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118TH CONGRESS
1ST SESSION

H. R. 456

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

JANUARY 24, 2023

Mr. CARTER of Georgia introduced the following bill; which was referred to the Committee on Energy and Commerce

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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 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.

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 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 reason-

ably expected to be made within 12 years of first marketing the drug.

''(2) CONSIDERATIONS.—For purposes of paragraph (1), the Secretary 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 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.''.

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