

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

A BILL

To provide for transparency in emergency use authorization of vaccine 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 “Safe Authorization for
5 Vaccines during Emergencies Act” or the “SAVE Act”.

6 **SEC. 2. TRANSPARENCY IN EMERGENCY USE AUTHORIZA-**
7 **TION OF VACCINE PRODUCTS.**

8 (a) EMERGENCY USE AUTHORIZATIONS.—

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

4 “(n) REQUIREMENTS WITH RESPECT TO VACCINE
5 PRODUCTS DURING PUBLIC HEALTH EMERGENCIES.—

6 “(1) EMERGENCY MEETING AND RECOMMENDA-
7 TIONS.—

8 “(A) EMERGENCY MEETING.—During a
9 public health emergency declared by the Sec-
10 retary under section 319 of the Public Health
11 Service Act and with respect to a request to au-
12 thorize the use of an unapproved product that
13 is a vaccine or an unapproved use of an ap-
14 proved product that is a vaccine intended to ad-
15 dress the public health threat that is the sub-
16 ject of such public health emergency, prior to
17 authorizing use of such product, subject to sub-
18 paragraph (B), the Secretary shall convene a
19 meeting at which the Food and Drug Adminis-
20 tration and the sponsor of the product present
21 data and information on the product to the
22 Vaccines and Related Biological Products Advi-
23 sory Committee for the purpose of reviewing
24 and providing recommendations with respect to
25 emergency use of the product.

1 “(B) EXCEPTION.—If the Secretary, in
2 consultation with the Commissioner, determines
3 that a meeting under subparagraph (A) with re-
4 spect to a product described in such subpara-
5 graph would not be in the public interest, the
6 Secretary may make a determination not to
7 convene such a meeting. In the event that the
8 Secretary determines not to convene such a
9 meeting pursuant to this subparagraph, the
10 Secretary shall issue a report to the Committee
11 on Health, Education, Labor, and Pensions of
12 the Senate and the Committee on Energy and
13 Commerce of the House of Representatives that
14 includes justification and relevant public health
15 grounds for such determination.

16 “(2) REQUIREMENT TO SEEK LICENSURE.—An
17 authorization under this section with respect to an
18 unapproved product that is a vaccine or an unap-
19 proved use of an approved product that is a vaccine
20 shall be conditioned on the sponsor seeking licensure
21 of the product, or the use, as applicable, under sec-
22 tion 351 of the Public Health Service Act, at the
23 discretion of the Secretary, within a time period de-
24 termined by the Secretary.”.

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

4 (A) by inserting “, including a summary
 5 review,” after “data or information”;

6 (B) by striking “505(i), 512(j), or 520(g)”
 7 and inserting “505, 510(k), 512(j), 513(f), 515,
 8 520(g), or 564 of this Act or section 351 of the
 9 Public Health Service Act”; and

10 (C) by striking “may indirectly reveal the
 11 existence of such application” and inserting “,
 12 including a summary review, may indirectly re-
 13 veal the existence of such application or contain
 14 data or information submitted in an application
 15 under such sections”.

16 (b) RECOMMENDATIONS WITH RESPECT TO VAC-
 17 CINES TO ADDRESS A PUBLIC HEALTH EMERGENCY.—
 18 Section 319 of the Public Health Service Act (42 U.S.C.
 19 247d) is amended by adding at the end the following:

20 “(c) RECOMMENDATIONS.—During a public health
 21 emergency declared by the Secretary under subsection (a),
 22 not later than 15 days after the authorization under sec-
 23 tion 564 of the Federal Food, Drug, and Cosmetic Act
 24 of an unapproved product that is a vaccine or an unap-
 25 proved use of an approved product that is a vaccine in-

1 tended to address the public health threat that is the sub-
2 ject of such public health emergency, the Advisory Com-
3 mittee on Immunization Practices shall submit to the Di-
4 rector of the Centers for Disease Control and Prevention,
5 the Secretary, the Committee on Health, Education,
6 Labor, and Pensions of the Senate, and the Committee
7 on Energy and Commerce of the House of Representa-
8 tives—

9 “(1) recommendations regarding vaccination,
10 including prioritization of populations for which the
11 vaccine is authorized; or

12 “(2) a report recommending that the Secretary
13 seek additional data or information in order for the
14 committees to develop recommendations described in
15 paragraph (1).”.

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