

119TH CONGRESS  
1ST SESSION

# S. 1862

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

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IN THE SENATE OF THE UNITED STATES

MAY 22, 2025

Mr. BARRASSO (for himself and Mr. HEINRICH) introduced the following bill;  
which was read twice and referred to the Committee on Finance

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## 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 1192(e) of the Social Security Act (42 U.S.C.  
 5 1320f–1(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 take 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 (as such term is defined in section  
 24 526(a)(2) of the Federal Food, Drug, and Cos-  
 25 metic Act)”.