

118TH CONGRESS
1ST SESSION

S. _____

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

Ms. HASSAN (for herself and Mr. BRAUN) introduced the following bill; which was read twice and referred to the Committee on _____

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.

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 “Improved Access to
5 Affordable Medications Act”.

1 **SEC. 2. AMENDMENTS TO ACTIONS FOR DELAYS OF GE-**
2 **NERIC DRUGS AND BIOSIMILAR BIOLOGICAL**
3 **PRODUCTS.**

4 Section 610 of division N of the Further Consolidated
5 Appropriations Act, 2020 (Public Law 116–94; 21 U.S.C.
6 355–2) is amended—

7 (1) in subsection (a)—

8 (A) in paragraph (1)(C)—

9 (i) by inserting “or contractual
10 terms” after “additional conditions”; and

11 (ii) by inserting “by the license hold-
12 er” after “covered product”;

13 (B) in paragraph (2)(A)(iii), by striking
14 “including any device” and inserting “including
15 any packaging, device, or accessory”;

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

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

21 “(4) the term ‘designated delivery service’
22 means any delivery service provided by a trade or
23 business that the Secretary determines—

24 “(A) is available to the general public
25 throughout the United States;

1 ten requests to purchase sufficient quan-
2 tities of the covered product to the license
3 holder for the relevant stage of develop-
4 ment, and each such request—”; and

5 (ii) in subclause (II), by inserting “or
6 by a designated delivery service” before the
7 semicolon at the end; and

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

10 “(ii) AUTHORIZATION.—The Sec-
11 retary shall, by written notice, authorize
12 the eligible product developer to obtain suf-
13 ficient quantities of an individual covered
14 product subject to a REMS with ETASU
15 for purposes of development and testing—

16 “(I) in the case of development
17 and testing that does not involve
18 human clinical trials, not later than
19 60 days after the date on which a re-
20 quest under clause (i) is received, if
21 the eligible product developer has
22 agreed to comply with any conditions
23 the Secretary determines necessary; or

24 “(II) in the case of development
25 and testing that involves human clin-

1 ical trials, not later than 120 days
2 after the date on which a request
3 under clause (i) is received, if the eli-
4 gible product developer has—

5 “(aa)(AA) submitted proto-
6 cols, informed consent docu-
7 ments, and informational mate-
8 rials for testing that include pro-
9 tections that provide safety pro-
10 tections comparable to those pro-
11 vided by the REMS for the cov-
12 ered product; or

13 “(BB) otherwise satisfied
14 the Secretary that such protec-
15 tions will be provided; and

16 “(bb) met any other require-
17 ments the Secretary may estab-
18 lish.”; and

19 (3) by adding at the end the following:

20 “(h) SAMPLES ACCESS POLICY.—Not later than 45
21 days after the date of approval of a covered product, or,
22 in the case of a covered product approved before the date
23 of enactment of the Improved Access to Affordable Medi-
24 cations Act, not later than 45 days after such date of en-
25 actment, each license holder of a covered product shall

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

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

7 “(2) shall include—

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

11 “(B) procedures for making such requests;

12 “(C) the address to which such requests
13 should be sent;

14 “(D) the official license holder for each
15 marketed product; and

16 “(E) the named corporate officer who is
17 responsible for receiving such requests.”.