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(Original Signature of Member)

117TH CONGRESS
1ST SESSION

H. R. _____

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

IN THE HOUSE OF REPRESENTATIVES

Mr. MCHENRY introduced the following bill; which was referred to the Committee on _____

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-

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

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

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

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

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

4 (4) apply to laboratory-developed tests per-
5 formed by laboratories and hospitals certified under
6 section 353 of the Public Health Service Act (42
7 U.S.C. 263a), and to such tests performed by clin-
8 ical laboratory companies.

9 (c) SUSPENSION ENFORCEMENT BY FDA.—

10 (1) IN GENERAL.—Except as provided in para-
11 graph (1), with respect to a diagnostic test or diag-
12 nostic device approved or cleared by a State pursu-
13 ant to subsection (a), the Secretary may not, for the
14 duration of the applicable public health emergency
15 engage in any enforcement action—

16 (A) with respect to the test or device, to
17 the extent that such test or device is distributed
18 and used within the State granting the approval
19 or clearance in accordance with the require-
20 ments of the State;

21 (B) against a State or State entity that
22 clears or approves the test or device in accord-
23 ance with this section; or

24 (C) against any State, entity of a State,
25 health care provider, health care facility, labora-

1 tory, educational institution, manufacturer, or
2 distributor that prepares, propagates, com-
3 pounds, assembles, or processes a diagnostic
4 test or diagnostic device by chemical, physical,
5 biological, or other procedure for such test or
6 device or develops, manufactures, distributes,
7 sells, administers, or evaluates such test—

8 (i) within the applicable State in ac-
9 cordance with the requirements of the
10 State; or

11 (ii) for the applicable State or individ-
12 uals or entities that are located within the
13 applicable State.

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

19 (d) ACTION BY FDA AFTER PUBLIC HEALTH EMER-
20 GENCY.—Not later than 180 days after the end of any
21 public health emergency under which a State exercises its
22 authority under subsection (a) with respect to a diagnostic
23 test or diagnostic device, if the Food and Drug Adminis-
24 tration has not cleared or approved such test or device
25 under chapter V of the Federal Food, Drug, and Cosmetic

1 Act, the Secretary shall review and make a final deter-
2 mination, within such 180-day period, with respect to such
3 test or device for clearance or approval.

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