

117TH CONGRESS  
2D SESSION

**S.** \_\_\_\_\_

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

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IN THE SENATE OF THE UNITED STATES

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Mr. KAINE (for himself, Ms. COLLINS, Ms. HASSAN, and Mr. PORTMAN) introduced the following bill; which was read twice and referred to the Committee on \_\_\_\_\_

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**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.”.