

**Calendar No. 109**118TH CONGRESS  
1ST SESSION**S. 1214**

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

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## IN THE SENATE OF THE UNITED STATES

APRIL 19, 2023

Ms. BALDWIN (for herself and Mr. BRAUN) introduced the following bill; which was read twice and referred to the Committee on Health, Education, Labor, and Pensions

JUNE 22, 2023

Reported by Mr. SANDERS, without amendment

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**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”.

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

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

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

9 (2) in subsection (b)—

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

15 (B) in paragraph (1), by inserting “, relat-  
 16 ing to the approved use or indication,” after  
 17 “the needs”;

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

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

24 “(f) APPROVED USE OR INDICATION DEFINED.—In  
 25 this section, the term ‘approved use or indication’ means  
 26 the use or indication approved under section 505 of this

1 Act or licensed under section 351 of the Public Health  
2 Service Act for a drug designated under section 526 for  
3 a rare disease or condition.”.

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

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