

114TH CONGRESS
1ST SESSION

H. R. 3678

To clarify the orphan drug exception to the annual fee on branded prescription pharmaceutical manufacturers and importers, and for other purposes.

IN THE HOUSE OF REPRESENTATIVES

OCTOBER 1, 2015

Mr. KELLY of Pennsylvania (for himself, Mrs. BLACK, Mr. NEAL, Mr. HOLDING, Mr. RANGEL, Ms. JENKINS of Kansas, Mr. TIBERI, Mr. MARCHANT, and Mr. NUNES) 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 orphan drug exception to 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 “Preserving Access to
5 Orphan Drugs Act of 2015”.

1 **SEC. 2. CLARIFICATION OF ORPHAN DRUG EXCEPTION TO**
2 **ANNUAL FEE ON BRANDED PRESCRIPTION**
3 **PHARMACEUTICAL MANUFACTURERS AND**
4 **IMPORTERS.**

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

9 “(3) EXCLUSION OF ORPHAN DRUG SALES.—

10 “(A) IN GENERAL.—The term ‘branded
11 prescription drug sales’ shall not include sales
12 of any drug or biological product—

13 “(i) with respect to which a credit was
14 allowed for any taxable year under section
15 45C of the Internal Revenue Code of 1986;

16 “(ii) with respect to which a credit
17 was allowable for any taxable year begin-
18 ning before January 1, 2011, under such
19 section 45C (without regard to whether
20 such credit was claimed or received); or

21 “(iii) which was any drug or biological
22 product approved or licensed prior to Jan-
23 uary 1, 2011, by the Food and Drug Ad-
24 ministration, for marketing solely for 1 or
25 more rare diseases or conditions.

1 “(B) EXPIRATION.—Subparagraph (A)
 2 shall not apply with respect to any drug or bio-
 3 logical product after the date on which such
 4 drug or biological product is approved or li-
 5 censed by the Food and Drug Administration
 6 for marketing for any indication other than the
 7 treatment of a rare disease or condition.

8 “(C) RARE DISEASE OR CONDITION.—In
 9 this paragraph, the term ‘rare disease or condi-
 10 tion’ has the meaning given such term under
 11 section 45C(d)(1) of the Internal Revenue Code
 12 of 1986.”.

13 (b) HOLD HARMLESS FOR COVERED ENTITIES WITH
 14 NO OR LIMITED ORPHAN DRUG SALES.—Subsection (b)
 15 of section 9008 of the Patient Protection and Affordable
 16 Care Act (26 U.S.C. 4001 note prec.; Public Law 111–
 17 148) is amended by adding at the end the following new
 18 paragraph:

19 “(5) ADJUSTMENT FOR CERTAIN COVERED EN-
 20 TITIES WITH NO OR LIMITED ORPHAN DRUG
 21 SALES.—If—

22 “(A) the fee under this section for a cal-
 23 endar year with respect to a covered entity (de-
 24 termined without regard to this paragraph), ex-
 25 ceeds

1 “(B) the fee that would be determined
2 under this section for such year with respect to
3 such entity if branded prescription drug sales of
4 all covered entities were determined without re-
5 gard to clauses (ii) and (iii) of subsection
6 (e)(3)(A),
7 then such entity’s fee under this section for such cal-
8 endar year shall be determined as described in sub-
9 paragraph (B).”.

10 (c) EFFECTIVE DATE.—The amendments made by
11 this section shall apply with respect to fees the annual
12 payment date for which under section 9008 of the Patient
13 Protection and Affordable Care Act (26 U.S.C. 4001 note
14 prec.; Public Law 111–148) is after December 31, 2014.

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