

113TH CONGRESS  
1ST SESSION

# H. R. 2315

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

---

## IN THE HOUSE OF REPRESENTATIVES

JUNE 11, 2013

Mr. GERLACH (for himself and Mr. NEAL) introduced the following bill; which was referred to the Committee on Energy and Commerce, and in addition to the Committee on Ways and Means, 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.

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 2013”.

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 (Public  
7 Law 111–148) is amended to read 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 or

16 “(ii) which is approved or licensed by  
17 the Food and Drug Administration for  
18 marketing solely for one or more rare dis-  
19 eases or conditions.

20 “(B) LIMITATION.—Subparagraph (A)  
21 shall not apply with respect to any drug or bio-  
22 logical product after the date on which the drug  
23 or biological product is approved or licensed by  
24 the Food and Drug Administration for mar-  
25 keting for any indication other than the treat-  
26 ment of a rare disease or condition.

1           “(C) RARE DISEASE OR CONDITION.—In  
2           this paragraph, the term ‘rare disease or condi-  
3           tion’ has the meaning given such term under  
4           section 45C(d)(1) of the Internal Revenue Code  
5           of 1986, except that in the case of any drug or  
6           biological product that has not been designated  
7           under section 526 of the Federal Food, Drug,  
8           and Cosmetic Act for a particular indication,  
9           determinations under such section 45C(d)(1)  
10          shall be made on the basis of the facts and cir-  
11          cumstances as of the date such drug or biologi-  
12          cal product is approved or licensed by the Food  
13          and Drug Administration for marketing for the  
14          treatment of such disease or condition.”.

15          (b) EFFECTIVE DATE.—The amendment made by  
16          this section shall take effect as if included in section 9008  
17          of the Patient Protection and Affordable Care Act (Public  
18          Law 111–148).

○