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(Original Signature of Member)

113TH CONGRESS
1ST SESSION

H. R. _____

To amend the Federal Food, Drug, and Cosmetic Act to provide for regulating medical software, and for other purposes.

IN THE HOUSE OF REPRESENTATIVES

Mrs. BLACKBURN introduced the following bill; which was referred to the Committee on _____

A BILL

To amend the Federal Food, Drug, and Cosmetic Act to provide for regulating medical software, 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 “Sensible Oversight for
5 Technology which Advances Regulatory Efficiency Act of
6 2013” or the “SOFTWARE Act of 2013”.

1 **SEC. 2. MEDICAL SOFTWARE.**

2 (a) DEFINITION OF MEDICAL SOFTWARE.—Section
3 201 of the Federal Food, Drug, and Cosmetic Act (21
4 U.S.C. 321) is amended by adding at the end the fol-
5 lowing:

6 “(ss) The term ‘medical software’ means software
7 that is intended for human or animal use and—

8 “(1)(A) is intended to be marketed to directly
9 change the structure or any function of the body of
10 man or other animals; or

11 “(B) is intended to be marketed for use by con-
12 sumers and makes recommendations for clinical ac-
13 tion that—

14 “(i) includes the use of a drug, device, or
15 procedure to cure or treat a disease or other
16 condition without requiring the involvement of a
17 health care provider; and

18 “(ii) if followed, would change the struc-
19 ture or any function of the body of man or
20 other animals;

21 “(2) is not software whose primary purpose is
22 integral to the functioning of a drug or device; and

23 “(3) is not a component of a device.”.

24 (b) REGULATION.—Subchapter A of chapter V of the
25 Federal Food, Drug, and Cosmetic Act (21 U.S.C. 351
26 et seq.) is amended by adding at the end the following:

1 **“SEC. 524B. MEDICAL SOFTWARE.**

2 “(a) IN GENERAL.—The provisions of this Act shall
3 apply with respect to medical software to the same extent
4 and in the same manner as such provisions apply with re-
5 spect to devices.

6 “(b) DELEGATION.—The Secretary shall delegate
7 primary jurisdiction for regulating medical software to the
8 center at the Food and Drug Administration charged with
9 regulating devices.”.

10 **SEC. 3. CLINICAL SOFTWARE AND HEALTH SOFTWARE.**

11 (a) DEFINITIONS.—Section 201 of the Federal Food,
12 Drug, and Cosmetic Act (21 U.S.C. 321), as amended by
13 section 2(a), is further amended by adding at the end the
14 following:

15 “(tt)(1) The term ‘clinical software’ means clinical
16 decision support software or other software (including any
17 associated hardware and process dependencies) intended
18 for human or animal use that—

19 “(A) captures, analyzes, changes, or presents
20 patient or population clinical data or information
21 and may recommend courses of clinical action, but
22 does not directly change the structure or any func-
23 tion of the body of man or other animals; and

24 “(B) is intended to be marketed for use only by
25 a health care provider in a health care setting.

1 “(2) The term ‘health software’ means software (in-
2 cluding any associated hardware and process depend-
3 encies) that is not medical software or clinical software
4 and—

5 “(A) that captures, analyzes, changes, or pre-
6 sents patient or population clinical data or informa-
7 tion;

8 “(B) that supports administrative or oper-
9 ational aspects of health care and is not used in the
10 direct delivery of patient care; or

11 “(C) whose primary purpose is to act as a plat-
12 form for a secondary software, to run or act as a
13 mechanism for connectivity, or to store data.”.

14 (b) PROHIBITION.—Subchapter A of chapter V of the
15 Federal Food, Drug, and Cosmetic Act (21 U.S.C. 351
16 et seq.), as amended by section 2(b), is further amended
17 by adding at the end the following:

18 **“SEC. 524C. CLINICAL SOFTWARE AND HEALTH SOFTWARE.**

19 “Clinical software and health software shall not be
20 subject to regulation under this Act.”.

21 (c) SENSE OF CONGRESS.—It is the sense of the Con-
22 gress that—

23 (1) clinical software and health software (as de-
24 fined in section 201(tt) of the Federal Food, Drug,
25 and Cosmetic Act, as added by subsection (a))—

1 (A) advance the goals of enhanced patient
2 safety and continued innovation;

3 (B) hold much promise to lower costs and
4 improve the health of patients; and

5 (C) can improve the quality and efficacy of
6 health care provider services; and

7 (2) the President and the Congress should work
8 together to develop and enact legislation that estab-
9 lishes a risk-based regulatory framework for such
10 clinical software and health software that reduces
11 regulatory burdens, promotes patient safety, and
12 fosters innovation.

13 **SEC. 4. EXCLUSION FROM DEFINITION OF DEVICE.**

14 Section 201(h) of the Federal Food, Drug, and Cos-
15 metic Act (21 U.S.C. 321) is amended—

16 (1) in paragraph (2), by striking “or other ani-
17 mals, or” and inserting “or other animals,”;

18 (2) in paragraph (3), by striking “and”; and

19 (3) by inserting after paragraph (3) the fol-
20 lowing new paragraphs:

21 “(4) is not medical software, or

22 “(5) is not clinical software or health software,
23 and”.