

112TH CONGRESS
1ST SESSION

S. _____

To amend the Federal Food, Drug, and Cosmetic Act to with respect to device review determinations and conflicts of interest, and for other purposes.

IN THE SENATE OF THE UNITED STATES

Ms. KLOBUCHAR (for herself, Mr. BURR, and Mr. BENNET) introduced the following bill; which was read twice and referred to the Committee on

A BILL

To amend the Federal Food, Drug, and Cosmetic Act to with respect to device review determinations and conflicts of interest, and for other purposes.

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 Regu-
5 latory Improvement Act”.

6 **SEC. 2. CLARIFICATION OF LEAST BURDENSOME.**

7 (a) PREMARKET APPROVAL.—Section 513(a)(3)(D)
8 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C.
9 360c(a)(3)(D)) is amended—

1 (1) by redesignating clause (iii) as clause (iv);

2 and

3 (2) by inserting after clause (ii) the following:

4 “(iii) In carrying out clause (ii), the Secretary—

5 “(I) shall not request information unrelated or
6 irrelevant to a demonstration of reasonable assur-
7 ance of device safety and effectiveness;

8 “(II) shall consider alternative approaches to
9 evaluating device safety and effectiveness in order to
10 reduce the time, effort, and cost of reaching proper
11 resolution of the issue;

12 “(III) shall use all reasonable mechanisms to
13 lessen review times and render regulatory decisions;

14 “(IV) shall determine whether pre-clinical data,
15 such as well-designed bench and animal testing, can
16 meet the statutory threshold for approval; and

17 “(V) if clinical data are needed, shall utilize,
18 whenever practicable, alternatives to randomized,
19 controlled clinical trials, such as the use of surrogate
20 endpoints.”.

21 (b) SUBSTANTIAL EQUIVALENCE DETERMINA-
22 TION.—Section 513(i)(1)(D) of the Federal Food, Drug,
23 and Cosmetic Act (21 U.S.C. 360c(i)(1)(D)) is amended—

24 (1) by striking “(D) Whenever” and inserting

25 “(D)(i) Whenever”; and

1 (2) by adding at the end the following:

2 “(ii) In carrying out clause (i), the Secretary—

3 “(I) shall focus on whether the device has the
4 same intended use as the predicate device and is as
5 safe and effective as a legally marketed device;

6 “(II) shall not request or accept information
7 unrelated or irrelevant to the substantial equivalence
8 evaluation;

9 “(III) shall review the labeling of the device to
10 assess the intended use of the device, and shall not
11 evaluate issues that do not present a major impact
12 on the intended use as set forth in the labeling;

13 “(IV) shall consider alternative approaches to
14 evaluating substantial equivalence in order to reduce
15 the time, effort, and cost of reaching proper resolu-
16 tion of the issue; and

17 “(V) shall use all reasonable mechanisms to
18 lessen review times and render regulatory deci-
19 sions.”.

20 **SEC. 3. CONFLICTS OF INTEREST.**

21 Section 712 of the Federal Food, Drug, and Cosmetic
22 Act (21 U.S.C. 379d–1) is amended to read as follows:

23 **“SEC. 712. CONFLICTS OF INTEREST.**

24 “Except as otherwise provided in this Act, each advi-
25 sory committee under the Federal Advisory Committee

1 Act that provides advice or recommendations to the Sec-
2 retary regarding activities of the Food and Drug Adminis-
3 tration is subject to the provisions in such Act and the
4 members of each such committee are subject to the provi-
5 sions regarding Federal employees and special Govern-
6 ment employees, as applicable, in title I of the Ethics in
7 Government Act of 1978 and section 208 of title 18,
8 United States Code.”.

9 **SEC. 4. MANAGEMENT AND INNOVATION REVIEW.**

10 (a) IN GENERAL.—Not later than 60 days after the
11 date of enactment of this Act, the Secretary of Health and
12 Human Services (referred to in this section as the “Sec-
13 retary”) shall enter into a contract with an eligible entity
14 to carry out the activities described in subsection (c).

15 (b) ELIGIBLE ENTITY.—To be eligible to enter into
16 a contract with the Secretary under subsection (a), an en-
17 tity shall—

18 (1) be an entity with experience in evaluating
19 the management and operating structure of large or-
20 ganizations; and

21 (2) submit to the Secretary an application at
22 such time, in such manner, and containing such in-
23 formation as the Secretary may require.

24 (c) ACTIVITIES.—The entity with which the Secretary
25 enters into the contract under subsection (a) shall, pursu-

1 ant to such contract, conduct an extensive review of the
2 management and regulatory processes at the Center for
3 Devices and Radiological Health of the Food and Drug
4 Administration to ensure any actions carried out by such
5 Center take into consideration the potential impacts on in-
6 novation with respect to medical devices and other prod-
7 ucts regulated by such Center.

8 (d) REPORT.—Not later than 1 year after the date
9 that the Secretary enters into the contract with the eligible
10 entity under subsection (a), such entity shall submit to
11 Congress and the Secretary a report that describes the
12 findings and recommendations of such entity based on the
13 review conducted under subsection (c).

14 (e) FUNDING.—To carry out this section, the Sec-
15 retary shall use funds otherwise available for the operation
16 of the Office of the Secretary.