

Union Calendar No. 451

116TH CONGRESS
2D SESSION

H. R. 4439

[Report No. 116–551]

To amend the Federal Food, Drug, and Cosmetic Act to make permanent the authority of the Secretary of Health and Human Services to issue priority review vouchers to encourage treatments for rare pediatric diseases.

IN THE HOUSE OF REPRESENTATIVES

SEPTEMBER 20, 2019

Mr. BUTTERFIELD (for himself, Mr. McCAUL, Ms. SPEIER, Mr. KELLY of Pennsylvania, Mr. ENGEL, Mr. BILIRAKIS, Ms. KELLY of Illinois, Mr. HUDSON, Mr. RUSH, and Mr. MULLIN) introduced the following bill; which was referred to the Committee on Energy and Commerce

SEPTEMBER 29, 2020

Additional sponsors: Mr. FITZPATRICK, Ms. DEGETTE, Mrs. RODGERS of Washington, Mrs. LURIA, Mr. RUTHERFORD, Mr. CARSON of Indiana, Mr. RODNEY DAVIS of Illinois, Ms. CLARKE of New York, Ms. BLUNT ROCHESTER, Ms. BARRAGÁN, Mr. SOTO, Mr. CÁRDENAS, Ms. KUSTER of New Hampshire, Mr. GRIFFITH, Mr. CARTER of Georgia, Mr. MARSHALL, Mr. COHEN, Mr. WOODALL, Mr. DEFazio, Mr. BALDERSON, Mr. MALINOWSKI, Mr. BROOKS of Alabama, Ms. LOFGREN, Mr. KING of Iowa, Ms. PORTER, Mr. MARCHANT, Mr. MCEACHIN, Mr. DESAULNIER, Mrs. LESKO, Mr. FORTENBERRY, Ms. BONAMICI, Ms. SHERRILL, and Mr. WILSON of South Carolina

SEPTEMBER 29, 2020

Reported with amendments; committed to the Committee of the Whole House on the State of the Union and ordered to be printed

[Strike out all after the enacting clause and insert the part printed in *italic*]

[For text of introduced bill, see copy of bill as introduced September 20, 2019]

A BILL

To amend the Federal Food, Drug, and Cosmetic Act to make permanent the authority of the Secretary of Health and Human Services to issue priority review vouchers to encourage treatments for rare pediatric diseases.

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 “Creating Hope Reau-*
 5 *thorization Act”.*

6 **SEC. 2. EXTENSION OF AUTHORITY TO ISSUE PRIORITY RE-**
 7 **VIEW VOUCHERS TO ENCOURAGE TREAT-**
 8 **MENTS FOR RARE PEDIATRIC DISEASES.**

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

11 *(1) by striking “September 30, 2020” each place*
 12 *it appears and inserting “September 30, 2024”; and*

13 *(2) by striking “September 30, 2022” and insert-*
 14 *ing “September 30, 2026”.*

Amend the title so as to read: “A bill to amend the Federal Food, Drug, and Cosmetic Act to extend the authority of the Secretary of Health and Human Services to issue priority review vouchers to encourage treatments for rare pediatric diseases.”.

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