116TH CONGRESS
1ST SESSION

S. 1140

To amend the Public Health Service Act with respect to the treatment under section 351(k)(7) of such Act (relating to exclusivity for reference products) of certain products deemed to have a biological product license pursuant to section 7002 of the Biologics Price Competition and Innovation Act of 2009.

IN THE SENATE OF THE UNITED STATES

APRIL 11, 2019

Ms. SMITH (for herself and Mr. CASSIDY) introduced the following bill; which was read twice and referred to the Committee on Health, Education, Labor, and Pensions

---

A BILL

To amend the Public Health Service Act with respect to the treatment under section 351(k)(7) of such Act (relating to exclusivity for reference products) of certain products deemed to have a biological product license pursuant to section 7002 of the Biologics Price Competition and Innovation Act of 2009.

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 ''Protecting Access to Biosimilars Act of 2019''.

SEC. 2. TREATMENT OF BIOLOGICAL PRODUCTS DEEMED LICENSED.

Section 351(k)(7) of the Public Health Service Act (42 U.S.C. 262(k)(7)) is amended by adding at the end the following:

''(D) DEEMED LICENSES.—

''(i) NO ADDITIONAL EXCLUSIVITY THROUGH DEEMING.—An approved application that is deemed to be a license for a biological product under this section pursuant to section 7002(e)(4) of the Biologics Price Competition and Innovation Act of 2009 shall not be treated as having been first licensed under subsection (a) for purposes of subparagraphs (A) and (B).

''(ii) LIMITATION ON EXCLUSIVITY APPLIES TO ANY REFERENCE PRODUCT.—Subparagraph (C) shall apply to any reference product, without regard to whether—

''(I) such product was first licensed under subsection (a); or

''(II) the approved application for such product was deemed to be a li-

cense for a biological product as described in clause (i).''.

○