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113TH CONGRESS
1ST SESSION

H. R. 3303

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

IN THE HOUSE OF REPRESENTATIVES

OCTOBER 22, 2013

Mrs. BLACKBURN (for herself, Mr. GENE GREEN of Texas, Mr. WALDEN, Ms. DEGETTE, Mr. BUTTERFIELD, and Mr. GINGREY of Georgia) introduced the following bill; which was referred to the Committee on Energy and Commerce

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A BILL

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

SEC. 2. MEDICAL SOFTWARE.

(a) DEFINITION OF MEDICAL SOFTWARE.—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) The term 'medical software' means software that is intended for human or animal use and—

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

''(B) is intended to be marketed for use by consumers and makes recommendations for clinical action that—

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

''(ii) if followed, would change the structure or any function of the body of man or other animals;

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

''(3) is not a component of a device.''.

(b) REGULATION.—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. MEDICAL SOFTWARE.

''(a) IN GENERAL.—The provisions of this Act shall apply with respect to medical software to the same extent and in the same manner as such provisions apply with respect to devices.

''(b) DELEGATION.—The Secretary shall delegate primary jurisdiction for regulating medical software to the center at the Food and Drug Administration charged with regulating devices.''.

SEC. 3. CLINICAL SOFTWARE AND HEALTH SOFTWARE.

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

''(tt)(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 medical software or 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.''.

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

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

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

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

(1) clinical software and health software (as defined in section 201(tt) of the Federal Food, Drug, and Cosmetic Act, as added by subsection (a))—

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

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

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

(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.

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—

(1) in paragraph (2), by striking ''or other animals, or'' and inserting ''or other animals,'';

(2) in paragraph (3), by striking ''and''; and

(3) by inserting after paragraph (3) the following new paragraphs:

''(4) is not medical software, or

''(5) is not clinical software or health software, and''.

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