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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

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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.

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 ''Lowering Costs by Improving Biosimilar Uptake Act''.

SEC. 2. DETERMINATION BY SECRETARY REGARDING CERTAIN BIOSIMILAR APPLICATION ELEMENTS.

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

"(ii) DETERMINATION BY SECRETARY REGARDING CERTAIN APPLICATION ELEMENTS.—

"(I) IN GENERAL.—The Secretary may determine, in the Secretary's discretion, that an element described in clause (i)(I), or in clause (i)(IV) with respect to the strength of a biological product, is unnecessary in an application submitted under this subsection.

"(II) USE OF DETERMINATION.—If the Secretary makes a determination under this clause that information demonstrating that the strength of the biological product is the same as that of the reference product as described in clause (i)(IV) is unnecessary, the term 'reference product' shall, for purposes of this section with respect to such biological product, in-

clude all applicable strengths of the reference product.''.

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