112TH CONGRESS
2D SESSION

S. 2193

To require the Food and Drug Administration to include devices in the postmarket risk identification and analysis system, to expedite the implementation of the unique device identification system for medical devices, and for other purposes.

IN THE SENATE OF THE UNITED STATES

MARCH 15, 2012

Mr. MERKLEY (for himself, Mr. GRASSLEY, Mr. BENNET, and Mr. KOHL) 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 require the Food and Drug Administration to include devices in the postmarket risk identification and analysis system, to expedite the implementation of the unique device identification system for medical devices, 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 ''Ensuring Safe Medical Devices for Patients''.

SEC. 2. ACTIVE POSTMARKET RISK IDENTIFICATION AND ANALYSIS.

(a) RECORDS AND REPORTS ON DEVICES.—Section 519 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360i) is amended by inserting after subsection (c) the following:

''(d) INCLUSION OF DEVICES IN THE POSTMARKET RISK IDENTIFICATION AND ANALYSIS SYSTEM.—Not later than 90 days after the date of enactment of the Ensuring Safe Medical Devices for Patients, the Secretary shall amend the procedures established and maintained under section 505(k)(3)(C) in order to expand the postmarket risk identification and analysis system established under such section to include and apply to devices in a comparable manner as such system includes and applies to drugs. The Secretary shall ensure that such amendments to the procedures shall give priority for inclusion in the postmarket risk identification and analysis system to class III and class II devices that are implantable, life-supporting or life-sustaining, or pose significant risk to users.''.

(b) UNIQUE DEVICE IDENTIFICATION SYSTEM.—Section 519(f) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360i(f)) is amended—

(1) by striking ''The Secretary shall promulgate'' and inserting ''Not later than December 31, 2012, the Secretary shall issue final''; and

(2) by adding at the end the following:

''The Secretary shall implement the unique device identification system under this subsection not later than 1 year after the date on which the final regulations are issued.''.

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