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(Original Signature of Member)

114TH CONGRESS
1ST SESSION

H. R. _____

To amend the Federal Food, Drug, and Cosmetic Act to reauthorize a program of priority review to encourage treatments for rare pediatric diseases, and for other purposes.

IN THE HOUSE OF REPRESENTATIVES

Mr. BUTTERFIELD introduced the following bill; which was referred to the Committee on _____

A BILL

To amend the Federal Food, Drug, and Cosmetic Act to reauthorize a program of priority review to encourage treatments for rare pediatric diseases, and for other purposes.

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”.

1 **SEC. 2. REAUTHORIZATION OF PROGRAM FOR PRIORITY**
2 **REVIEW TO ENCOURAGE TREATMENTS FOR**
3 **RARE PEDIATRIC DISEASES.**

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

6 (1) in subsection (a)—

7 (A) by amending paragraph (3) to read as
8 follows:

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

11 “(A) A disease that meets each of the fol-
12 lowing criteria:

13 “(i) The disease primarily affects indi-
14 viduals aged from birth to 18 years, in-
15 cluding age groups often called neonates,
16 infants, children, and adolescents.

17 “(ii) The disease is a rare disease or
18 condition, within the meaning of section
19 526.

20 “(C) Any form of sickle cell disease.

21 “(D) Any pediatric cancers.”; and

22 (B) in paragraph (4)(A)—

23 (i) in subparagraph (E), by striking

24 “and” at the end;

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

4 (iii) by adding at the end the fol-
5 lowing:

6 “(G) is for a drug or biological product for
7 which a priority review voucher has not been
8 issued under section 524 (relating to tropical
9 disease products).”; and
10 (2) in subsection (b), by striking paragraph (5).

11 **SEC. 3. LIMITATION ON PRIORITY REVIEW VOUCHERS FOR**
12 **TROPICAL DISEASE PRODUCTS.**

13 Subparagraph (A) of section 524(a)(4) of the Federal
14 Food, Drug, and Cosmetic Act (21 U.S.C. 360n(a)(4)) is
15 amended—

16 (1) in clause (i), by striking “and” at the end;

17 (2) in clause (ii), by inserting “and” at the end;

18 and

19 (3) by adding at the end the following:

20 “(iii) contains an assurance (satisfac-
21 tory to the Secretary) that the drug for
22 which the application is submitted has not
23 been approved for commercial marketing
24 for any tropical disease indication by a
25 government authority outside of the United

1 States for more than 24 months before the
2 application is submitted;”.