

113TH CONGRESS
2^D SESSION

S. _____

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

IN THE SENATE OF THE UNITED STATES

Mrs. FISCHER (for herself, Mr. KING, and Mr. RUBIO) introduced the following bill; which was read twice and referred to the Committee on _____

A BILL

To amend the Federal Food, Drug, and Cosmetic Act to provide for regulating clinical and health 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 “Preventing Regulatory
5 Overreach To Enhance Care Technology Act of 2014” or
6 the “PROTECT Act of 2014”.

7 **SEC. 2. FINDINGS; SENSE OF CONGRESS.**

8 (a) FINDINGS.—Congress finds as follows:

1 (1) The mobile health and mobile application
2 economy was created in the United States and is
3 now being exported globally, with the market ex-
4 pected to exceed \$26,000,000,000 by 2017.

5 (2) The United States mobile application econ-
6 omy is responsible for nearly 500,000 new jobs in
7 the United States.

8 (3) Consumer health information technologies,
9 including smart phones and tablets, have the poten-
10 tial to transform health care delivery through re-
11 duced systemic costs, improved patient safety, and
12 better clinical outcomes.

13 (4) Clinical and health software innovation cy-
14 cles evolve and move faster than the existing regu-
15 latory approval processes.

16 (5) Consumers and innovators need a new risk-
17 based framework for the oversight of clinical and
18 health software that improves on the framework of
19 the Food and Drug Administration.

20 (6) A working group convened jointly by the
21 Food and Drug Administration, the Federal Com-
22 munications Commission, and the Office of the Na-
23 tional Coordinator for Health Information Tech-
24 nology identified in a report that there are several
25 major barriers to the effective regulation of health

1 information technology that cannot be alleviated
2 without changes to existing law.

3 (b) SENSE OF CONGRESS.—It is the sense of Con-
4 gress that—

5 (1) the President and Congress must intervene
6 to facilitate interagency coordination across regu-
7 lators that focuses agency efforts on fostering health
8 information technology and mobile health innovation
9 while better protecting patient safety, improving
10 health care, and creating jobs in the United States;

11 (2) the President and the Congress should work
12 together to develop and enact legislation that estab-
13 lishes a risk-based regulatory framework for such
14 clinical software and health software that reduces
15 regulatory burdens, fosters innovation, and, most
16 importantly, improves patient safety;

17 (3) The National Institute of Standards and
18 Technology should be the Federal agency that has
19 oversight over technical standards used by clinical
20 software; and

21 (4) The National Institute of Standards and
22 Technology, in collaboration with the Federal Com-
23 munications Commission, the National Patient Safe-
24 ty Foundation, and the Office of the National Coor-
25 dinator for Health Information Technology, should

1 work on next steps, beyond current oversight efforts,
2 regarding health information technology, such as col-
3 laborating with nongovernmental entities to develop
4 certification processes and to promote best practice
5 standards.

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

7 (a) DEFINITIONS.—Section 201 of the Federal Food,
8 Drug, and Cosmetic Act (21 U.S.C. 321) is amended by
9 adding at the end the following:

10 “(ss)(1) The term ‘clinical software’ means clinical
11 decision support software or other software (including any
12 associated hardware and process dependencies) intended
13 for human or animal use that—

14 “(A) captures, analyzes, changes, or presents
15 patient or population clinical data or information
16 and may recommend courses of clinical action, but
17 does not directly change the structure or any func-
18 tion of the body of man or other animals; and

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

21 “(2) The term ‘health software’ means software (in-
22 cluding any associated hardware and process depend-
23 encies) that is not clinical software and—

1 “(A) that captures, analyzes, changes, or pre-
2 sents patient or population clinical data or informa-
3 tion;

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

7 “(C) whose primary purpose is to act as a plat-
8 form for a secondary software, to run or act as a
9 mechanism for connectivity, or to store data.

10 “(3) The terms ‘clinical software’ and ‘health soft-
11 ware’ do not include software—

12 “(A) that is intended to interpret patient-spe-
13 cific device data and directly diagnose a patient or
14 user without the intervention of a health care pro-
15 vider;

16 “(B) that conducts analysis of radiological or
17 imaging data in order to provide patient-specific di-
18 agnostic and treatment advice to a health care pro-
19 vider;

20 “(C) whose primary purpose is integral to the
21 function of a drug or device; or

22 “(D) that is a component of a device.”.

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

1 **“SEC. 524B. CLINICAL SOFTWARE AND HEALTH SOFTWARE.**

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

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

5 Section 201(h) of the Federal Food, Drug, and Cos-
6 metic Act (21 U.S.C. 321(h)) is amended by adding at
7 the end “The term ‘device’ does not include clinical soft-
8 ware or health software.”.