H.R. 4712

[Report No. 116–]

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

JULY --, 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.
Be it enacted by the Senate and House of Representa-
tives of the United States of America in Congress assembled,

SECTION 1. SHORT TITLE.

This Act may be cited as the “Fairness in Orphan
Drug Exclusivity Act”.

SEC. 2. LIMITATIONS ON EXCLUSIVE APPROVAL OR LICEN-
SURE 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), by striking “Except as pro-
vided in subsection (b)” and inserting “Except as
provided in subsection (b) or (f)”; and

(2) by adding at the end the following:

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

“(1) In General.—For a drug designated under
section 526 for a rare disease or condition pursuant
to the criteria set forth in subsection (a)(2)(B) of such
section, the Secretary shall not grant, recognize, or
apply exclusive approval or licensure under sub-
section (a), and, if such exclusive approval or licen-
sure has been granted, recognized, or applied, shall re-
voke such exclusive approval or licensure, unless the
sponsor of the application for such drug dem-
onstrates—
“(A) with respect to an application approved or a license issued after the date of enactment of this subsection, upon such approval or issuance, that there is no reasonable expectation at the time of such approval or issuance that the cost of developing and making available in the United States such drug for such disease or condition will be recovered from sales in the United States of such drug, taking into account all sales made or reasonably expected to be made within 12 years of first marketing the drug; or

“(B) with respect to an application approved or a license issued on or prior to the date of enactment of this subsection, not later than 60 days after such date of enactment, that there was no reasonable expectation at the time of such approval or issuance that the cost of developing and making available in the United States such drug for such disease or condition would be recovered from sales in the United States of such drug, taking into account all sales made or reasonably expected to be made within 12 years of first marketing the drug.

“(2) CONSIDERATIONS.—For purposes of subparagraphs (A) and (B) of paragraph (1), the Sec-
retary and the sponsor of the application for the drug
designated for a rare disease or condition described in
such paragraph shall consider sales from all drugs
that—

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

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

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

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

(2) the date on which such drug is 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) or becomes the subject of an application for such approval or licensure; and

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