

Union Calendar No. 470

116TH CONGRESS
2^D SESSION

H. R. 4712

[Report No. 116-572]

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

NOVEMBER 16, 2020

Additional sponsors: Mr. TONKO, Mr. KIM, Mr. SOTO, and Mr. TAYLOR

NOVEMBER 16, 2020

Reported with an amendment; committed to the Committee of the Whole House on the State of the Union and ordered to be printed

[Strike out all after the enacting clause and insert the part printed in italic]

[For text of introduced bill, see copy of bill as introduced on October 17, 2019]

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—*

10 *(1) in subsection (a), by striking “Except as pro-*
11 *vided in subsection (b)” and inserting “Except as*
12 *provided in subsection (b) or (f)”;* and

13 *(2) by adding at the end the following:*

14 *“(f) LIMITATIONS ON EXCLUSIVE APPROVAL, CERTIFI-*
15 *CATION, OR LICENSE.—*

16 *“(1) IN GENERAL.—For a 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 such*
19 *section, the Secretary shall not grant, recognize, or*
20 *apply exclusive approval or licensure under sub-*
21 *section (a), and, if such exclusive approval or licen-*
22 *sure has been granted, recognized, or applied, shall re-*
23 *voke such exclusive approval or licensure, unless the*
24 *sponsor of the application for such drug dem-*
25 *onstrates—*

1 “(A) with respect to an application ap-
2 proved or a license issued after the date of enact-
3 ment of this subsection, upon such approval or
4 issuance, that there is no reasonable expectation
5 at the time of such approval or issuance that the
6 cost of developing and making available in the
7 United States such drug for such disease or con-
8 dition will be recovered from sales in the United
9 States of such drug, taking into account all sales
10 made or reasonably expected to be made within
11 12 years of first marketing the drug; or

12 “(B) with respect to an application ap-
13 proved or a license issued on or prior to the date
14 of enactment of this subsection, not later than 60
15 days after such date of enactment, that there was
16 no reasonable expectation at the time of such ap-
17 proval or issuance that the cost of developing
18 and making available in the United States such
19 drug for such disease or condition would be re-
20 covered from sales in the United States of such
21 drug, taking into account all sales made or rea-
22 sonably expected to be made within 12 years of
23 first marketing the drug.

24 “(2) CONSIDERATIONS.—For purposes of sub-
25 paragraphs (A) and (B) of paragraph (1), the Sec-

1 retary and the sponsor of the application for the drug
2 designated for a rare disease or condition described in
3 such paragraph shall consider sales from all drugs
4 that—

5 “(A) are developed or marketed by the same
6 sponsor or manufacturer of the drug (or a licen-
7 sor, predecessor in interest, or other related enti-
8 ty to the sponsor or manufacturer); and

9 “(B) are covered by the same designation
10 under section 526.

11 “(3) CRITERIA.—No drug designated under sec-
12 tion 526 for a rare disease or condition pursuant to
13 the criteria set forth in subsection (a)(2)(B) of such
14 section shall be eligible for exclusive approval or licen-
15 sure under this section unless it met such criteria
16 under such subsection on the date on which the drug
17 was approved or licensed.”.

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

1 (1) *the date on which such drug is designated or*
2 *becomes the subject of a designation request under*
3 *such section;*

4 (2) *the date on which such drug is approved*
5 *under section 505 of such Act (21 U.S.C. 355) or li-*
6 *icensed under section 351 of the Public Health Service*
7 *Act (42 U.S.C. 262) or becomes the subject of an ap-*
8 *plication for such approval or licensure; and*

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

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