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117TH CONGRESS
1ST SESSION

H. R. 719

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

IN THE HOUSE OF REPRESENTATIVES

FEBRUARY 2, 2021

Mr. MCHENRY (for himself, Mr. ROY, and Mr. COMER) introduced the following bill; which was referred to the Committee on Energy and Commerce

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A BILL

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

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 ''Right to Test Act''.

SEC. 2. STATE APPROVAL OF DIAGNOSTIC TESTS.

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

(referred to in this section as the ''Secretary'') under section 319 of the Public Health Service Act (42 U.S.C. 247d) or by a State in accordance with the law of the State, the public health department of such State (or such other State entity as designated by the governor of the State) may clear or approve diagnostic tests or diagnostic devices, for use in that State during the applicable public health emergency only.

(b) APPLICATION.—An approval or clearance pursuant to subsection (a) may—

(1) allow for the preparation, compounding, assembly, propagation, manufacture, development, sale, distribution, or use of a specified diagnostic test or diagnostic device to address the health diagnostic needs of the State during the public health emergency;

(2) apply to a diagnostic test or diagnostic device needed to address the health diagnostic needs of the State during the public health emergency, as determined by the State, including, but not limited to, a test or device that uses reagents or swabbing (including self-swab);

(3) apply to the testing of patients if the State certifies that the test can be validated, as determined 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

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

(i) within the applicable State in accordance with the requirements of the State; or

(ii) for the applicable State or individuals or entities that are located within the applicable State.

(2) EXCEPTION.—The provisions of paragraph (1) shall not apply with respect to a State if the governor of the State requests that enforcement continue in the State during the public health emergency.

(d) ACTION BY FDA AFTER PUBLIC HEALTH EMERGENCY.—Not later than 180 days after the end of any public health emergency under which a State exercises its authority under subsection (a) with respect to a diagnostic test or diagnostic device, if the Food and Drug Administration has not cleared or approved such test or device under chapter V of the Federal Food, Drug, and Cosmetic Act, the Secretary shall review and make a final determination, within such 180-day period, with respect to such test or device for clearance or approval.

(e) DIAGNOSTIC TESTS AND DIAGNOSTIC DEVICES.—In this section, the terms ''diagnostic test'' and ''diagnostic device'' include in vitro diagnostic products, laboratory developed tests, viral tests, serological and antibody tests, and any other test used to identify, analyze, or investigate a disease.

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