112TH CONGRESS
1ST SESSION

S. 1423

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

IN THE SENATE OF THE UNITED STATES

JULY 27, 2011

Mr. TOOMEY (for himself, Mr. CASEY, and Mr. WYDEN) introduced the following bill; which was read twice and referred to the Committee on Finance

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A BILL

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

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 2011''.

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

(a) IN GENERAL.—Paragraph (3) of section 9008(e) of the Patient Protection and Affordable Care Act (Public Law 111–148) 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; or

''(ii) which is approved or licensed by the Food and Drug Administration for marketing solely for one or more rare diseases or conditions.

''(B) LIMITATION.—Subparagraph (A) shall not apply with respect to any drug or biological product after the date on which the 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.—In 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, except that in the case of any drug or biological product that has not been designated under section 526 of the Federal Food, Drug and Cosmetic Act for a particular indication, determinations under such section 45C(d)(1) shall be made on the basis of the facts and circumstances as of the date such drug or biological product is approved or licensed by the Food and Drug Administration for marketing for the treatment of such disease or condition.".

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

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