

114TH CONGRESS
1ST SESSION

H. R. 3618

To clarify the exclusion of orphan drug sales from the calculation of the annual fee on branded prescription pharmaceutical manufacturers and importers, and for other purposes.

IN THE HOUSE OF REPRESENTATIVES

SEPTEMBER 25, 2015

Mr. LANCE (for himself, Mr. PASCARELL, Ms. LINDA T. SÁNCHEZ of California, Mr. TIBERI, and Mr. HOLDING) introduced the following bill; which was referred to the Committee on Ways and Means, and in addition to the Committee on Energy and Commerce, for a period to be subsequently determined by the Speaker, in each case for consideration of such provisions as fall within the jurisdiction of the committee concerned

A BILL

To clarify the exclusion of orphan drug sales from the calculation of the annual fee on branded prescription pharmaceutical manufacturers and importers, and for other purposes.

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 “Orphan Drug Fairness
5 Act”.

1 **SEC. 2. EXCLUSION OF ORPHAN DRUG SALES.**

2 (a) IN GENERAL.—Paragraph (3) of section 9008(e)
3 of the Patient Protection and Affordable Care Act (26
4 U.S.C. 4001 note prec.; Public Law 111–148) is amended
5 to read as follows:

6 “(3) EXCLUSION OF ORPHAN DRUG SALES.—
7 The term ‘branded prescription drug sales’ shall not
8 include sales of any drug or biological product with
9 respect to which a credit was allowable for any tax-
10 able year under section 45C of the Internal Revenue
11 Code of 1986, regardless of whether such credit was
12 claimed and received. The preceding sentence shall
13 not apply with respect to any such drug or biological
14 product after the date on which such drug or bio-
15 logical product is approved by the Food and Drug
16 Administration for marketing for any indication
17 other than the treatment of the rare disease or con-
18 dition with respect to which such credit was allow-
19 able.”.

20 (b) EFFECTIVE DATE.—The amendment made by
21 subsection (a) shall take effect as if included in section
22 9008 of the Patient Protection and Affordable Care Act
23 (26 U.S.C. 4001 note prec.; Public Law 111–148).

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