

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.

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

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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