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.

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 “Advancing Hope Act of 2015”.

SEC. 2. REAUTHORIZATION OF PROGRAM FOR PRIORITY REVIEW TO ENCOURAGE TREATMENTS FOR RARE PEDIATRIC DISEASES.
Section 529 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360ff) is amended—
(1) in subsection (a)—
(A) by amending paragraph (3) to read as follows:

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

“(A) A disease that meets each of the following criteria:

“(i) The disease primarily affects individuals aged from birth to 18 years, including age groups often called neonates, infants, children, and adolescents.

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

“(B) Any form of sickle cell disease.

“(C) Any pediatric cancers.”; and

(B) in paragraph (4)—

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

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

(iii) by adding at the end the following:

“(G) is for a drug or biological product for which a priority review voucher has not been
issued under section 524 (relating to tropical disease products).”;

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

and

(3) in subsection (d)(2), in the second sentence, by striking the period and inserting “, but the sponsor of a drug that intends to request a priority review voucher under this section shall notify the Secretary of such intent upon submission of an application under section 505 or section 351 of the Public Health Service Act that is the basis of such request.”.