112TH CONGRESS
1ST SESSION

S. 1700

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

IN THE SENATE OF THE UNITED STATES

OCTOBER 13, 2011

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

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A BILL

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

Be it enacted by the Senate and House of Representatives of the United States of America in Congress assembled,

SECTION 1. SHORT TITLE.

This Act may be cited as the ''Medical Device Regulatory Improvement Act''.

SEC. 2. CLARIFICATION OF LEAST BURDENSOME.

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

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

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

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

''(I) shall not request information unrelated or irrelevant to a demonstration of reasonable assurance of device safety and effectiveness;

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

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

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

''(V) if clinical data are needed, shall utilize, whenever practicable, alternatives to randomized, controlled clinical trials, such as the use of surrogate endpoints.''.

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

(1) by striking ''(D) Whenever'' and inserting ''(D)(i) Whenever''; and

(2) by adding at the end the following:

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

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

''(II) shall not request or accept information unrelated or irrelevant to the substantial equivalence evaluation;

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

''(IV) shall consider alternative approaches to evaluating substantial equivalence in order to reduce the time, effort, and cost of reaching proper resolution of the issue; and

''(V) shall use all reasonable mechanisms to lessen review times and render regulatory decisions.''.

SEC. 3. CONFLICTS OF INTEREST.

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

''SEC. 712. CONFLICTS OF INTEREST.

''Except as otherwise provided in this Act, each advisory committee under the Federal Advisory Committee

Act that provides advice or recommendations to the Secretary regarding activities of the Food and Drug Administration is subject to the provisions in such Act and the members of each such committee are subject to the provisions regarding Federal employees and special Government employees, as applicable, in title I of the Ethics in Government Act of 1978 and section 208 of title 18, United States Code.''.

SEC. 4. MANAGEMENT AND INNOVATION REVIEW.

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

(b) ELIGIBLE ENTITY.—To be eligible to enter into a contract with the Secretary under subsection (a), an entity shall—

(1) be an entity with experience in evaluating the management and operating structure of large organizations; and

(2) submit to the Secretary an application at such time, in such manner, and containing such information as the Secretary may require.

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

ant to such contract, conduct an extensive review of the management and regulatory processes at the Center for Devices and Radiological Health of the Food and Drug Administration to ensure any actions carried out by such Center take into consideration the potential impacts on innovation with respect to medical devices and other products regulated by such Center.

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

(e) FUNDING.—To carry out this section, the Secretary shall use funds otherwise available for the operation of the Office of the Secretary.

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