[~116H938RH]

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(Original Signature of Member)

117TH CONGRESS
1ST SESSION

H. R. 2853

To amend the Federal Food, Drug, and Cosmetic Act, with respect to eligibility for approval of a subsequent generic drug, to remove the barrier to that approval posed by the 180-day exclusivity period afforded to a first generic applicant that has not yet received final approval, and for other purposes.

IN THE HOUSE OF REPRESENTATIVES

Mr. SCHRADER 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 eligibility for approval of a subsequent generic drug, to remove the barrier to that approval posed by the 180-day exclusivity period afforded to a first generic applicant that has not yet received final approval, 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 ''Bringing Low-cost Options and Competition while Keeping Incentives for New Generics Act of 2021'' or the ''BLOCKING Act of 2021''.

SEC. 2. CHANGE CONDITIONS OF FIRST GENERIC EXCLUSIVITY TO SPUR ACCESS AND COMPETITION.

Clause (iv) of section 505(j)(5)(B) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355(j)(5)(B)) is amended—

(1) in subclause (I), after ''180 days after the date of the first commercial marketing of the drug (including the commercial marketing of the listed drug) by any first applicant'' by inserting ''or by an applicant whose application is approved pursuant to subclause (III)''; and

(2) by adding at the end the following new subclause:

''(III) APPLICANT APPROVAL.—An application containing a certification described in paragraph (2)(A)(vii)(IV) that is for a drug for which a first applicant has submitted an application containing such a certification can be approved notwithstanding the eligibility of a first applicant for the 180-day exclusivity period described in subclause (II)(aa) if each of the following conditions is met:

''(aa) The approval of such an application could be made effective, but for the eligibility of a first applicant for 180-day exclusivity under this clause.

''(bb) At least 30 months have passed since the date of submission of an application for the drug by at least one first applicant.

''(cc) Approval of an application for the drug submitted by at least one first applicant is not precluded under clause (iii).

''(dd) No application for the drug submitted by any first applicant is approved at the time the conditions under items (aa), (bb), and (cc) are all met, regardless of whether such an application is subsequently approved.''.