I

116TH CONGRESS
2D SESSION

H. R. 8190

To amend the Public Health Service Act to deem any insulin that is determined by the Secretary to be biosimilar to the reference product to be interchangeable with the reference product, and for other purposes.

IN THE HOUSE OF REPRESENTATIVES

SEPTEMBER 8, 2020

Mr. GROTHMAN introduced the following bill; which was referred to the Committee on Energy and Commerce

---

A BILL

To amend the Public Health Service Act to deem any insulin that is determined by the Secretary to be biosimilar to the reference product to be interchangeable with the reference product, 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 ''Biosimilar Insulin Access Act of 2020''.

SEC. 2. DEEMING BIOSIMILAR INSULIN TO BE INTERCHANGEABLE.

(a) IN GENERAL.—Section 351(k)(3) of the Public Health Service Act (42 U.S.C. 262(k)(3)) is amended by adding at the end the following:

''(B) BIOSIMILAR INSULIN.—

''(i) DEEMED INTERCHANGEABLE.—Notwithstanding paragraph (4), an insulin is deemed to be interchangeable with the reference product if the insulin is determined by the Secretary to be biosimilar to the reference product.

''(ii) SHORTENING EXCLUSIVITY FOR FIRST INTERCHANGEABLE PRODUCT.—

''(I) ACTION INSTITUTED.—If an action is instituted under subsection (l)(6) against the applicant that submitted the application for an insulin that is the first approved interchangeable biosimilar biological product, paragraph (6) shall apply with respect to such insulin without regard to paragraph (6)(A).

''(II) ACTION NOT INSTITUTED.—If such an action is not instituted with respect to an insulin

that is approved as an interchangeable biosimilar biological product, the Secretary shall make a determination on the interchangeability of any second or subsequent biological product without regard to the delay otherwise required by paragraph (6).

''(iii) APPLICABILITY.—Clause (i) applies without regard to whether the insulin is determined to be biosimilar to the reference product, or deemed to be licensed pursuant to this section, before or after the date of enactment of the Biosimilar Insulin Access Act of 2020.''.

(b) CONFORMING CHANGES.—Section 351(k)(3) of the Public Health Service Act (42 U.S.C. 262(k)(3)) is amended—

(1) by striking ''Upon review'' and inserting the following:

''(A) IN GENERAL.—Upon review'';

(2) by striking ''(A) the Secretary'' and inserting the following:

''(i) the Secretary'';

(3) by striking ''(i) is biosimilar'' and inserting the following:

"(I) is biosimilar";

(4) by striking "(ii) can be" and inserting the following:

"(II) can be"; and

(5) by striking "(B) the applicant" and inserting the following:

"(ii) the applicant".

○