113TH CONGRESS
2D 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 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.

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 ''Preventing Regulatory Overreach To Enhance Care Technology Act of 2014'' or the ''PROTECT Act of 2014''.

SEC. 2. FINDINGS; SENSE OF CONGRESS.

(a) FINDINGS.—Congress finds as follows:

(1) The mobile health and mobile application economy was created in the United States and is

now being exported globally, with the market expected to exceed $26,000,000,000 by 2017.

(2) The United States mobile application economy is responsible for nearly 500,000 new jobs in the United States.

(3) Consumer technologies such as smart phones and tablets have the potential to transform health care delivery through reduced systemic costs, improved patient safety, and better clinical outcomes.

(4) The Food and Drug Administration has sought to expand its enforcement discretion by regulating the dynamic mobile health and mobile application market through the sub-regulatory guidance, ''Final Guidance on Mobile Medical Applications'', issued by the Food and Drug Administration on September 25, 2013. In so doing, the Food and Drug Administration has set aside economic impact analysis and failed to defer to Congress' stated preference under the Food and Drug Administration Safety and Innovation Act (Public Law 112–144) that the agency make recommendations to Congress about a new risk-based, regulatory framework.

(5) Clinical and health software innovation cycles evolve and move faster than the existing regulatory approval processes.

(6) The current Food and Drug Administration structure for regulating health care technology was conceived in an era of discreet devices and wired connections that ill-suits the new environment of nimble applications that often are run wirelessly and hosted on the Internet. The role that the Food and Drug Administration has taken in regulating such technology exceeds the role Congress expected the agency to take.

(7) Consumers and innovators need a new framework for the oversight of clinical and health software that improves on the framework of the Food and Drug Administration.

(8) A working group convened jointly by the Food and Drug Administration, the Federal Communications Commission, and the Office of the National Coordinator for Health Information Technology identified in a report that there are several major barriers to the effective regulation of mobile health and health software that cannot be alleviated without changes to existing law.

(b) SENSE OF CONGRESS.—It is the sense of Congress that—

(1) the President and Congress must intervene to facilitate interagency coordination across regulators that focuses agency efforts on fostering health information technology and mobile health innovation while better protecting patient safety, improving health care, and creating jobs in the United States;

(2) the President and the Congress should work together to develop and enact legislation that establishes a risk-based regulatory framework for such clinical software and health software that reduces regulatory burdens, promotes patient safety, and fosters innovation;

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

(4) The National Institute of Standards and Technology, in collaboration with the Federal Communications Commission, the National Patient Safety Foundation, and the Office of the National Coordinator for Health Information Technology, should work on next steps, beyond current oversight efforts, regarding health information technology, such as

granting nongovernmental entities the authority to recommend certification processes and to encourage best practice standards.

SEC. 3. CLINICAL SOFTWARE AND HEALTH SOFTWARE.

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

''(ss)(1) The term 'clinical software' means clinical decision support software or other software (including any associated hardware and process dependencies) intended for human or animal use that—

''(A) captures, analyzes, changes, or presents patient or population clinical data or information and may recommend courses of clinical action, but does not directly change the structure or any function of the body of man or other animals; and

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

''(2) The term 'health software' means software (including any associated hardware and process dependencies) that is not clinical software and—

''(A) that captures, analyzes, changes, or presents patient or population clinical data or information;

''(B) that supports administrative or operational aspects of health care and is not used in the direct delivery of patient care; or

''(C) whose primary purpose is to act as a platform for a secondary software, to run or act as a mechanism for connectivity, or to store data.

''(3) The terms 'clinical software' and 'health software' do not include software—

''(A) that is intended to diagnose a patient or user, including by interpreting patient specific imaging data;

''(B) whose primary purpose is integral to the function of a drug or device; or

''(C) that is a component of a device.''.

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

''SEC. 524B. CLINICAL SOFTWARE AND HEALTH SOFTWARE.

''Clinical software and health software shall not be subject to regulation under this Act.''.

SEC. 4. EXCLUSION FROM DEFINITION OF DEVICE.

Section 201(h) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 321) is amended by adding at the end ''The term 'device' does not include clinical software or health software.''.