

116TH CONGRESS
1ST SESSION

H. R. 4538

To amend title III of the Public Health Service Act to limit the orphan drug exclusion under the drug discount program under section 340B of such title.

IN THE HOUSE OF REPRESENTATIVES

SEPTEMBER 26, 2019

Mr. WELCH (for himself and Mr. MCKINLEY) introduced the following bill;
which was referred to the Committee on Energy and Commerce

A BILL

To amend title III of the Public Health Service Act to limit the orphan drug exclusion under the drug discount program under section 340B of such title.

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 “Closing Loopholes for
5 Orphan Drugs Act”.

6 **SEC. 2. LIMITING THE ORPHAN DRUG EXCLUSION UNDER**
7 **340B DRUG DISCOUNT PROGRAM.**

8 (a) IN GENERAL.—Section 340B(e) of the Public
9 Health Service Act (42 U.S.C. 256b(e)) is amended by

1 inserting before the period at the end the following: “when
2 transferred, prescribed, sold, or otherwise used for the
3 rare condition or disease for which such drug is so des-
4 ignated”.

5 (b) EFFECTIVE DATE.—The amendment made by
6 subsection (a) shall apply with respect to covered out-
7 patient drugs purchased on or after the date of the enact-
8 ment of this Act.

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