

119TH CONGRESS  
1ST SESSION

**S.** \_\_\_\_\_

To amend title XI of the Social Security Act to provide for the treatment of orphan drugs under the Medicare Drug Price Negotiation Program.

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IN THE SENATE OF THE UNITED STATES

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Mr. WELCH (for himself, Mr. WYDEN, and Ms. CORTEZ MASTO) introduced the following bill; which was read twice and referred to the Committee on \_\_\_\_\_

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**A BILL**

To amend title XI of the Social Security Act to provide for the treatment of orphan drugs under the Medicare 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 “No Big Blockbuster  
5 Bailouts Act”.

6 **SEC. 2. TREATMENT OF ORPHAN DRUGS UNDER THE MEDI-**  
7 **CARE DRUG PRICE NEGOTIATION PROGRAM.**

8 (a) IN GENERAL.—Section 1192(e) of the Social Se-  
9 curity Act (42 U.S.C. 1320f–1(e)) is amended—

1 (1) in paragraph (1), in the matter preceding  
2 subparagraph (A), by striking “through (4)” and in-  
3 serting “and (3)”;

4 (2) in paragraph (3)—

5 (A) by striking subparagraph (A);

6 (B) by redesignating subparagraphs (B)  
7 and (C) as subparagraphs (A) and (B), respec-  
8 tively; and

9 (C) in subparagraph (A)(iii), as redesign-  
10 nated by subparagraph (B) of this paragraph,  
11 by striking “with respect to” and inserting  
12 “subject to paragraph (4), with respect to”; and  
13 (3) by striking paragraph (4) and inserting the  
14 following new paragraph:

15 “(4) TREATMENT OF ORPHAN DRUGS.—In the  
16 case of a drug that is designated as a drug for one  
17 or more rare diseases or conditions and for which  
18 the only approved indication (or indications) is for  
19 one or more such rare diseases or conditions (as  
20 such term is defined in section 526(a)(2) of the Fed-  
21 eral Food, Drug, and Cosmetic Act), paragraph  
22 (3)(A) shall be applied by substituting  
23 ‘\$400,000,000’ for ‘\$200,000,000’ in clause (i) of  
24 such paragraph.”.

1       (b) APPLICATION.—The amendments made by sub-  
2 section (a) shall apply with respect to initial price applica-  
3 bility years (as defined in section 1191(b) of the Social  
4 Security Act (42 U.S.C. 1320f(b))) beginning on or after  
5 January 1, 2028.