

117TH CONGRESS
1ST SESSION

S. 250

To amend the Federal Food, Drug, and Cosmetic Act with respect to limitations on exclusive approval or licensure of orphan drugs, and for other purposes.

IN THE SENATE OF THE UNITED STATES

FEBRUARY 4, 2021

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

A BILL

To amend the Federal Food, Drug, and Cosmetic Act with respect to limitations on exclusive approval or licensure of orphan drugs, and for other purposes.

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 “Fairness in Orphan
5 Drug Exclusivity 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), by striking “Except as
2 provided in subsection (b)” and inserting “Except as
3 provided in subsection (b) or (f)”; and

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

5 “(f) LIMITATIONS ON EXCLUSIVE APPROVAL, CER-
6 TIFICATION, OR LICENSE.—

7 “(1) IN GENERAL.—For a drug designated
8 under section 526 for a rare disease or condition
9 pursuant to the criteria set forth in subsection
10 (a)(2)(B) of such section, the Secretary shall not
11 grant, recognize, or apply exclusive approval or licen-
12 sure under subsection (a), and, if such exclusive ap-
13 proval or licensure has been granted, recognized, or
14 applied, shall revoke such exclusive approval or licen-
15 sure, unless the sponsor of the application for such
16 drug demonstrates—

17 “(A) with respect to an application ap-
18 proved or a license issued after the date of en-
19 actment of this subsection, upon such approval
20 or issuance, that there is no reasonable expecta-
21 tion at the time of such approval or issuance
22 that the cost of developing and making avail-
23 able in the United States such drug for such
24 disease or condition will be recovered from sales
25 in the United States of such drug, taking into

1 account all sales made or reasonably expected
2 to be made within 12 years of first marketing
3 the drug; or

4 “(B) with respect to an application ap-
5 proved or a license issued on or prior to the
6 date of enactment of this subsection, not later
7 than 60 days after such date of enactment, that
8 there was no reasonable expectation at the time
9 of such approval or issuance that the cost of de-
10 veloping and making available in the United
11 States such drug for such disease or condition
12 would be recovered from sales in the United
13 States of such drug, taking into account all
14 sales made or reasonably expected to be made
15 within 12 years of first marketing the drug.

16 “(2) CONSIDERATIONS.—For purposes of sub-
17 paragraphs (A) and (B) of paragraph (1), the Sec-
18 retary and the sponsor of the application for the
19 drug designated for a rare disease or condition de-
20 scribed in such paragraph shall consider sales from
21 all drugs that—

22 “(A) are developed or marketed by the
23 same sponsor or manufacturer of the drug (or
24 a licensor, predecessor in interest, or other re-

1 lated entity to the sponsor or manufacturer);
2 and

3 “(B) are covered by the same designation
4 under section 526.

5 “(3) CRITERIA.—No drug designated under
6 section 526 for a rare disease or condition pursuant
7 to the criteria set forth in subsection (a)(2)(B) of
8 such section shall be eligible for exclusive approval
9 or licensure under this section unless it met such
10 criteria under such subsection on the date on which
11 the drug was approved or licensed.”.

12 (b) RULE OF CONSTRUCTION.—The amendments
13 made in subsection (a) shall apply to any drug that has
14 been or is hereafter designated under section 526 of the
15 Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360bb)
16 for a rare disease or condition pursuant to the criteria
17 under subsection (a)(2)(B) of such section regardless of—

18 (1) the date on which such drug is designated
19 or becomes the subject of a designation request
20 under such section;

21 (2) the date on which such drug is approved
22 under section 505 of such Act (21 U.S.C. 355) or
23 licensed under section 351 of the Public Health
24 Service Act (42 U.S.C. 262) or becomes the subject
25 of an application for such approval or licensure; and

1 (3) the date on which such drug is granted ex-
2 clusive approval or licensure under section 527 of
3 the Federal Food, Drug, and Cosmetic Act (21
4 U.S.C. 360cc) or becomes the subject of a request
5 for such exclusive approval or licensure.

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