117TH CONGRESS
2D SESSION

S. 4185

To set forth limitations on exclusivity for orphan drugs.

IN THE SENATE OF THE UNITED STATES

MAY 11 (legislative day, MAY 10), 2022

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

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A BILL

To set forth limitations on exclusivity for orphan drugs.

Be it enacted by the Senate and House of Representatives of the United States of America in Congress assembled,

SECTION 1. SHORT TITLE.

This Act may be cited as the ''Retaining Access and Restoring Exclusivity Act'' or the ''RARE Act''.

SEC. 2. LIMITATIONS ON EXCLUSIVE APPROVAL OR LICENSURE OF ORPHAN DRUGS.

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

(1) in subsection (a), in the matter following paragraph (2), by striking ''same disease or condi-

tion'' and inserting ''same approved use or indication within such rare disease or condition'';

(2) in subsection (b)—

(A) in the matter preceding paragraph (1), by striking ''same rare disease or condition'' and inserting ''same approved use or indication for which such 7-year period applies to such already approved drug''; and

(B) in paragraph (1), by inserting '', relating to the approved use or indication,'' after ''the needs'';

(3) in subsection (c)(1), by striking ''same rare disease or condition as the already approved drug'' and inserting ''same use or indication for which the already approved or licensed drug was approved or licensed''; and

(4) by adding at the end the following:

''(f) APPROVED USE OR INDICATION DEFINED.—In this section, the term 'approved use or indication' means the use or indication approved under section 505 of this Act or licensed under section 351 of the Public Health Service Act for a drug designated under section 526 for a rare disease or condition.''.

(b) APPLICATION OF AMENDMENTS.—The amendments made by subsection (a) shall apply with respect to

any drug designated under section 526 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360bb), regardless of the date on which the drug was so designated, and regardless of the date on which the drug was approved under section 505 of such Act (21 U.S.C. 355) or licensed under section 351 of the Public Health Service Act (42 U.S.C. 262).

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