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112TH CONGRESS
2D SESSION

H. R. 5341

To improve postmarket risk identification and analysis with respect to devices, and for other purposes.

IN THE HOUSE OF REPRESENTATIVES

MAY 7, 2012

Mrs. CAPPS introduced the following bill; which was referred to the Committee on Energy and Commerce

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A BILL

To improve postmarket risk identification and analysis with respect to 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 ''Sentinel Assurance for Effective Devices Act of 2012''.

SEC. 2. INCLUSION OF DEVICES IN POSTMARKET RISK IDENTIFICATION AND ANALYSIS SYSTEM; UNIQUE DEVICE IDENTIFICATION SYSTEM.

(a) INCLUSION OF DEVICES IN POSTMARKET RISK IDENTIFICATION AND ANALYSIS SYSTEM.—Section 522 of

the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360l) is amended by adding at the end the following:

''(d) INCLUSION OF DEVICES IN THE POSTMARKET RISK IDENTIFICATION AND ANALYSIS SYSTEM.—

''(1) IN GENERAL.—Except as provided in paragraph (2), 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.

''(2) EXCEPTIONS.—In carrying out this subsection:

''(A) The Secretary shall not apply the procedures of section 505(k)(3)(C)(i)(II) to devices.

''(B) Section 505(k)(3)(C)(i)(III)(bb) is deemed to refer to private sector health-related electronic data (such as medical device utilization data, health insurance claims data, and procedure and device registries).

''(C) Section 505(k)(3)(C)(iv)(II) is deemed to refer to the Data Extraction and Longitudinal Time Analysis system instead of the Vaccine Safety Datalink.

''(3) PRIORITY.—In carrying out this subsection, the Secretary shall give priority to postmarket risk identification and analysis with respect to class II and class III devices.

''(4) STAKEHOLDER INPUT.—To help ensure effective implementation of the system described in paragraph (1) with respect to devices, the Secretary shall engage outside stakeholders in development of the system, and gather information from outside stakeholders regarding the content of an effective sentinel program, through a public hearing, advisory committee meeting, maintenance of a public docket, or other similar public measures.

''(5) DATA.—In carrying out this subsection, the Secretary shall use data with respect to devices cleared under section 510(k) or approved under section 515, which may include claims data, patient survey data, standardized analytic files that allow for the pooling and analysis of data from disparate data environments, and any other data deemed appropriate by the Secretary.

''(6) VOLUNTARY SURVEYS.—Chapter 35 of title 44, United States Code, shall not apply to the collection of voluntary information from health care providers, such as voluntary surveys or question-

naires, initiated by the Secretary for purposes of postmarket risk identification for devices.''.

(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 for class III devices not later than 1 year after the date on which the final regulations are issued, for implantable, life-sustaining, and life-supporting devices not later than 3 years after such date, and for all other devices not later than 5 years after such date.''.

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