

114TH CONGRESS
1ST SESSION

H. R. 2423

To amend the Federal Food, Drug, and Cosmetic Act with respect to valid scientific evidence.

IN THE HOUSE OF REPRESENTATIVES

MAY 19, 2015

Mr. SHIMKUS 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 with respect to valid scientific evidence.

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. VALID SCIENTIFIC EVIDENCE.**

4 Section 513(a)(3)(B) of the Federal Food, Drug, and
5 Cosmetic Act (21 U.S.C. 360c(a)(3)(B)) is amended—

6 (1) by redesignating clauses (i) and (ii) as sub-
7 clauses (I) and (II), respectively;

8 (2) by striking “(B) If the Secretary” and in-
9 serting “(B)(i) If the Secretary”; and

10 (3) by adding at the end the following:

1 “(ii) Valid scientific evidence for purposes
2 of clause (i) may include:

3 “(I) evidence described in well-docu-
4 mented case histories, including registry
5 data, that are collected and monitored
6 under an acceptable protocol;

7 “(II) studies published in peer-re-
8 viewed journals; and

9 “(III) data collected in countries other
10 than the United States so long as such
11 data otherwise meets the criteria specified
12 in this subparagraph.

13 “(iii) In the case of a study published in
14 a peer-reviewed journal that is offered as valid
15 scientific evidence for purposes of clause (i), the
16 Secretary may request data underlying the
17 study if—

18 “(I) the Secretary, in making such re-
19 quest, complies with the requirement of
20 subparagraph (D)(ii) to consider the least
21 burdensome appropriate means of evalu-
22 ating device effectiveness or subsection
23 (i)(1)(D) to consider the least burdensome
24 means of determining substantial equiva-
25 lence, as applicable;

1 “(II) the Secretary furnishes a written
2 rationale for so requesting the underlying
3 data together with such request; and

4 “(III) if the requested underlying data
5 for such a study are unavailable, the Sec-
6 retary shall consider such study to be part
7 of the totality of the evidence with respect
8 to the device, as the Secretary determines
9 appropriate.”.

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