

117TH CONGRESS
2D SESSION

S. 3496

To improve research and development of medical countermeasures for novel pathogens.

IN THE SENATE OF THE UNITED STATES

JANUARY 13 (legislative day, JANUARY 10), 2022

Mr. BRAUN (for himself and Mr. KAINE) introduced the following bill; which was read twice and referred to the Committee on Health, Education, Labor, and Pensions

A BILL

To improve research and development of medical countermeasures for novel pathogens.

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 “Promoting Access to
5 Critical Countermeasures by Ensuring Specimen Samples
6 to Diagnostics Act” or the “Promoting ACCESS to
7 Diagnostics Act”.

1 **SEC. 2. ACCESSING SPECIMEN SAMPLES AND DIAGNOSTIC**
2 **TESTS.**

3 (a) IMPROVING RESEARCH AND DEVELOPMENT OF
4 MEDICAL COUNTERMEASURES FOR NOVEL PATHO-
5 GENS.—

6 (1) SAMPLE ACCESS.—Not later than 1 year
7 after the date of enactment of this Act, the Sec-
8 retary of Health and Human Services (referred to in
9 this subsection as the “Secretary”) shall make pub-
10 licly available policies and procedures related to pub-
11 lic and private entities accessing specimens of, or
12 specimens containing, pathogens or suitable surro-
13 gates for, or alternatives to, such pathogens as the
14 Secretary determines appropriate to support public
15 health preparedness and response activities or bio-
16 medical research for purposes of the development
17 and validation, as applicable, of medical products to
18 address emerging infectious diseases and for use to
19 otherwise respond to emerging infectious diseases.
20 Such policies and procedures shall take into account,
21 as appropriate, any applicable existing Federal re-
22 sources.

23 (2) GUIDANCE.—The Secretary shall issue
24 guidance regarding the procedures for carrying out
25 paragraph (1), including—

1 (A) the method for requesting such sam-
 2 ples;

3 (B) considerations for sample availability
 4 and use of suitable surrogates or alternatives to
 5 such pathogens, as appropriate, including appli-
 6 cable safeguard and security measures; and

7 (C) information required to be provided in
 8 order to receive such samples or suitable surro-
 9 gates or alternatives.

10 (b) EARLIER DEVELOPMENT OF DIAGNOSTIC
 11 TESTS.—Title III of the Public Health Service Act is
 12 amended by inserting after section 319A (42 U.S.C.
 13 247d–1) the following:

14 **“SEC. 319B. EARLIER DEVELOPMENT OF DIAGNOSTIC**
 15 **TESTS.**

16 “The Secretary may contract with public and private
 17 entities, as appropriate, to increase capacity in the rapid
 18 development, validation, manufacture, and dissemination
 19 of diagnostic tests, as appropriate, to State, local, and
 20 Tribal health departments and other appropriate entities
 21 for immediate public health response activities to address
 22 emerging infectious diseases that have significant poten-
 23 tial to cause a public health emergency.”.

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