

119TH CONGRESS
1ST SESSION

S. 3019

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

IN THE SENATE OF THE UNITED STATES

OCTOBER 21, 2025

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

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

(2) in paragraph (3)—

(A) by striking subparagraph (A);

(B) by redesignating subparagraphs (B) and (C) as subparagraphs (A) and (B), respectively; and

(C) in subparagraph (A)(iii), as redesignated by subparagraph (B) of this paragraph, by striking “with respect to” and inserting “subject to paragraph (4), with respect to”; and

(3) by striking paragraph (4) and inserting the following new paragraph:

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

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