118TH CONGRESS
1ST SESSION

S. 1120

To improve the actions available to eligible product developers in the event of delays in receiving covered product for purposes of generic drug or biosimilar biological product development.

IN THE SENATE OF THE UNITED STATES

MARCH 30, 2023

Ms. HASSAN (for herself and 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 improve the actions available to eligible product developers in the event of delays in receiving covered product for purposes of generic drug or biosimilar biological product development.

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 ''Improved Access to Affordable Medications Act''.

SEC. 2. AMENDMENTS TO ACTIONS FOR DELAYS OF GENERIC DRUGS AND BIOSIMILAR BIOLOGICAL PRODUCTS.

Section 610 of division N of the Further Consolidated Appropriations Act, 2020 (Public Law 116–94; 21 U.S.C. 355–2) is amended—

(1) in subsection (a)—

(A) in paragraph (1)(C)—

(i) by inserting ''or contractual terms'' after ''additional conditions''; and

(ii) by inserting ''by the license holder'' after ''covered product'';

(B) in paragraph (2)(A)(iii), by striking ''including any device'' and inserting ''including any packaging, device, or accessory'';

(C) by redesignating paragraphs (3) through (10) as paragraphs (4) through (11), respectively;

(D) by inserting after paragraph (3) the following:

''(4) the term 'designated delivery service' means any delivery service provided by a trade or business that the Secretary determines—

''(A) is available to the general public throughout the United States;

''(B) records electronically to its database, kept in the regular course of its business, or marks on the cover in which any item referred to in this section is to be delivered, the date on which such item was given to such trade or business for delivery; and

''(C) provides overnight or 2-day delivery service throughout the United States;'';

(E) in paragraph (6), as so redesignated, by inserting ''including the parent company of such holder'' after ''covered product''; and

(F) in paragraph (11), as so redesignated—

(i) in subparagraph (A), in the matter preceding clause (i), by inserting '', at any time,'' after ''conduct testing''; and

(ii) in subparagraph (B), by inserting '', at any time,'' after ''fulfill'';

(2) in subsection (b)(2)—

(A) in subparagraph (A)(iii)—

(i) in the matter preceding subclause (I), by striking ''a written request to purchase sufficient quantities of the covered product to the license holder, and such request—'' and inserting ''one or more writ-

ten requests to purchase sufficient quantities of the covered product to the license holder for the relevant stage of development, and each such request—''; and

(ii) in subclause (II), by inserting ''or by a designated delivery service'' before the semicolon at the end; and

(B) in subparagraph (B), by amending clause (ii) to read as follows:

''(ii) AUTHORIZATION.—The Secretary shall, by written notice, authorize the eligible product developer to obtain sufficient quantities of an individual covered product subject to a REMS with ETASU for purposes of development and testing—

''(I) in the case of development and testing that does not involve human clinical trials, not later than 60 days after the date on which a request under clause (i) is received, if the eligible product developer has agreed to comply with any conditions the Secretary determines necessary; or

''(II) in the case of development and testing that involves human clin-

ical trials, not later than 120 days after the date on which a request under clause (i) is received, if the eligible product developer has—

"(aa)(AA) submitted protocols, informed consent documents, and informational materials for testing that include protections that provide safety protections comparable to those provided by the REMS for the covered product; or

"(BB) otherwise satisfied the Secretary that such protections will be provided; and

"(bb) met any other requirements the Secretary may establish."; and

(3) by adding at the end the following:

"(h) SAMPLES ACCESS POLICY.—Not later than 45 days after the date of approval of a covered product, or, in the case of a covered product approved before the date of enactment of the Improved Access to Affordable Medications Act, not later than 45 days after such date of enactment, each license holder of a covered product shall

make available its policy on evaluating and responding to requests submitted under subsection (b)(2)(A). Such policy shall—

''(1) be made public and readily available, such as by posting such policy on a publicly available website; and

''(2) shall include—

''(A) contact information for the license holder to facilitate communication about written requests described in subsection (b)(2)(A)(iii);

''(B) procedures for making such requests;

''(C) the address to which such requests should be sent;

''(D) the official license holder for each marketed product; and

''(E) the named corporate officer who is responsible for receiving such requests.''.

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