II

117TH CONGRESS
2D SESSION

S. 3516

To require the Secretary of Health and Human Services to provide emergency use authorization with respect to certain COVID–19 diagnostic tests approved for use in the European Union.

IN THE SENATE OF THE UNITED STATES

JANUARY 18, 2022

Mr. SASSE 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 provide emergency use authorization with respect to certain COVID–19 diagnostic tests approved for use in the European Union.

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 ''Increase Access to COVID Testing Act''.

SEC. 2. EMERGENCY USE APPROVAL OF CERTAIN COVID–19 TESTS.

(a) IN GENERAL.—For the duration of the public health emergency declared under section 319 of the Public Health Service Act (42 U.S.C. 247d) with respect to COVID–19, the Secretary of Health and Human Services shall authorize the introduction into interstate commerce, pursuant to section 564 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360bbb–3), without regard for any specific criteria under subsection (c)(2) of such section, of any antigen diagnostic test to detect SARS–CoV–2 that is described in subsection (b), upon request by the manufacturer under such section 564.

(b) TESTS DESCRIBED.—An antigen diagnostic test to detect SARS–CoV–2 described in this subsection is such a test—

(1) that is included on the common list of COVID–19 rapid antigen tests of the European Commission Directorate-General for Health and Food Safety; and

(2) for which the emergency use authorization request is for an at-home, or other non-laboratory site, use, without a prescription.

(c) TERMS OF AUTHORIZATION.—

(1) IN GENERAL.—A diagnostic test authorized as described in subsection (a) shall be subject to the

same terms and requirements as other products authorized under section 564 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360bbb–3).

(2) CHANGE IN STATUS IN THE EU.—In the case of an antigen diagnostic test authorized as described in subsection (a), if the European Commission Directorate-General for Health and Food Safety removes such test from the common list described in subsection (b)(1), the Secretary of Health and Human Services, not later than 30 days after such removal from the common list, shall conduct a review of the test to determine whether the emergency use authorization under section 564 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360bbb–3) should continue.

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