

117TH CONGRESS
2D SESSION

S. 4303

To provide for a period of exclusivity for first interchangeable biological products.

IN THE SENATE OF THE UNITED STATES

MAY 25, 2022

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

A BILL

To provide for a period of exclusivity for first interchangeable biological products.

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 “Interchangeable Bio-
5 logics Clarity Act”.

6 **SEC. 2. CLARIFICATIONS TO EXCLUSIVITY PROVISIONS FOR**
7 **FIRST INTERCHANGEABLE BIOSIMILAR BIO-**
8 **LOGICAL PRODUCTS.**

9 Section 351(k)(6) of the Public Health Service Act
10 (42 U.S.C. 262(k)(6)) is amended—

1 (1) in the matter preceding subparagraph (A)—

2 (A) by striking “Upon review of” and in-
3 sserting “The Secretary shall not make approval
4 effective of”;

5 (B) by striking “relying on” and inserting
6 “for an interchangeable biological product that
7 relies on”; and

8 (C) by striking “the Secretary shall not
9 make a determination under paragraph (4) that
10 the second or subsequent biological product is
11 interchangeable for any condition of use”; and

12 (2) in the flush text that follows subparagraph
13 (C), by striking the period and inserting “, and the
14 term ‘first interchangeable biosimilar biological prod-
15 uct’ means any interchangeable biosimilar biological
16 product that is approved on the first day on which
17 such a product is approved as interchangeable with
18 the reference product.”.

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