reauthorization Act of 2017, initiate  
12 one or more pilot projects relating to providing time-  
13 ly and reliable information on the safety and effec-  
14 tiveness of devices approved under section 515,  
15 cleared under section 510(k), or classified under sec-  
16 tion 513(f)(2), in which a manufacturer or manufac-  
17 turers of a device or device type voluntarily partici-  
18 pate. Any such project shall meet each of the fol-  
19 lowing criteria:

1           “(A) The project is designed to efficiently  
2           generate reliable and timely safety and active  
3           surveillance data for use by the Secretary or  
4           manufacturers of the devices that are involved  
5           in the pilot project.

6           “(B) The project informs, to the extent ap-  
7           plicable, the development of methods, systems,  
8           data criteria, and programs that could be used  
9           to support safety and active surveillance activi-  
10          ties for any device.

11          “(C) The project shall be designed and  
12          conducted in coordination with a comprehensive  
13          system for evaluating device technology that op-  
14          erates under a governing board with appro-  
15          priate representation of stakeholders, including  
16          patient groups and device manufacturers.

17          “(D) The project uses electronic health  
18          data including, as appropriate, claims data, pa-  
19          tient survey data, and any other data, as the  
20          Secretary determines appropriate.

21          “(E) The project prioritizes devices and  
22          device types that meet one or more of the fol-  
23          lowing criteria:

24                  “(i) Devices and device types for  
25                  which the collection and analysis of real

1 world evidence regarding a device's safety  
2 and effectiveness is likely to advance public  
3 health.

4 “(ii) Devices and device types that are  
5 widely used.

6 “(iii) Devices and device types, the  
7 failure of which has significant health con-  
8 sequences.

9 “(iv) Devices and device types for  
10 which the Secretary—

11 “(I) has received public rec-  
12 ommendations in accordance with  
13 paragraph (2)(B); and

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

18 “(2) PARTICIPATION.—The Secretary shall es-  
19 tablish the conditions and processes—

20 “(A) under which a manufacturer of a de-  
21 vice may voluntarily participate in a pilot  
22 project described in paragraph (1); and

23 “(B) for facilitating public recommenda-  
24 tions for devices to be prioritized under such a  
25 pilot project, including requirements for the

1 data necessary to support such a recommenda-  
2 tion.

3 “(3) CONTINUATION OF ONGOING PROJECTS.—

4 The Secretary may continue or expand projects, with  
5 respect to providing timely and reliable information  
6 on the safety and effectiveness of devices approved  
7 under section 515, cleared under section 510(k), or  
8 classified under section 513(f)(2), that are being  
9 carried out as of the date of the enactment of the  
10 FDA Reauthorization Act of 2017. The Secretary  
11 shall, beginning on such date of enactment, take  
12 such steps as may be necessary —

13 “(A) to ensure such projects meet the re-  
14 quirements of subparagraphs (A) through (E)  
15 of paragraph (1); and

16 “(B) to increase the voluntary participa-  
17 tion in such projects of manufacturers of de-  
18 vices and facilitate public recommendations for  
19 any devices prioritized under such a project.

20 “(4) IMPLEMENTATION.—

21 “(A) CONTRACTING AUTHORITY.—The  
22 Secretary may carry out a pilot project meeting  
23 the criteria specified in subparagraphs (A)  
24 through (E) of paragraph (1) or a project con-  
25 tinued or expanded under paragraph (3) by en-

1           tering into contracts, cooperative agreements,  
2           grants, or other appropriate agreements with  
3           public or private entities that have a significant  
4           presence in the United States and meet the fol-  
5           lowing conditions:

6                   “(i) If such an entity is a component  
7                   of another organization, the entity and the  
8                   organization have established an agree-  
9                   ment under which appropriate security  
10                  measures are implemented to maintain the  
11                  confidentiality and privacy of the data de-  
12                  scribed in paragraph (1)(D) and such  
13                  agreement ensures that the entity will not  
14                  make an unauthorized disclosure of such  
15                  data to the other components of the orga-  
16                  nization in breach of requirements with re-  
17                  spect to confidentiality and privacy of such  
18                  data established under such security meas-  
19                  ures.

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

1                   “(I) The entity or entities shall  
2 continue to comply with the require-  
3 ments with respect to confidentiality  
4 and privacy referred to in clause (i)  
5 under this subparagraph with respect  
6 to all data disclosed to the entity  
7 under such an agreement.

8                   “(II) The entity or entities shall  
9 return any data disclosed to such enti-  
10 ty pursuant to this subsection and to  
11 which it would not otherwise have ac-  
12 cess or, if returning such data is not  
13 practicable, destroy the data.

14                   “(iii) The entity or entities shall have  
15 one or more qualifications with respect  
16 to—

17                   “(I) research, statistical, epi-  
18 demiologic, or clinical capability and  
19 expertise to conduct and complete the  
20 activities under this subsection, in-  
21 cluding the capability and expertise to  
22 provide the Secretary access to de-  
23 identified data consistent with the re-  
24 quirements of this subsection;

1                   “(II) an information technology  
2                   infrastructure to support electronic  
3                   data and operational standards to  
4                   provide security for such data, as ap-  
5                   propriate;

6                   “(III) experience with, and exper-  
7                   tise on, the development of research  
8                   on, and surveillance of, device safety  
9                   and effectiveness using electronic  
10                  health data; or

11                  “(IV) such other expertise which  
12                  the Secretary determines necessary to  
13                  carry out such a project.

14                  “(B) REVIEW OF CONTRACT IN THE  
15                  EVENT OF A MERGER OR ACQUISITION.—The  
16                  Secretary shall review any contract, cooperative  
17                  agreement, grant, or other appropriate agree-  
18                  ment entered into under this paragraph with an  
19                  entity meeting the conditions specified in sub-  
20                  paragraph (A) in the event of a merger or ac-  
21                  quisition of the entity in order to ensure that  
22                  the requirements specified in this subsection  
23                  will continue to be met.

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

1       tion of a manufacturer in pilot projects under this  
2       subsection shall not affect the eligibility of such  
3       manufacturer to participate in any quarterly report-  
4       ing program with respect to devices carried out  
5       under section 519 or 522. The Secretary may deter-  
6       mine that, for a specified time period to be deter-  
7       mined by the Secretary, a manufacturer's participa-  
8       tion in a pilot project under this subsection or a  
9       project continued or expanded under paragraph (3)  
10      may meet the applicable requirements of section 519  
11      or 522, if—

12               “(A) the project has demonstrated success  
13               in capturing relevant adverse event information;  
14               and

15               “(B) the Secretary has established proce-  
16               dures for making adverse event and safety in-  
17               formation collected from such project public, to  
18               the extent possible.

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

22               “(A) individually identifiable health infor-  
23               mation so collected shall not be disclosed when  
24               presenting any information from such project;  
25               and



1           “(B) any such disclosure shall be made in  
2           compliance with regulations issued pursuant to  
3           section 264(e) of the Health Insurance Port-  
4           ability and Accountability Act of 1996 (42  
5           U.S.C. 1320d–2 note) and sections 552 and  
6           552a of title 5, United States Code.

7           “(7) LIMITATIONS.—

8           “(A) IN GENERAL.—No pilot project under  
9           this subsection undertaken in coordination with  
10          the comprehensive system described in para-  
11          graph (1)(C), shall allow for an entity partici-  
12          pating in such program, other than the Sec-  
13          retary or the Secretary’s designee, to make de-  
14          terminations of safety or effectiveness, or sub-  
15          stantial equivalence, for purposes of the Act.

16          “(B) NO USE OF FEES.—Pilot projects ini-  
17          tiated under this subsection may not primarily  
18          utilize funds collected pursuant to the Medical  
19          Device User Fee Amendments of 2017.

20          “(8) OTHER PROJECTS REQUIRED TO COM-  
21          PLY.—Paragraphs (1)(B), (4)(A)(i), (4)(A)(ii), (5),  
22          and (6) shall apply with respect to any pilot pro-  
23          gram undertaken in coordination with the com-  
24          prehensive system described in paragraph (1)(C)  
25          that relates to the use of real world evidence for de-

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

4 “(9) REPORT TO CONGRESS.—Not later than  
5 18 months after the date of enactment of this Act,  
6 and annually thereafter, the Secretary shall submit  
7 to the Committee on Energy and Commerce of the  
8 House of Representatives and the Committee on  
9 Health, Education, Labor and Pensions of the Sen-  
10 ate a report containing a description of the pilot  
11 projects being conducted under this subsection and  
12 projects continued or expanded pursuant to para-  
13 graph (3), including for each such project—

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

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

21 “(C) the data sources used to conduct such  
22 project;

23 “(D) the devices or device categories in-  
24 volved in such project;

1           “(E) the number of patients involved in  
2           such project; and

3           “(F) the findings of the project in relation  
4           to device safety, including adverse events, mal-  
5           functions, and other safety information.

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

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

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

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

