

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

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.

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. GAO REPORT ON DIAGNOSTIC TESTS.**

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

1 and the Committee on Health, Education, Labor and Pen-
2 sions of the Senate a report describing the response of
3 entities described in subsection (b) to the COVID–19 pan-
4 demic with respect to the development, regulatory evalua-
5 tion, and deployment of diagnostic tests.

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

8 (1) laboratories, including public health, aca-
9 demic, clinical, and commercial laboratories;

10 (2) diagnostic test manufacturers;

11 (3) State, local, Tribal, and territorial govern-
12 ments; and

13 (4) the Food and Drug Administration, the
14 Centers for Disease Control and Prevention, the
15 Centers for Medicare & Medicaid Services, the Na-
16 tional Institutes of Health, and other relevant Fed-
17 eral agencies, as appropriate.

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

20 (1) a description of actions taken by entities de-
21 scribed in subsection (b) to develop, evaluate, and
22 deploy diagnostic tests;

23 (2) an assessment of the coordination of Fed-
24 eral agencies in the development, regulatory evalua-
25 tion, and deployment of diagnostic tests;

1 (3) an assessment of the standards used by the
2 Food and Drug Administration to evaluate diag-
3 nostic tests;

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

9 (5) a description of—

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

18 (B) the standards used by States and ter-
19 ritories when deciding when to authorize labora-
20 tories to develop or perform diagnostic tests;

21 (6) an assessment of the steps taken by labora-
22 tories and diagnostic test manufacturers to validate
23 diagnostic tests, as well as the evidence collected by
24 such entities to support validation; and

1 (7) based on available reports, an assessment of
2 the accuracy and sensitivity of a representative sam-
3 ple of available diagnostic tests.

4 (d) DEFINITION.—In this section, the term “diag-
5 nostic test” means an in vitro diagnostic product (as de-
6 fined in section 809.3(a) of title 21, Code of Federal Regu-
7 lations) for—

8 (1) the detection of SARS-CoV-2;

9 (2) the diagnosis of the virus that causes
10 COVID-19; or

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

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