119TH CONGRESS
2D SESSION

S. 4332

To require the Secretary of Health and Human Services to make determinations of the exclusivity periods for which licensed biological products are eligible.

IN THE SENATE OF THE UNITED STATES

APRIL 16 (legislative day, APRIL 14), 2026

Ms. HASSAN (for herself and Mr. BUDD) 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 make determinations of the exclusivity periods for which licensed biological products are eligible.

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 ''Medication Competition Act''.

SEC. 2. DETERMINATION OF REFERENCE PRODUCT EXCLUSIVITY.

Section 351(k)(9)(A)(iv) of the Public Health Service Act (42 U.S.C. 262(k)(9)(A)(iv)) is amended—

(1) by inserting ''determine any applicable exclusivity period under paragraph (6) or (7), and shall'' after ''the Secretary shall'';

(2) by striking the period at the end and inserting '', as follows:''; and

(3) by adding at the end the following:

''(I) EXCLUSIVITY FOR FIRST INTERCHANGEABLE BIOLOGICAL PRODUCTS.—

''(aa) PRODUCTS LICENSED ON OR AFTER THE DATE OF ENACTMENT.—With respect to a biological product licensed under this subsection on or after the date of enactment of the Medication Competition Act, the Secretary shall include on the list published under this subparagraph any applicable exclusivity period under paragraph (6), not later than 30 days after the earliest date on which an expiration date of such an exclusivity period can be known pursuant to paragraph (6).

"(bb) PRODUCTS LICENSED BEFORE THE DATE OF ENACTMENT.—With respect to a biological product licensed under this subsection before the date of enactment of the Medication Competition Act, the Secretary shall include on the list published under this subparagraph any applicable exclusivity period under paragraph (6), not later than 30 days after the later of such date of enactment or the earliest date on which an expiration date of such an exclusivity period can be known pursuant to paragraph (6).

"(II) EXCLUSIVITY FOR REFERENCE PRODUCTS.—

"(aa) PRODUCTS LICENSED ON OR AFTER THE DATE OF ENACTMENT.—With respect to a biological product licensed under subsection (a) on or after the date of enactment of the Medica-

tion Competition Act, the Secretary shall include on the list published under this subparagraph the expiration date of any exclusivity period under paragraph (7), not later than 30 days after licensure of the biological product.

''(bb) PRODUCTS LICENSED BEFORE THE DATE OF ENACTMENT.—With respect to any biological product licensed under subsection (a) before the date of enactment of the Medication Competition Act, the Secretary shall include on the list published under this subparagraph the expiration date of any exclusivity period under paragraph (7), not later than 2 years after such date of enactment.''.

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