

119TH CONGRESS
2D SESSION

S. 3716

To set forth limitations on exclusive approval or licensure of drugs designated for rare diseases or conditions.

IN THE SENATE OF THE UNITED STATES

JANUARY 28, 2026

Ms. BALDWIN introduced the following bill; which was read twice and referred to the Committee on Health, Education, Labor, and Pensions

A BILL

To set forth limitations on exclusive approval or licensure of drugs designated for rare diseases or conditions.

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 “Retaining Access and
5 Restoring Exclusivity Act” or the “RARE Act”.

6 **SEC. 2. LIMITATIONS ON EXCLUSIVE APPROVAL OR LICEN-**
7 **SURE OF ORPHAN DRUGS.**

8 (a) IN GENERAL.—Section 527 of the Federal Food,
9 Drug, and Cosmetic Act (21 U.S.C. 360cc) is amended—

1 (1) in subsection (a), in the matter following
2 paragraph (2), by striking “same disease or condi-
3 tion” and inserting “same approved use or indica-
4 tion within such rare disease or condition”;

5 (2) in subsection (b)—

6 (A) in the matter preceding paragraph (1),
7 by striking “same rare disease or condition”
8 and inserting “same approved use or indication
9 for which such 7-year period applies to such al-
10 ready approved or licensed drug”; and

11 (B) in paragraph (1), by inserting “, relat-
12 ing to the approved use or indication,” after
13 “the needs”;

14 (3) in subsection (c)(1), by striking “same rare
15 disease or condition as the already approved drug”
16 and inserting “same use or indication for which the
17 already approved or licensed drug was approved or
18 licensed”; and

19 (4) by adding at the end the following:

20 “(f) APPROVED USE OR INDICATION DEFINED.—In
21 this section, the term ‘approved use or indication’ means
22 the use or indication approved under section 505 of this
23 Act or licensed under section 351 of the Public Health
24 Service Act for a drug designated under section 526 for
25 a rare disease or condition.”.

1 (b) APPLICATION OF AMENDMENTS.—The amend-
2 ments made by subsection (a) shall apply with respect to
3 any drug designated under section 526 of the Federal
4 Food, Drug, and Cosmetic Act (21 U.S.C. 360bb), regard-
5 less of the date on which the drug was so designated, and
6 regardless of the date on which the drug was approved
7 under section 505 of such Act (21 U.S.C. 355) or licensed
8 under section 351 of the Public Health Service Act (42
9 U.S.C. 262).

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