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Public Law 117–8
117th Congress

An Act

Apr. 23, 2021
[S. 164]

To educate health care providers and the public on biosimilar biological products, and for other purposes.

Be it enacted by the Senate and House of Representatives of the United States of America in Congress assembled,

Advancing Education on Biosimilars Act of 2021.
42 USC 201 note.

SECTION 1. SHORT TITLE.

This Act may be cited as the "Advancing Education on Biosimilars Act of 2021".

SEC. 2. EDUCATION ON BIOLOGICAL PRODUCTS.

Subpart 1 of part F of title III of the Public Health Service Act (42 U.S.C. 262 et seq.) is amended by adding at the end the following:

42 USC 263–1.

"SEC. 352A. EDUCATION ON BIOLOGICAL PRODUCTS.

"(a) INTERNET WEBSITE.—

"(1) IN GENERAL.—The Secretary may maintain and operate an internet website to provide educational materials for health care providers, patients, and caregivers, regarding the meaning of the terms, and the standards for review and licensing of, biological products, including biosimilar biological products and interchangeable biosimilar biological products.

"(2) CONTENT.—Educational materials provided under paragraph (1) may include—

"(A) explanations of key statutory and regulatory terms, including 'biosimilar' and 'interchangeable', and clarification regarding the use of interchangeable biosimilar biological products;

"(B) information related to development programs for biological products, including biosimilar biological products and interchangeable biosimilar biological products and relevant clinical considerations for prescribers, which may include, as appropriate and applicable, information related to the comparability of such biological products;

"(C) an explanation of the process for reporting adverse events for biological products, including biosimilar biological products and interchangeable biosimilar biological products; and

"(D) an explanation of the relationship between biosimilar biological products and interchangeable biosimilar biological products licensed under section 351(k) and reference products (as defined in section 351(i)), including the standards for review and licensing of each such type of biological product.

"(3) FORMAT.—The educational materials provided under paragraph (1) may be—

"(A) in formats such as webinars, continuing education modules, videos, fact sheets, infographics, stakeholder toolkits, or other formats as appropriate and applicable; and

"(B) tailored for the unique needs of health care providers, patients, caregivers, and other audiences, as the Secretary determines appropriate.

"(4) OTHER INFORMATION.—In addition to the information described in paragraph (2), the Secretary shall continue to publish—

"(A) the action package of each biological product licensed under subsection (a) or (k) of section 351; or

"(B) the summary review of each biological product licensed under subsection (a) or (k) of section 351.

"(5) CONFIDENTIAL AND TRADE SECRET INFORMATION.—This subsection does not authorize the disclosure of any trade secret, confidential commercial or financial information, or other matter described in section 552(b) of title 5.

"(b) CONTINUING EDUCATION.—The Secretary shall advance education and awareness among health care providers regarding biological products, including biosimilar biological products and interchangeable biosimilar biological products, as appropriate, including by developing or improving continuing education programs that advance the education of such providers on the prescribing of, and relevant clinical considerations with respect to, biological products, including biosimilar biological products and interchangeable biosimilar biological products.".

Approved April 23, 2021.

LEGISLATIVE HISTORY—S. 164:

CONGRESSIONAL RECORD, Vol. 167 (2021):
Mar. 3, considered and passed Senate.
Apr. 14, considered and passed House.

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