

116TH CONGRESS  
2D SESSION

# S. 3769

To allow States to approve the use of diagnostic tests during a public health emergency.

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## IN THE SENATE OF THE UNITED STATES

MAY 19, 2020

Mr. CRUZ (for himself, Mr. BRAUN, Mrs. LOEFFLER, and Mr. LEE) 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 allow States to approve the use of diagnostic tests during a public health emergency.

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 “Right to Test Act”.

5 **SEC. 2. STATE APPROVAL OF DIAGNOSTIC TESTS.**

6 (a) IN GENERAL.—Notwithstanding chapter V of the  
7 Federal Food, Drug, and Cosmetic Act (21 U.S.C. 351  
8 et seq.) and section 353 of the Public Health Service Act  
9 (42 U.S.C. 263a), during any public health emergency de-  
10 clared by the Secretary of Health and Human Services

1 (referred to in this section as the “Secretary”) under sec-  
2 tion 319 of the Public Health Service Act (42 U.S.C.  
3 247d) or by a State in accordance with the law of the  
4 State, the public health department of such State (or such  
5 other State entity as designated by the governor of the  
6 State) may clear or approve diagnostic tests or diagnostic  
7 devices, for use in that State during the applicable public  
8 health emergency only.

9 (b) APPLICATION.—An approval or clearance pursu-  
10 ant to subsection (a) may—

11 (1) allow for the preparation, compounding, as-  
12 sembly, propagation, manufacture, development,  
13 sale, distribution, or use of a specified diagnostic  
14 test or diagnostic device to address the health diag-  
15 nostic needs of the State during the public health  
16 emergency;

17 (2) apply to a diagnostic test or diagnostic de-  
18 vice needed to address the health diagnostic needs of  
19 the State during the public health emergency, as de-  
20 termined by the State, including, but not limited to,  
21 a test or device that uses reagents or swabbing (in-  
22 cluding self-swab);

23 (3) apply to the testing of patients if the State  
24 certifies that the test can be validated, as deter-  
25 mined by the State; and

(4) apply to laboratory-developed tests performed by laboratories and hospitals certified under section 353 of the Public Health Service Act (42 U.S.C. 263a), and to such tests performed by clinical laboratory companies.

(c) SUSPENSION ENFORCEMENT BY FDA.—

(1) IN GENERAL.—Except as provided in paragraph (1), with respect to a diagnostic test or diagnostic device approved or cleared by a State pursuant to subsection (a), the Secretary may not, for the duration of the applicable public health emergency engage in any enforcement action—

(A) with respect to the test or device, to the extent that such test or device is distributed and used within the State granting the approval or clearance in accordance with the requirements of the State;

(B) against a State or State entity that clears or approves the test or device in accordance with this section; or

(C) against any State, entity of a State, health care provider, health care facility, laboratory, educational institution, manufacturer, or distributor that prepares, propagates, compounds, assembles, or processes a diagnostic

1 test or diagnostic device by chemical, physical,  
2 biological, or other procedure for such test or  
3 device or develops, manufactures, distributes,  
4 sells, administers, or evaluates such test—

5 (i) within the applicable State in ac-  
6 cordance with the requirements of the  
7 State; or

8 (ii) for the applicable State or individ-  
9 uals or entities that are located within the  
10 applicable State.

11 (2) EXCEPTION.—The provisions of paragraph  
12 (1) shall not apply with respect to a State if the gov-  
13 ernor of the State requests that enforcement con-  
14 tinue in the State during the public health emer-  
15 gency.

16 (d) ACTION BY FDA AFTER PUBLIC HEALTH EMER-  
17 GENCY.—Not later than 180 days after the end of any  
18 public health emergency under which a State exercises its  
19 authority under subsection (a) with respect to a diagnostic  
20 test or diagnostic device, if the Food and Drug Adminis-  
21 tration has not cleared or approved such test or device  
22 under chapter V of the Federal Food, Drug, and Cosmetic  
23 Act, the Secretary shall review and make a final deter-  
24 mination, within such 180-day period, with respect to such  
25 test or device for clearance or approval.

1       (e) DIAGNOSTIC TESTS AND DIAGNOSTIC DE-  
2 VICES.—In this section, the terms “diagnostic test” and  
3 “diagnostic device” include in vitro diagnostic products,  
4 laboratory developed tests, viral tests, serological and anti-  
5 body tests, and any other test used to identify, analyze,  
6 or investigate a disease.

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