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116TH CONGRESS
2D SESSION

H. R. 6155

To amend the Biologics Price Competition and Innovation Act of 2009 to make improvements with respect to the transition of biological products, and for other purposes.

IN THE HOUSE OF REPRESENTATIVES

MARCH 9, 2020

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

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A BILL

To amend the Biologics Price Competition and Innovation Act of 2009 to make improvements with respect to the transition of biological products, 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. STREAMLINING THE TRANSITION OF BIOLOGICAL PRODUCTS.

(a) CONTINUED REVIEW OF CERTAIN APPLICATIONS.—Section 7002(e)(4)(B) of the Biologics Price Competition and Innovation Act of 2009 (Public Law 111–148) is amended—

(1) by striking clauses (i), (ii), and (vi); and

(2) by inserting before clause (iii) the following:

''(i) IN GENERAL.—With respect to an application for a biological product submitted under subsection (b) or (j) of section 505 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355) that is filed not later than March 23, 2019, and that is pending (or tentatively approved) as of March 23, 2020—

''(I) the Secretary shall continue to review such application under such section 505, even if such review continues after March 23, 2020; and

''(II) upon approval of such application, such application shall be deemed to be a license for the biological product under section 351 of the Public Health Service Act, pursuant to subparagraph (A), and any period of exclusivity, as applicable, shall be determined in accordance with such section.

''(ii) TREATMENT OF LISTED DRUGS.—With respect to a drug that is a biological product that has been deemed li-

censed under section 351 of the Public Health Service Act (42 U.S.C. 262) pursuant to subparagraph (A) and that is referenced in an application described in clause (i), such drug shall—

"(I) continue to be identified as a listed drug on the list published pursuant to section 505(j)(7) of the Federal Food, Drug, and Cosmetic Act, and the information for such drug on such list shall not be revised (or removed) unless and until the date on which each application described in clause (i) that references such drug is—

"(aa) no longer pending review (or the approval of such drug is tentative) under section 505 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355); or

"(bb) removed from such list in accordance with subparagraph (C) of such section 505(j)(7);

"(II) be subject only to requirements applicable to biological products licensed under section 351 of the Public Health Service Act (42 U.S.C. 262); and

"(III) be deemed to be a reference product under such section 351 on the date on which the last application described in clause (i) that references such drug is no longer pending review (or tentatively approved) under section 505 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355).".

(b) CERTAIN INSULIN PRODUCTS DEEMED INTERCHANGEABLE BIOSIMILARS.—Section 7002(e)(4) of the Biologics Price Competition and Innovation Act of 2009 (Public Law 111–148) is amended by adding at the end the following:

"(C) CERTAIN INSULIN PRODUCTS DEEMED INTERCHANGEABLE BIOSIMILARS.—

"(i) IN GENERAL.—In carrying out subparagraph (A), a covered insulin product shall be deemed to be an interchangeable biosimilar biological product licensed

under section 351(k) of the Public Health Service Act.

''(ii) DEFINITIONS.—In this subparagraph:

''(I) The terms 'biosimilar' and 'interchangeable' have the meaning given such terms in section 351(i) of the Public Health Service Act.

''(II) The term 'covered insulin product' means a biological product (including a chemically synthesized polypeptide) that is—

''(aa) an insulin product; and

''(bb) approved under section 505 of the Federal Food, Drug, and Cosmetic Act pursuant to an application submitted under subsection (b)(2) of such section.''.

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