I

115TH CONGRESS
1ST SESSION

H. R. 872

To amend the Federal Food, Drug, and Cosmetic Act to enhance medical device communications and ensure device cleanliness.

IN THE HOUSE OF REPRESENTATIVES

FEBRUARY 6, 2017

Mr. TED LIEU of California (for himself, Ms. JUDY CHU of California, Mr. CUMMINGS, Ms. NORTON, Ms. MOORE, and Ms. SLAUGHTER) introduced the following bill; which was referred to the Committee on Energy and Commerce

---

A BILL

To amend the Federal Food, Drug, and Cosmetic Act to enhance medical device communications and ensure device cleanliness.

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 ''Disclosure; and Encouragement of Verification, Innovation, Cleaning, and Efficiency Act of 2017'' or the ''DEVICE Act of 2017''.

SEC. 2. REPORTING REQUIREMENT FOR DESIGN AND REPROCESSING INSTRUCTION CHANGES.

(a) ADULTERATION.—Section 501 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 351) is amended by inserting after paragraph (j) the following:

''(k) If it is a device with respect to which the manufacturer is in violation of the reporting requirement in section 510(q) (relating to design and reprocessing changes).''.

(b) REQUIREMENT.—Section 510 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360) is amended by adding at the end the following:

''(q) REPORTING REQUIREMENT FOR DEVICE DESIGN CHANGES.—Before making a change to the design of a device, or the reprocessing instructions of a device, that is marketed in interstate commerce, the manufacturer of the device shall give written notice of the change to the Food and Drug Administration.''.

SEC. 3. REPORTING REQUIREMENT FOR CERTAIN COMMUNICATIONS TO FOREIGN HEALTH CARE PROVIDERS.

(a) ADULTERATION.—Section 501 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 351), as amended by section 2 of this Act, is further amended by inserting after paragraph (k) the following:

''(l) If it is a device with respect to which the manufacturer is in violation of the reporting requirement in section 510(r) (relating to communications to foreign health care providers).''.

(b) REQUIREMENT.—Section 510 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360), as amended by section 2 of this Act, is further amended by adding at the end the following:

''(r) REPORTING REQUIREMENT FOR CERTAIN COMMUNICATIONS TO FOREIGN HEALTH CARE PROVIDERS.—

''(1) REQUIREMENT.—The manufacturer of a device that is marketed in interstate commerce shall give written notice to the Food and Drug Administration of any communication described in paragraph (2) not more than 5 calendar days after making such communication.

''(2) COMMUNICATION DESCRIBED.—A communication is described in this paragraph if the communication—

''(A) is made by the manufacturer of the device or an affiliate of the manufacturer;

''(B) relates to a change to the design of the device, a change to the recommended reprocessing protocols, if any, for the device, or a safety concern about the device; and

''(C) is widely disseminated (including on a voluntary basis) to health care providers in a foreign country.

''(3) AFFILIATE.—In this subsection, the term 'affiliate' means a business entity that has a relationship with a second business entity if, directly or indirectly—

''(A) one business entity controls, or has the power to control, the other business entity; or

''(B) a third party controls, or has the power to control, both of the business entities.''.

SEC. 4. RAPID ASSESSMENT TESTS INTENDED TO ENSURE PROPER REPROCESSING.

(a) INCLUSION IN DEVICE DEFINITION.—Section 201 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 321) is amended—

(1) in paragraph (h)—

(A) in subparagraph (2), by striking ''or'' at the end;

(B) in subparagraph (3), by striking ''and'' at the end and inserting ''or''; and

(C) by inserting after subparagraph (3) the following:

''(4) a rapid assessment test intended to ensure the proper reprocessing of a reusable device (as defined in paragraph (ss)), and''; and

(2) by adding at the end the following:

''(ss) The term 'reusable device' means a device that—

''(1) is intended to be used more than one time; and

''(2) must be sanitized (whether through cleaning, disinfection, or sterilization) to ensure that the device is safe and effective for such intended use.''.

(b) INSTRUCTIONS FOR USE AND VALIDATION DATA.—Section 510 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360), as amended by sections 2 and 3 of this Act, is further amended by adding at the end the following:

''(s) INSTRUCTIONS FOR USE AND VALIDATION DATA.—

''(1) INITIAL LIST.—Not later than 1 year after the date of enactment of this subsection, the Secretary shall by regulation develop and publish a list of types of rapid assessment tests described in section 201(h)(4) for which reports under subsection (k) must include—

"(A) instructions for use that have been validated in a manner specified by the Secretary; and

"(B) validation data, of the types specified by the Secretary.

"(2) UPDATES.—The Secretary shall by regulation periodically update the list required by paragraph (1).

"(3) ENFORCEMENT.—Beginning on the date of publication of the initial list under paragraph (1), the Secretary shall not accept any notification under subsection (k) for clearance of a type of rapid assessment test that is included on such list unless such notification includes instructions for use and validation data in accordance with paragraph (1).".

○