

113TH CONGRESS
1ST SESSION

H. R. 3005

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 diagnostic tests.

IN THE HOUSE OF REPRESENTATIVES

AUGUST 2, 2013

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 in diagnostic tests.

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 2013”.

1 **SEC. 2. CLARIFICATION REGARDING RESEARCH USE ONLY**
2 **PRODUCTS.**

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

6 “(o) **PRODUCTS WITH RESEARCH USE ONLY LABEL-**
7 **ING.**—

8 “(1) **IN GENERAL.**—A product whose labeling
9 bears the statement described in section
10 809.10(c)(2)(i) of title 21, Code of Federal Regula-
11 tions, as in effect on the date of the enactment of
12 this subsection, may not be deemed to be mis-
13 branded under this Act on the basis that the manu-
14 facturer or distributor of the product—

15 “(A) sells the product to an end user who
16 uses the product in a manner inconsistent with
17 such statement; or

18 “(B) engages in business communications
19 regarding the product with an end user of the
20 product.

21 “(2) **BUSINESS COMMUNICATIONS DEFINED.**—
22 In this subsection, the term ‘business communica-
23 tions’, with respect to a product with labeling de-
24 scribed in paragraph (1)—

25 “(A) means oral, written, or electronic con-
26 tact between a manufacturer or distributor of

1 such product and an end user regarding the
2 functioning of such product; and

3 “(B) includes any such contact consisting
4 of technical support, customer service, assist-
5 ance with the installation of such product, com-
6 munication relating to ensuring the perform-
7 ance of the product, and other similar contacts.

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

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