

114TH CONGRESS  
2D SESSION

# H. R. 4965

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

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IN THE HOUSE OF REPRESENTATIVES

APRIL 15, 2016

Mr. TED LIEU of California 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 enhance medical device communications and ensure device cleanliness.

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 “Disclosure; and En-  
5 couragement of Verification, Innovation, Cleaning, and  
6 Efficiency Act of 2016”.

1 **SEC. 2. REPORTING REQUIREMENT FOR DESIGN AND RE-**  
2 **PROCESSING INSTRUCTION CHANGES.**

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

6 “(k) If it is a device with respect to which the manu-  
7 facturer is in violation of the reporting requirement in sec-  
8 tion 510(q) (relating to design and reprocessing  
9 changes).”.

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

13 “(q) REPORTING REQUIREMENT FOR DEVICE DE-  
14 SIGN CHANGES.—Before making a change to the design  
15 of a device, or the reprocessing instructions of a device,  
16 that is marketed in interstate commerce, the manufacturer  
17 of the device shall give written notice of the change to  
18 the Food and Drug Administration.”.

19 **SEC. 3. REPORTING REQUIREMENT FOR CERTAIN COMMU-**  
20 **NICATIONS TO FOREIGN HEALTH CARE PRO-**  
21 **VIDERS.**

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

1 “(l) If it is a device with respect to which the manu-  
2 facturer is in violation of the reporting requirement in sec-  
3 tion 510(r) (relating to communications to foreign health  
4 care providers).”.

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

9 “(r) REPORTING REQUIREMENT FOR CERTAIN COM-  
10 MUNICATIONS TO FOREIGN HEALTH CARE PROVIDERS.—

11 “(1) REQUIREMENT.—The manufacturer of a  
12 device that is marketed in interstate commerce shall  
13 give written notice to the Food and Drug Adminis-  
14 tration of any communication described in para-  
15 graph (2) not more than 5 calendar days after mak-  
16 ing such communication.

17 “(2) COMMUNICATION DESCRIBED.—A commu-  
18 nication is described in this paragraph if the com-  
19 munication—

20 “(A) is made by the manufacturer of the  
21 device or an affiliate of the manufacturer;

22 “(B) relates to a change to the design of  
23 the device, a change to the recommended re-  
24 processing protocols, if any, for the device, or a  
25 safety concern about the device; and

1           “(C) is widely disseminated (including on a  
2           voluntary basis) to health care providers in a  
3           foreign country.

4           “(3) AFFILIATE.—In this subsection, the term  
5           ‘affiliate’ means a business entity that has a rela-  
6           tionship with a second business entity if, directly or  
7           indirectly—

8                   “(A) one business entity controls, or has  
9                   the power to control, the other business entity;  
10                  or

11                   “(B) a third party controls, or has the  
12                  power to control, both of the business entities.”.

13 **SEC. 4. RAPID ASSESSMENT TESTS INTENDED TO ENSURE**  
14 **PROPER REPROCESSING.**

15           (a) INCLUSION IN DEVICE DEFINITION.—Section  
16 201 of the Federal Food, Drug, and Cosmetic Act (21  
17 U.S.C. 321) is amended—

18                   (1) in paragraph (h)—

19                           (A) in subparagraph (2), by striking “or”  
20                           at the end;

21                           (B) in subparagraph (3), by striking “and”  
22                           at the end and inserting “or”; and

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

1           “(4) a rapid assessment test intended to ensure  
2           the proper reprocessing of a reusable device (as de-  
3           fined in paragraph (ss)), and”;

4           (2) by adding at the end the following:

5           “(ss) The term ‘reusable device’ means a device  
6 that—

7           “(1) is intended to be used more than one time;

8           and

9           “(2) must be sanitized (whether through clean-  
10          ing, disinfection, or sterilization) to ensure that the  
11          device is safe and effective for such intended use.”.

12          (b) INSTRUCTIONS FOR USE AND VALIDATION  
13 DATA.—Section 510 of the Federal Food, Drug, and Cos-  
14 metic Act (21 U.S.C. 360), as amended by sections 2 and  
15 3 of this Act, is further amended by adding at the end  
16 the following:

17          “(s) INSTRUCTIONS FOR USE AND VALIDATION  
18 DATA.—

19           “(1) INITIAL LIST.—Not later than 1 year after  
20          the date of enactment of this subsection, the Sec-  
21          retary shall by regulation develop and publish a list  
22          of types of rapid assessment tests described in sec-  
23          tion 201(h)(4) for which reports under subsection  
24          (k) must include—

1           “(A) instructions for use that have been  
2           validated in a manner specified by the Sec-  
3           retary; and

4           “(B) validation data, of the types specified  
5           by the Secretary.

6           “(2) UPDATES.—The Secretary shall by regula-  
7           tion periodically update the list required by para-  
8           graph (1).

9           “(3) ENFORCEMENT.—Beginning on the date  
10          of publication of the initial list under paragraph (1),  
11          the Secretary shall not accept any notification under  
12          subsection (k) for clearance of a type of rapid as-  
13          sessment test that is included on such list unless  
14          such notification includes instructions for use and  
15          validation data in accordance with paragraph (1).”.

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