

118TH CONGRESS
1ST SESSION

H. R. 5539

To amend title XI of the Social Security Act to expand and clarify the exclusion for orphan drugs under the Drug Price Negotiation Program.

IN THE HOUSE OF REPRESENTATIVES

SEPTEMBER 18, 2023

Mr. JOYCE of Pennsylvania (for himself and Mr. NICKEL) introduced the following bill; which was referred to the Committee on Energy and Commerce, and in addition to the Committee on Ways and Means, for a period to be subsequently determined by the Speaker, in each case for consideration of such provisions as fall within the jurisdiction of the committee concerned

A BILL

To amend title XI of the Social Security Act to expand and clarify the exclusion for orphan drugs under the Drug Price Negotiation Program.

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 “Optimizing Research
5 Progress Hope And New Cures Act” or the “ORPHAN
6 Cures Act”.

1 **SEC. 2. EXPANDING AND CLARIFYING THE EXCLUSION FOR**
2 **ORPHAN DRUGS UNDER THE DRUG PRICE**
3 **NEGOTIATION PROGRAM.**

4 Section 1191(e) of the Social Security Act (42 U.S.C.
5 1320f(e)) is amended—

6 (1) in paragraph (1), by adding at the end the
7 following new subparagraph:

8 “(C) TREATMENT OF FORMER ORPHAN
9 DRUGS.—In calculating the amount of time that
10 has elapsed with respect to the approval of a
11 drug or licensure of a biological product under
12 subparagraph (A)(ii) and subparagraph (B)(ii),
13 respectively, the Secretary shall not taken into
14 account any period during which such drug or
15 product was a drug described in paragraph
16 (3)(A).”; and

17 (2) in paragraph (3)(A)—

18 (A) by striking “only one rare disease or
19 condition” and inserting “one or more rare dis-
20 eases or conditions”; and

21 (B) by striking “such disease or condition”
22 and inserting “one or more rare diseases or
23 conditions”.

○