II

118TH CONGRESS
1ST SESSION

S. 1522

To require the Secretary of Health and Human Services to conduct a study on the designation of biosimilar biological products as interchangeable.

IN THE SENATE OF THE UNITED STATES

MAY 10, 2023

Mr. MARSHALL 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 require the Secretary of Health and Human Services to conduct a study on the designation of biosimilar biological products as interchangeable.

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

SECTION 1. STUDY ON THE SUBSTITUTION OF INTERCHANGEABLE BIOLOGICAL PRODUCTS.

(a) REPORT ON BIOSIMILAR BIOLOGICAL PRODUCT INTERCHANGEABILITY.—Not later than 4 years after the date of enactment of this Act, the Secretary of Health and Human Services (referred to in this section as the ''Secretary''), acting through the Commissioner of Food and Drugs, shall submit to the Committee on Health, Edu-

cation, Labor, and Pensions of the Senate and the Committee on Energy and Commerce of the House of Representatives a report on the designation of biosimilar biological products as interchangeable, under section 351(k)(4) of the Public Health Service Act (42 U.S.C. 262(k)(4)). Such report shall—

(1) describe any challenges faced by manufacturers in developing and obtaining approval under section 351(k) of such Act for biosimilar biological products that receive such interchangeability designation;

(2) summarize the experience of the Food and Drug Administration in reviewing applications for biosimilar biological products that seek an interchangeability designation, including compared to applications for biosimilar biological products under such section 351(k) that do not seek such designation;

(3) summarize, at a high level, the data and information that the Food and Drug Administration has reviewed to support applications for interchangeability under section 351(k)(4) of such Act, including data from switching studies, and the differences between the findings from such data and information compared to the data and information that the

Food and Drug Administration has reviewed for biosimilar biological products that have not received a designation of interchangeability;

(4) describe the existing authority of the Food and Drug Administration to determine, on a case-by-case basis, the evidence needed to support an interchangeability designation, and how the Food and Drug Administration has used such authority, including the factors that the agency may consider when making those judgements;

(5) describe how the Food and Drug Administration has considered real-world evidence or other data and information, including from use of the biological product in other countries, in determining whether a biosimilar biological product meets the criteria for the interchangeability designation;

(6) describe the differences between the regulatory and scientific considerations for determining a biological product to be interchangeable under section 351(k)(4) of such Act (42 U.S.C. 262(k)(4)) and the system for assigning therapeutic equivalence ratings to drugs approved under section 505 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355); and

(7) assess the uptake of biosimilar biological products, and the impact of the efforts of the Food and Drug Administration to improve adoption of biosimilar biological products through multimedia education and curriculum materials.

(b) STAKEHOLDER INPUT.—For purposes of developing the report described in subsection (a), the Secretary may convene workshops or listening sessions, establish dockets to receive public comment, or use other means to obtain input from interested stakeholders.

(c) INFORMATION DISCLOSURE.—Nothing in this section shall be construed to authorize the disclosure of information that is prohibited from disclosure under section 301(j) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 331(j)) or section 1905 of title 18, United States Code, or subject to withholding under paragraph (4) of section 552(b) of title 5, United States Code (commonly referred to as the ''Freedom of Information Act'').

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