

114TH CONGRESS  
1ST SESSION

# H. R. 298

To amend chapter V of the Federal Food, Drug, and Cosmetic Act to permit the sale of, and access to, “research use only” products.

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IN THE HOUSE OF REPRESENTATIVES

JANUARY 13, 2015

Mr. BURGESS (for himself and Ms. SPEIER) introduced the following bill;  
which was referred to the Committee on Energy and Commerce

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## A BILL

To amend chapter V of the Federal Food, Drug, and Cosmetic Act to permit the sale of, and access to, “research use only” products.

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 “Medical Testing Avail-  
5 ability Act of 2015”.

6 **SEC. 2. CLARIFICATION REGARDING RESEARCH USE ONLY**  
7 **PRODUCTS.**

8 Section 520 of the Federal Food, Drug, and Cosmetic  
9 Act (21 U.S.C. 360j) is amended by adding at the end  
10 the following subsection:

1       “(o) PRODUCTS WITH RESEARCH USE ONLY LABEL-  
2   ING.—

3           “(1) IN GENERAL.—A product whose labeling  
4   bears the statement described in section  
5   809.10(c)(2)(i) of title 21, Code of Federal Regula-  
6   tions, as in effect on the date of the enactment of  
7   this subsection, may not be deemed to be adulter-  
8   ated or misbranded under this Act on the basis that  
9   the manufacturer or distributor of the product—

10           “(A) sells the product to an end user who  
11   uses the product in a manner inconsistent with  
12   such statement; or

13           “(B) engages in business communications  
14   regarding the product with an end user of the  
15   product.

16           “(2) BUSINESS COMMUNICATIONS DEFINED.—  
17   In this subsection, the term ‘business communica-  
18   tions’, with respect to a product with labeling de-  
19   scribed in paragraph (1)—

20           “(A) means oral, written, or electronic con-  
21   tact between a manufacturer or distributor of  
22   such product and an end user regarding the  
23   functioning of such product; and

24           “(B) includes any such contact consisting  
25   of technical support, customer service, assist-

1           ance with the installation of such product, com-  
2           munication relating to ensuring the perform-  
3           ance of the product, and other similar contacts.

4           “(3) SUNSET.—This subsection shall cease to  
5           be effective on the last day of the five-year period  
6           beginning on the date of enactment of this section.”.

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