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114TH CONGRESS
1ST SESSION

H. R. 1537

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

MARCH 23, 2015

Mr. BUTTERFIELD (for himself, Mr. MCCAUL, Mr. VAN HOLLEN, Mr. KELLY of Pennsylvania, and Mr. COHEN) introduced the following bill; which was referred to the Committee on Energy and Commerce

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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.

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)(A)—

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

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

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

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

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

(1) in clause (i), by striking ''and'' at the end;

(2) in clause (ii), by inserting ''and'' at the end; and

(3) by adding at the end the following:

''(iii) contains an assurance (satisfactory to the Secretary) that the drug for which the application is submitted has not been approved for commercial marketing for any tropical disease indication by a government authority outside of the United

States for more than 24 months before the application is submitted;''.

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