

116TH CONGRESS
1ST SESSION

H. R. 4712

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 HOUSE OF REPRESENTATIVES

OCTOBER 17, 2019

Ms. DEAN (for herself, Mr. VEASEY, Mr. CARTER of Georgia, and Mr. MCKINLEY) introduced the following bill; which was referred to the Committee on Energy and Commerce

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)(i) 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 without a time limitation; or

3 “(ii) with respect to an application ap-
4 proved or a license issued on or prior to the
5 date of enactment of this subsection, not later
6 than 60 days after such date of enactment, that
7 there was no reasonable expectation at the time
8 of such approval or issuance that the cost of de-
9 veloping and making available in the United
10 States such drug for such disease or condition
11 would be recovered from sales in the United
12 States of such drug, taking into account all
13 sales made or reasonably expected to be made
14 without a time limitation; and

15 “(B) annually for the duration of the 7-
16 year period described in subsection (a) with re-
17 spect to the drug, that there continues to be no
18 reasonable expectation that the cost of devel-
19 oping and making available in the United
20 States such drug for such disease or condition
21 will be recovered from sales in the United
22 States of such drug, taking into account all
23 sales made or reasonably expected to be made
24 without a time limitation.

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

7 “(A) are developed or marketed by the
8 same sponsor or manufacturer of the drug (or
9 a licensor, predecessor in interest, or other re-
10 lated entity to the sponsor or manufacturer);
11 and

12 “(B) contain the same active moiety as the
13 drug, regardless of whether or not the drugs
14 also contain different or additional active
15 moieties.

16 “(3) CRITERIA.—No drug designated under
17 section 526 for a rare disease or condition pursuant
18 to the criteria set forth in subsection (a)(2)(B) of
19 such section shall be eligible for exclusive approval
20 or licensure under this section unless it met such
21 criteria under such subsection on the date on which
22 the drug was approved or licensed.”.

23 (b) RULE OF CONSTRUCTION.—The amendments
24 made in subsection (a) shall apply to any drug that has
25 been or is hereafter designated under section 526 of the

1 Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360bb)
2 for a rare disease or condition pursuant to the criteria
3 under subsection (a)(2)(B) of such section regardless of—

4 (1) the date on which such drug is designated
5 or becomes the subject of a designation request
6 under such section;

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

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

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