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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

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A BILL

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

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 ''Promoting Access to Critical Countermeasures by Ensuring Specimen Samples to Diagnostics Act'' or the ''Promoting ACCESS to Diagnostics Act''.

SEC. 2. ACCESSING SPECIMEN SAMPLES AND DIAGNOSTIC TESTS.

(a) IMPROVING RESEARCH AND DEVELOPMENT OF MEDICAL COUNTERMEASURES FOR NOVEL PATHOGENS.—

(1) SAMPLE ACCESS.—Not later than 1 year after the date of enactment of this Act, the Secretary of Health and Human Services (referred to in this subsection as the ''Secretary'') shall make publicly available policies and procedures related to public and private entities accessing specimens of, or specimens containing, pathogens or suitable surrogates for, or alternatives to, such pathogens as the Secretary determines appropriate to support public health preparedness and response activities or biomedical research for purposes of the development and validation, as applicable, of medical products to address emerging infectious diseases and for use to otherwise respond to emerging infectious diseases. Such policies and procedures shall take into account, as appropriate, any applicable existing Federal resources.

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

(A) the method for requesting such samples;

(B) considerations for sample availability and use of suitable surrogates or alternatives to such pathogens, as appropriate, including applicable safeguard and security measures; and

(C) information required to be provided in order to receive such samples or suitable surrogates or alternatives.

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

"SEC. 319B. EARLIER DEVELOPMENT OF DIAGNOSTIC TESTS.

''The Secretary may contract with public and private entities, as appropriate, to increase capacity in the rapid development, validation, manufacture, and dissemination of diagnostic tests, as appropriate, to State, local, and Tribal health departments and other appropriate entities for immediate public health response activities to address emerging infectious diseases that have significant potential to cause a public health emergency.''.

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