

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

A BILL

To improve postmarket risk identification and analysis with
respect to devices, 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 “Sentinel Assurance for
5 Effective Devices Act of 2012”.

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

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

1 the Federal Food, Drug, and Cosmetic Act (21 U.S.C.
2 360l) is amended by adding at the end the following:

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

5 “(1) IN GENERAL.—Except as provided in para-
6 graph (2), the Secretary shall amend the procedures
7 established and maintained under section
8 505(k)(3)(C) in order to expand the postmarket risk
9 identification and analysis system established under
10 such section to include and apply to devices.

11 “(2) EXCEPTIONS.—In carrying out this sub-
12 section:

13 “(A) The Secretary shall not apply the
14 procedures of section 505(k)(3)(C)(i)(II) to de-
15 vices.

16 “(B) Section 505(k)(3)(C)(i)(III)(bb) is
17 deemed to refer to private sector health-related
18 electronic data (such as medical device utiliza-
19 tion data, health insurance claims data, and
20 procedure and device registries).

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

1 “(3) PRIORITY.—In carrying out this sub-
2 section, the Secretary shall give priority to
3 postmarket risk identification and analysis with re-
4 spect to class II and class III devices.

5 “(4) STAKEHOLDER INPUT.—To help ensure ef-
6 fective implementation of the system described in
7 paragraph (1) with respect to devices, the Secretary
8 shall engage outside stakeholders in development of
9 the system, and gather information from outside
10 stakeholders regarding the content of an effective
11 sentinel program, through a public hearing, advisory
12 committee meeting, maintenance of a public docket,
13 or other similar public measures.

14 “(5) DATA.—In carrying out this subsection,
15 the Secretary shall use data with respect to devices
16 cleared under section 510(k) or approved under sec-
17 tion 515, which may include claims data, patient
18 survey data, standardized analytic files that allow
19 for the pooling and analysis of data from disparate
20 data environments, and any other data deemed ap-
21 propriate by the Secretary.

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

1 naires, initiated by the Secretary for purposes of
2 postmarket risk identification for devices.”.

3 (b) UNIQUE DEVICE IDENTIFICATION SYSTEM.—

4 Section 519(f) of the Federal Food, Drug, and Cosmetic
5 Act (21 U.S.C. 360i(f)) is amended—

6 (1) by striking “The Secretary shall promul-
7 gate” and inserting “Not later than December 31,
8 2012, the Secretary shall issue final”; and

9 (2) by adding at the end the following: “The
10 Secretary shall implement the unique device identi-
11 fication system under this subsection for class III
12 devices not later than 1 year after the date on which
13 the final regulations are issued, for implantable, life-
14 sustaining, and life-supporting devices not later than
15 3 years after such date, and for all other devices not
16 later than 5 years after such date.”.

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