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(Original Signature of Member)

118TH CONGRESS  
1ST SESSION

**H. R.** \_\_\_\_\_

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.

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IN THE HOUSE OF REPRESENTATIVES

Mr. CARTER of Georgia introduced the following bill; which was referred to the Committee on \_\_\_\_\_

\_\_\_\_\_  
**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”.

1 **SEC. 2. LIMITATIONS ON EXCLUSIVE APPROVAL OR LICEN-**  
2 **SURE OF ORPHAN DRUGS.**

3 Section 527 of the Federal Food, Drug, and Cosmetic  
4 Act (21 U.S.C. 360cc) is amended—

5 (1) in subsection (a), by striking “Except as  
6 provided in subsection (b)” and inserting “Except as  
7 provided in subsection (b) or (f)”; and

8 (2) by adding at the end the following:

9 “(f) LIMITATIONS ON EXCLUSIVE APPROVAL, CER-  
10 TIFICATION, OR LICENSE.—

11 “(1) IN GENERAL.—For a drug designated  
12 under section 526 for a rare disease or condition  
13 pursuant to the criteria set forth in subsection  
14 (a)(2)(B) of such section, the Secretary shall not  
15 grant, recognize, or apply exclusive approval or licen-  
16 sure under subsection (a), and, if such exclusive ap-  
17 proval or licensure has been granted, recognized, or  
18 applied, shall revoke such exclusive approval or licen-  
19 sure, unless the sponsor of the application for such  
20 drug demonstrates with respect to an application ap-  
21 proved or a license issued after the date of enact-  
22 ment of this subsection, upon such approval or  
23 issuance, that there is no reasonable expectation at  
24 the time of such approval or issuance that the cost  
25 of developing and making available in the United  
26 States such drug for such disease or condition will

1 be recovered from sales in the United States of such  
2 drug, taking into account all sales made or reason-  
3 ably expected to be made within 12 years of first  
4 marketing the drug.

5 “(2) CONSIDERATIONS.—For purposes of para-  
6 graph (1), the Secretary and the sponsor of the ap-  
7 plication for the drug designated for a rare disease  
8 or condition described in such paragraph shall con-  
9 sider sales from all drugs that—

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

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

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