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117TH CONGRESS
1ST SESSION

S. 1645

To provide for an accelerated approval pathway for certain drugs that are authorized to be lawfully marketed in other countries.

IN THE SENATE OF THE UNITED STATES

MAY 13, 2021

Mr. BRAUN introduced the following bill; which was read twice and referred to the Committee on Health, Education, Labor, and Pensions

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A BILL

To provide for an accelerated approval pathway for certain drugs that are authorized to be lawfully marketed in other countries.

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 ''Accelerated Drug Approval for Prescription Therapies Act'' or the ''ADAPT Act''.

SEC. 2. ACCELERATED APPROVAL OF CERTAIN DRUGS THAT ARE AUTHORIZED TO BE LAWFULLY MARKETED IN OTHER COUNTRIES.

Chapter V of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 351 et seq.) is amended by inserting after section 506 the following:

"SEC. 506–1. ACCELERATED APPROVAL OF CERTAIN DRUGS THAT ARE AUTHORIZED TO BE LAWFULLY MARKETED IN OTHER COUNTRIES.

''(a) IN GENERAL.—The Secretary may approve an application for approval for a drug under subsection (c) or (j) of section 505 that is currently authorized to be marketed in one or more of the countries included in the list under section 802(b)(1), upon a determination by the Secretary that the sponsor has submitted evidence sufficient to demonstrate all of the criteria under subsection (b)(1).

''(b) CRITERIA.—

''(1) IN GENERAL.—The Secretary may approve a drug under subsection (a) only if the Secretary determines that there is evidence that—

''(A) at the time of application, the drug is authorized to be marketed in a country included in the list under section 802(b)(1);

"(B) the drug is safe and clinically effective and has a satisfactory history of clinical trials and data;

"(C) the manufacturer is capable of manufacturing the drug safely and consistently, and can assure the safety of the supply chain outside the United States;

"(D) all relevant United States patents or legal exclusivities are expired;

"(E) absent reciprocal marketing approval, the drug is not approved for marketing in the United States;

"(F) the Secretary has not, because of any concern relating to safety or effectiveness, rescinded or withdrawn any such approval; and

"(G) there is a public health or unmet medical need for the drug in the United States.

"(2) LIMITATION.—Approval of a drug under this section may, as the Secretary determines appropriate, be subject to 1 or both of the following requirements:

"(A) The sponsor conduct appropriate postapproval studies to verify and describe the predicted effect on irreversible morbidity or mortality or other clinical benefit of the drug.

''(B) The sponsor submit copies of all promotional materials related to the product during the preapproval review period and, following approval and for such period thereafter as the Secretary determines to be appropriate, at least 30 days prior to dissemination of the materials.

''(c) TIMELINE.—The Secretary shall make a determination on an application described in subsection (a) not later than 180 days after the date of submission of such application.''.

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