

114TH CONGRESS
1ST SESSION

S. 1878

To extend the pediatric priority review voucher program.

IN THE SENATE OF THE UNITED STATES

JULY 28, 2015

Mr. CASEY (for himself and Mr. ISAKSON) introduced the following bill; which was read twice and referred to the Committee on Health, Education, Labor, and Pensions

A BILL

To extend the pediatric priority review voucher program.

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 “Advancing Hope Act
5 of 2015”.

6 **SEC. 2. REAUTHORIZATION OF PROGRAM FOR PRIORITY**
7 **REVIEW TO ENCOURAGE TREATMENTS FOR**
8 **RARE PEDIATRIC DISEASES.**

9 Section 529 of the Federal Food, Drug, and Cosmetic
10 Act (21 U.S.C. 360ff) is amended—

11 (1) in subsection (a)—

1 (A) by amending paragraph (3) to read as
2 follows:

3 “(3) RARE PEDIATRIC DISEASE.—The term
4 ‘rare pediatric disease’ means any of the following:

5 “(A) A disease that meets each of the fol-
6 lowing criteria:

7 “(i) The disease primarily affects indi-
8 viduals aged from birth to 18 years, in-
9 cluding age groups often called neonates,
10 infants, children, and adolescents.

11 “(ii) The disease is a rare disease or
12 condition, within the meaning of section
13 526.

14 “(B) Any form of sickle cell disease.

15 “(C) Any pediatric cancers.”; and

16 (B) in paragraph (4)—

17 (i) in subparagraph (E), by striking
18 “and” at the end;

19 (ii) in subparagraph (F), by striking
20 the period at the end and inserting “;
21 and”; and

22 (iii) by adding at the end the fol-
23 lowing:

24 “(G) is for a drug or biological product for
25 which a priority review voucher has not been

1 issued under section 524 (relating to tropical
2 disease products).”;

3 (2) in subsection (b), by striking paragraph (5);

4 and

5 (3) in subsection (d)(2), in the second sentence,
6 by striking the period and inserting “, but the spon-
7 sor of a drug that intends to request a priority re-
8 view voucher under this section shall notify the Sec-
9 retary of such intent upon submission of an applica-
10 tion under section 505 or section 351 of the Public
11 Health Service Act that is the basis of such re-
12 quest.”.

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