

116TH CONGRESS
1ST SESSION

S. _____

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

Ms. SMITH introduced the following bill; which was read twice and referred to the Committee on _____

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.

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 “Protecting Access to
5 Biosimilars Act of 2019”.

1 **SEC. 2. TREATMENT OF BIOLOGICAL PRODUCTS DEEMED**
2 **LICENSED.**

3 Section 351(k)(7) of the Public Health Service Act
4 (42 U.S.C. 262(k)(7)) is amended by adding at the end
5 the following:

6 “(D) DEEMED LICENSES.—

7 “(i) NO ADDITIONAL EXCLUSIVITY
8 THROUGH DEEMING.—An approved appli-
9 cation that is deemed to be a license for a
10 biological product under this section pursu-
11 ant to section 7002(e)(4) of the Biologics
12 Price Competition and Innovation Act of
13 2009 shall not be treated as having been
14 first licensed under subsection (a) for pur-
15 poses of subparagraphs (A) and (B).

16 “(ii) LIMITATION ON EXCLUSIVITY AP-
17 PLIES TO ANY REFERENCE PRODUCT.—
18 Subparagraph (C) shall apply to any ref-
19 erence product, without regard to wheth-
20 er—

21 “(I) such product was first li-
22 censed under subsection (a); or

23 “(II) the approved application for
24 such product was deemed to be a li-
25 cense for a biological product as de-
26 scribed in clause (i).”.