116TH CONGRESS
2D SESSION

H. R. 4712

AN ACT

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 Representatives 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 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), by striking ''Except as provided 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, CERTIFICATION, 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 subsection (a), and, if such exclusive approval or licensure has been granted, recognized, or applied, shall revoke such exclusive approval or licensure, unless the sponsor of the application for such drug demonstrates—

''(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 Secretary and the sponsor of the application for the drug designated for a rare disease or condition de-

scribed 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 licensor, predecessor in interest, or other related entity to the sponsor or manufacturer); and

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

"(3) CRITERIA.—No 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 shall be eligible for exclusive approval or licensure 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 subsection (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.

SEC. 3. DETERMINATION OF BUDGETARY EFFECTS.

The budgetary effects of this Act, for the purpose of complying with the Statutory Pay-As-You-Go Act of 2010, shall be determined by reference to the latest statement titled ''Budgetary Effects of PAYGO Legislation'' for this Act, submitted for printing in the Congressional Record by the Chairman of the House Budget Committee, provided that such statement has been submitted prior to the vote on passage.

Passed the House of Representatives November 17, 2020.

Attest:

Clerk.

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