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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.

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.

Be it enacted by the Senate and House of Representatives of the United States of America in Congress assembled,

SECTION 1. SHORT TITLE.

This Act may be cited as the ''Preserving Access to Orphan Drugs Act of 2018''.

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

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

''(3) EXCLUSION OF ORPHAN DRUG SALES.—

''(A) IN GENERAL.—The term 'branded prescription drug sales' shall not include sales of any drug or biological product—

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

''(ii) with respect to which a credit was allowable for any taxable year beginning before January 1, 2011, under such section 45C (without regard to whether such credit was claimed or received), or

''(iii) which was any drug or biological product approved or licensed prior to January 1, 2011, by the Food and Drug Administration, for marketing solely for 1 or more rare diseases or conditions.

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

logical product after the date on which such drug or biological product is approved or licensed by the Food and Drug Administration for marketing for any indication other than the treatment of a rare disease or condition.

''(C) RARE DISEASE OR CONDITION.—For purposes of this paragraph, the term 'rare disease or condition' has the meaning given such term under section 45C(d)(1) of the Internal Revenue Code of 1986.''.

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

''(5) ADJUSTMENT FOR CERTAIN COVERED ENTITIES WITH NO OR LIMITED ORPHAN DRUG SALES.—If—

''(A) the fee under this section for a calendar year with respect to a covered entity (determined without regard to this paragraph), exceeds

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

all covered entities were determined without regard to clauses (ii) and (iii) of subsection (e)(3)(A),

then such entity's fee under this section for such calendar year shall be determined as described in subparagraph (B).''.

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

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