

118TH CONGRESS
1ST SESSION

S. 2672

To require the Secretary of Health and Human Services to develop a strategic framework to improve the development and distribution of diagnostic tests in response to chemical, biological, radiological, or nuclear threats.

IN THE SENATE OF THE UNITED STATES

JULY 27, 2023

Ms. SMITH (for herself and Ms. COLLINS) introduced the following bill; which was read twice and referred to the Committee on Health, Education, Labor, and Pensions

A BILL

To require the Secretary of Health and Human Services to develop a strategic framework to improve the development and distribution of diagnostic tests in response to chemical, biological, radiological, or nuclear threats.

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 “Improving Develop-
5 ment and Distribution of Diagnostic Tests Act”.

1 **SEC. 2. IMPROVING DEVELOPMENT AND DISTRIBUTION OF**
2 **DIAGNOSTIC TESTS.**

3 Section 319B of the Public Health Service Act (42
4 U.S.C. 247d–2) is amended to read as follows:

5 **“SEC. 319B. IMPROVING DEVELOPMENT AND DISTRIBUTION OF**
6 **DIAGNOSTIC TESTS.**

7 “(a) FRAMEWORK.—The Secretary shall develop,
8 make publicly available not later than 1 year after the date
9 of enactment of the Improving Development and Distribu-
10 tion of Diagnostic Tests Act, and update not less fre-
11 quently than every 3 years thereafter, a strategic frame-
12 work for the rapid development, validation, authorization,
13 manufacture, procurement, and distribution of diagnostic
14 tests, and for rapid scaling of testing capacity, in response
15 to chemical, biological, radiological, or nuclear threats, in-
16 cluding infectious diseases for which a public health emer-
17 gency is declared under section 319, or that has signifi-
18 cant potential to cause such a public health emergency.

19 Such strategic framework shall take into consideration—

20 “(1) domestic capacity, including any such ca-
21 pacity established through partnerships with public
22 and private entities pursuant to subsection (c), to
23 support the development, validation, authorization,
24 manufacture, procurement, and distribution of tests;

25 “(2) novel technologies and platforms that may
26 be used to improve testing capabilities, including

1 high-throughput laboratory diagnostics, and point-
2 of-care diagnostics, and any such technologies to im-
3 prove the accessibility of such tests, and facilitate
4 the development and manufacture of diagnostic
5 tests;

6 “(3) medical supply needs related to testing, in-
7 cluding diagnostic testing, equipment, supplies, and
8 component parts, and any potential vulnerabilities
9 related to the availability of such medical supplies
10 and related planning, consistent with section
11 2811(b)(4)(J);

12 “(4) strategies for the rapid and efficient dis-
13 tribution of tests locally, regionally, or nationwide
14 and scaling laboratory testing capacity; and

15 “(5) assessing such strategies through drills
16 and operational exercises carried out under section
17 2811(b)(4)(G), as appropriate.

18 “(b) COORDINATION.—To inform the development
19 and update of the framework under subsection (a), and
20 in carrying out activities to implement such framework,
21 the Secretary shall coordinate with industry, States, local
22 governmental entities, Indian Tribes and Tribal organiza-
23 tions, Urban Indian organizations, and other relevant pub-
24 lic and private entities.

1 “(c) CAPACITY BUILDING.—The Secretary may con-
2 tract with public and private entities, as appropriate, to
3 increase domestic capacity in the rapid development, vali-
4 dation, authorization, manufacture, procurement, and dis-
5 tribution of diagnostic tests, as appropriate, to State,
6 local, and Tribal health departments and other appro-
7 priate entities for immediate public health response activi-
8 ties to address an infectious disease with respect to which
9 a public health emergency is declared under section 319,
10 or that has significant potential to cause such a public
11 health emergency.”.

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