II

118TH CONGRESS
1ST SESSION

S. 1441

To establish a Center for Biomedical Innovation and Development in order to accelerate innovation and development of advanced medical countermeasure products.

IN THE SENATE OF THE UNITED STATES

MAY 4, 2023

Mr. CORNYN (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 establish a Center for Biomedical Innovation and Development in order to accelerate innovation and development of advanced medical countermeasure products.

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 ''Accelerating Biomedical Innovation Act''.

SEC. 2. CENTER FOR BIOMEDICAL INNOVATION AND DEVELOPMENT PROGRAM.

Title III of the Public Health Service Act (42 U.S.C. 241 et seq.) is amended by inserting after section 319L–1 the following:

"SEC. 319L–2. CENTER FOR BIOMEDICAL INNOVATION AND DEVELOPMENT PROGRAM.

''(a) ESTABLISHMENT OF CONSORTIUM.—Not later than 1 year after the date of enactment of this section, the Secretary shall establish a consortium of not fewer than 3 institutions of higher education (as defined in section 101 of the Higher Education Act), to accelerate innovation and development of advanced medical countermeasure products, including biological products and devices, selected by the Biomedical Advanced Research and Development Agency (referred to in this section as 'BARDA'). Such consortium shall be known as the Center for Biomedical Innovation and Development (referred to in this section as the 'Center').

''(b) SELECTION OF PARTICIPATING INSTITUTIONS.—In selecting institutions of higher education to participate in the Center under subsection (a), the Secretary shall—

''(1) select eligible institutions that have—

''(A) expertise and capabilities in current good manufacturing practices, as defined in

part 117 of title 21 Code of Federal Regulations (or successor regulations);

''(B) experience in technology innovation, including advanced manufacturing technologies, that may assist in countermeasure and advanced research and development;

''(C) facilities with flexible and adaptable advanced process development capabilities; and

''(D) other relevant qualifications, as determined by the Secretary;

''(2) select at least one institution with the capability to handle secure and classified information, as appropriate; and

''(3) prioritize institutions most likely to aid in the advancement and innovation of the medical countermeasure products, the manufacturing processes for such products, and the execution and design of clinical trials.

''(c) CENTER ACTIVITIES.—The Center established under subsection (a) shall assist public and private entities in accelerating nonclinical research discoveries with respect to medical countermeasures through advanced development and clinical trials. The activities of the Center may include—

''(1) advanced process development and pilot manufacturing to support clinical trials;

''(2) technical assistance;

''(3) contract award management;

''(4) referral and coordination with potential manufacturing partners;

''(5) regulatory assistance;

''(6) technology transfer; and

''(7) program management.

''(d) ELIGIBLE PRODUCTS.—A drug or device (including a combination of one or more drugs or devices) is eligible for consideration and referral by the Director of BARDA to the Center if such drug or device incorporates a novel technology, or uses an established technique or technology in a novel way, that will substantially—

''(1) further development of a drug or device of interest;

''(2) fulfil an unmet need; or

''(3) develop the manufacturing process for a drug or device.

''(e) INTERNATIONAL COORDINATION.—The Director of BARDA, in collaboration with the Assistant Secretary for Global Affairs and the Center established under subsection (a), shall coordinate, as appropriate, with inter-

national partners to enhance global health security by encouraging other initiatives, similar to the program described in subsection (a), under which international advanced development networks support an expanded worldwide strategy for vaccine, drug, device, and other countermeasure research, development, and manufacturing.''.

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