

115TH CONGRESS  
2D SESSION

# H. R. 7324

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

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## IN THE HOUSE OF REPRESENTATIVES

DECEMBER 17, 2018

Mr. KELLY of Pennsylvania 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

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## 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 2018”.

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.—Section 9008(e)(3) of the Patient  
6 Protection and Affordable Care Act is amended to read  
7 as follows:

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

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

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

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

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

25 “(B) EXPIRATION.—Subparagraph (A)  
26 shall not apply with respect to any drug or bio-

1           logical product after the date on which such  
2           drug or biological product is approved or li-  
3           censed by the Food and Drug Administration  
4           for marketing for any indication other than the  
5           treatment of a rare disease or condition.

6                   “(C) RARE DISEASE OR CONDITION.—For  
7           purposes of this paragraph, the term ‘rare dis-  
8           ease or condition’ has the meaning given such  
9           term under section 45C(d)(1) of the Internal  
10           Revenue Code of 1986.”.

11           (b) HOLD HARMLESS FOR COVERED ENTITIES WITH  
12           NO OR LIMITED ORPHAN DRUG SALES.—Section 9008(b)  
13           of the Patient Protection and Affordable Care Act is  
14           amended by adding at the end the following new para-  
15           graph:

16                   “(5) ADJUSTMENT FOR CERTAIN COVERED EN-  
17           TITIES WITH NO OR LIMITED ORPHAN DRUG  
18           SALES.—If—

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

23                   “(B) the fee that would be determined  
24           under this section for such year with respect to  
25           such entity if branded prescription drug sales of

1           all covered entities were determined without re-  
2           gard to clauses (ii) and (iii) of subsection  
3           (e)(3)(A),  
4           then such entity's fee under this section for such cal-  
5           endar year shall be determined as described in sub-  
6           paragraph (B).”.

7           (c) EFFECTIVE DATE.—The amendments made by  
8           this section shall apply with respect to fees the annual  
9           payment date for which under section 9008 of the Patient  
10          Protection and Affordable Care Act is after December 31,  
11          2018.

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