

117TH CONGRESS
2D SESSION

H. R. 7047

To amend title III of the Public Health Service Act with respect to the determination by the Secretary regarding certain biosimilar application elements, and for other purposes.

IN THE HOUSE OF REPRESENTATIVES

MARCH 9, 2022

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

A BILL

To amend title III of the Public Health Service Act with respect to the determination by the Secretary regarding certain biosimilar application elements, and for other purposes.

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 “Lowering Costs by Im-
5 proving Biosimilar Uptake Act”.

1 **SEC. 2. DETERMINATION BY SECRETARY REGARDING CER-**
2 **TAIN BIOSIMILAR APPLICATION ELEMENTS.**

3 Section 351(k)(2)(A)(ii) of the Public Health Service
4 Act (262(k)(2)(A)(ii)) is amended to read as follows:

5 “(ii) DETERMINATION BY SECRETARY
6 REGARDING CERTAIN APPLICATION ELE-
7 MENTS.—

8 “(I) IN GENERAL.—The Sec-
9 retary may determine, in the Sec-
10 retary’s discretion, that an element
11 described in clause (i)(I), or in clause
12 (i)(IV) with respect to the strength of
13 a biological product, is unnecessary in
14 an application submitted under this
15 subsection.

16 “(II) USE OF DETERMINATION.—
17 If the Secretary makes a determina-
18 tion under this clause that informa-
19 tion demonstrating that the strength
20 of the biological product is the same
21 as that of the reference product as de-
22 scribed in clause (i)(IV) is unneces-
23 sary, the term ‘reference product’
24 shall, for purposes of this section with
25 respect to such biological product, in-

- 1 include all applicable strengths of the
- 2 reference product.”.

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