II

116TH CONGRESS
2D SESSION

S. 4427

To provide for transparency in emergency use authorization of vaccine products, and for other purposes.

IN THE SENATE OF THE UNITED STATES

AUGUST 4, 2020

Ms. HASSAN (for herself, Mr. BRAUN, and Ms. MURKOWSKI) 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 provide for transparency in emergency use authorization of vaccine products, and for other purposes.

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 ''Safe Authorization for Vaccines during Emergencies Act'' or the ''SAVE Act''.

SEC. 2. TRANSPARENCY IN EMERGENCY USE AUTHORIZATION OF VACCINE PRODUCTS.

(a) EMERGENCY USE AUTHORIZATIONS.—

(1) IN GENERAL.—Section 564 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360bbb–3) is amended by adding at the end the following:

''(n) REQUIREMENTS WITH RESPECT TO VACCINE PRODUCTS DURING PUBLIC HEALTH EMERGENCIES.—

''(1) EMERGENCY MEETING AND RECOMMENDATIONS.—

''(A) EMERGENCY MEETING.—During a public health emergency declared by the Secretary under section 319 of the Public Health Service Act and with respect to a request to authorize the use of an unapproved product that is a vaccine or an unapproved use of an approved product that is a vaccine intended to address the public health threat that is the subject of such public health emergency, prior to authorizing use of such product, subject to subparagraph (B), the Secretary shall convene a meeting at which the Food and Drug Administration and the sponsor of the product present data and information on the product to the Vaccines and Related Biological Products Advisory Committee for the purpose of reviewing and providing recommendations with respect to emergency use of the product.

''(B) EXCEPTION.—If the Secretary, in consultation with the Commissioner, determines that a meeting under subparagraph (A) with respect to a product described in such subparagraph would not be in the public interest, the Secretary may make a determination not to convene such a meeting. In the event that the Secretary determines not to convene such a meeting pursuant to this subparagraph, the Secretary shall issue a report to the Committee on Health, Education, Labor, and Pensions of the Senate and the Committee on Energy and Commerce of the House of Representatives that includes justification and relevant public health grounds for such determination.

''(2) REQUIREMENT TO SEEK LICENSURE.—An authorization under this section with respect to an unapproved product that is a vaccine or an unapproved use of an approved product that is a vaccine shall be conditioned on the sponsor seeking licensure of the product, or the use, as applicable, under section 351 of the Public Health Service Act, at the discretion of the Secretary, within a time period determined by the Secretary.''.

(2) CONFIDENTIAL INFORMATION.—Section 564(h)(1) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360bbb–3(h)(1)) is amended—

(A) by inserting ", including a summary review," after "data or information";

(B) by striking "505(i), 512(j), or 520(g)" and inserting "505, 510(k), 512(j), 513(f), 515, 520(g), or 564 of this Act or section 351 of the Public Health Service Act"; and

(C) by striking "may indirectly reveal the existence of such application" and inserting ", including a summary review, may indirectly reveal the existence of such application or contain data or information submitted in an application under such sections".

(b) RECOMMENDATIONS WITH RESPECT TO VACCINES TO ADDRESS A PUBLIC HEALTH EMERGENCY.—Section 319 of the Public Health Service Act (42 U.S.C. 247d) is amended by adding at the end the following:

"(c) RECOMMENDATIONS.—During a public health emergency declared by the Secretary under subsection (a), not later than 15 days after the authorization under section 564 of the Federal Food, Drug, and Cosmetic Act of an unapproved product that is a vaccine or an unapproved use of an approved product that is a vaccine in-

tended to address the public health threat that is the subject of such public health emergency, the Advisory Committee on Immunization Practices shall submit to the Director of the Centers for Disease Control and Prevention, the Secretary, the Committee on Health, Education, Labor, and Pensions of the Senate, and the Committee on Energy and Commerce of the House of Representatives—

''(1) recommendations regarding vaccination, including prioritization of populations for which the vaccine is authorized; or

''(2) a report recommending that the Secretary seek additional data or information in order for the committees to develop recommendations described in paragraph (1).''.

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