

117TH CONGRESS  
1ST SESSION

# S. 164

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

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IN THE SENATE OF THE UNITED STATES

FEBRUARY 2, 2021

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

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## A BILL

To educate health care providers and the public on biosimilar biological products, 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 “Advancing Education  
5 on Biosimilars Act of 2021”.

6 **SEC. 2. EDUCATION ON BIOLOGICAL PRODUCTS.**

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

1 **“SEC. 352A. EDUCATION ON BIOLOGICAL PRODUCTS.**

2 “(a) INTERNET WEBSITE.—

3 “(1) IN GENERAL.—The Secretary may main-  
4 tain and operate an internet website to provide edu-  
5 cational materials for health care providers, patients,  
6 and caregivers, regarding the meaning of the terms,  
7 and the standards for review and licensing of, bio-  
8 logical products, including biosimilar biological prod-  
9 ucts and interchangeable biosimilar biological prod-  
10 ucts.

11 “(2) CONTENT.—Educational materials pro-  
12 vided under paragraph (1) may include—

13 “(A) explanations of key statutory and  
14 regulatory terms, including ‘biosimilar’ and  
15 ‘interchangeable’, and clarification regarding  
16 the use of interchangeable biosimilar biological  
17 products;

18 “(B) information related to development  
19 programs for biological products, including bio-  
20 similar biological products and interchangeable  
21 biosimilar biological products and relevant clin-  
22 ical considerations for prescribers, which may  
23 include, as appropriate and applicable, informa-  
24 tion related to the comparability of such biologi-  
25 cal products;

1           “(C) an explanation of the process for re-  
2           porting adverse events for biological products,  
3           including biosimilar biological products and  
4           interchangeable biosimilar biological products;  
5           and

6           “(D) an explanation of the relationship be-  
7           tween biosimilar biological products and inter-  
8           changeable biosimilar biological products li-  
9           censed under section 351(k) and reference  
10          products (as defined in section 351(i)), includ-  
11          ing the standards for review and licensing of  
12          each such type of biological product.

13          “(3) FORMAT.—The educational materials pro-  
14          vided under paragraph (1) may be—

15               “(A) in formats such as webinars, con-  
16               tinuing education modules, videos, fact sheets,  
17               infographics, stakeholder toolkits, or other for-  
18               mats as appropriate and applicable; and

19               “(B) tailored for the unique needs of  
20               health care providers, patients, caregivers, and  
21               other audiences, as the Secretary determines  
22               appropriate.

23          “(4) OTHER INFORMATION.—In addition to the  
24          information described in paragraph (2), the Sec-  
25          retary shall continue to publish—

1           “(A) the action package of each biological  
2           product licensed under subsection (a) or (k) of  
3           section 351; or

4           “(B) the summary review of each biological  
5           product licensed under subsection (a) or (k) of  
6           section 351.

7           “(5) CONFIDENTIAL AND TRADE SECRET IN-  
8           FORMATION.—This subsection does not authorize  
9           the disclosure of any trade secret, confidential com-  
10          mercial or financial information, or other matter de-  
11          scribed in section 552(b) of title 5.

12          “(b) CONTINUING EDUCATION.—The Secretary shall  
13          advance education and awareness among health care pro-  
14          viders regarding biological products, including biosimilar  
15          biological products and interchangeable biosimilar biologi-  
16          cal products, as appropriate, including by developing or  
17          improving continuing education programs that advance  
18          the education of such providers on the prescribing of, and  
19          relevant clinical considerations with respect to, biological  
20          products, including biosimilar biological products and  
21          interchangeable biosimilar biological products.”.

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