	(Original Signature of Member)
113TH CONGRESS 1ST SESSION	H.R
	l Food, Drug, and Cosmetic Act to provide for regulating dical software, and for other purposes.
IN THE	HOUSE OF REPRESENTATIVES
Mrs. Blackburn	introduced the following bill; which was referred to the

## 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.

Committee on

- 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
- and may recommend courses of clinical action, but
- does not directly change the structure or any func-
- tion of the body of man or other animals; and
- 24 "(B) is intended to be marketed for use only by
- 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".