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116TH CONGRESS
2D SESSION

H. R. 6839

To direct the Comptroller General of the United States to submit a report describing the response of certain entities to the COVID–19 pandemic with respect to the development, regulatory evaluation, and deployment of diagnostic tests.

IN THE HOUSE OF REPRESENTATIVES

MAY 12, 2020

Ms. SPANBERGER (for herself and Mr. GONZALEZ of Ohio) introduced the following bill; which was referred to the Committee on Energy and Commerce

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A BILL

To direct the Comptroller General of the United States to submit a report describing the response of certain entities to the COVID–19 pandemic with respect to the development, regulatory evaluation, and deployment of diagnostic tests.

Be it enacted by the Senate and House of Representatives of the United States of America in Congress assembled,

SECTION 1. GAO REPORT ON DIAGNOSTIC TESTS.

(a) GAO STUDY.—Not later than 18 months after the date of enactment of this Act, the Comptroller General of the United States shall submit to the Committee on Energy and Commerce of the House of Representatives

and the Committee on Health, Education, Labor and Pensions of the Senate a report describing the response of entities described in subsection (b) to the COVID–19 pandemic with respect to the development, regulatory evaluation, and deployment of diagnostic tests.

(b) ENTITIES DESCRIBED.—Entities described in this subsection include—

(1) laboratories, including public health, academic, clinical, and commercial laboratories;

(2) diagnostic test manufacturers;

(3) State, local, Tribal, and territorial governments; and

(4) the Food and Drug Administration, the Centers for Disease Control and Prevention, the Centers for Medicare & Medicaid Services, the National Institutes of Health, and other relevant Federal agencies, as appropriate.

(c) CONTENTS.—The report under subsection (a) shall include—

(1) a description of actions taken by entities described in subsection (b) to develop, evaluate, and deploy diagnostic tests;

(2) an assessment of the coordination of Federal agencies in the development, regulatory evaluation, and deployment of diagnostic tests;

(3) an assessment of the standards used by the Food and Drug Administration to evaluate diagnostic tests;

(4) an assessment of the clarity of Federal agency guidance related to testing, including the ability for individuals without medical training to understand which diagnostic tests had been evaluated by the Food and Drug Administration;

(5) a description of—

(A) actions taken and clinical processes employed by States and territories that have authorized laboratories to develop and perform diagnostic tests not authorized, approved, or cleared by the Food and Drug Administration, including actions of such States and territories to evaluate the accuracy and sensitivity of such tests; and

(B) the standards used by States and territories when deciding when to authorize laboratories to develop or perform diagnostic tests;

(6) an assessment of the steps taken by laboratories and diagnostic test manufacturers to validate diagnostic tests, as well as the evidence collected by such entities to support validation; and

(7) based on available reports, an assessment of the accuracy and sensitivity of a representative sample of available diagnostic tests.

(d) DEFINITION.—In this section, the term ''diagnostic test'' means an in vitro diagnostic product (as defined in section 809.3(a) of title 21, Code of Federal Regulations) for—

(1) the detection of SARS–CoV–2;

(2) the diagnosis of the virus that causes COVID–19; or

(3) the detection of antibodies specific to SARS–CoV–2, such as a serological test.

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