116TH CONGRESS
2D SESSION

S. 3780

To encourage domestic advanced manufacturing of critical drugs and devices in order to address economic, health, and security concerns, combat shortages of critical drugs and devices, and promote increased domestic diversification of, and independence from foreign reliance on, pharmaceutical and medical device supply chains.

IN THE SENATE OF THE UNITED STATES

MAY 20, 2020

Mr. PETERS 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 encourage domestic advanced manufacturing of critical drugs and devices in order to address economic, health, and security concerns, combat shortages of critical drugs and devices, and promote increased domestic diversification of, and independence from foreign reliance on, pharmaceutical and medical device supply chains.

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 ''Help Onshore Manufacturing Efficiencies for Drugs and Devices Act'' or the ''HOME Act''.

SEC. 2. INVESTMENTS IN DOMESTIC ADVANCED MANUFACTURING AND PREPAREDNESS.

Part A of title III of the Public Health Service Act (42 U.S.C. 241 et seq.) is amended by adding at the end the following:

"SEC. 310B. INVESTMENTS IN DOMESTIC ADVANCED MANUFACTURING FOR CRITICAL DRUGS AND DEVICES.

''(a) ESTABLISHMENT.—There is established within the Office of the Assistant Secretary for Preparedness and Response of the Department of Health and Human Services, the 'Center for Domestic Advanced Manufacturing of Critical Drugs and Devices' (referred to in this section as the 'Center').

''(b) PURPOSE.—The purpose of the Center for Domestic Advanced Manufacturing of Critical Drugs and Devices shall be to implement a program to invest in the advanced manufacturing for critical drugs and devices, and to increase domestic production of critical drugs and devices, throughout the United States.

''(c) DIRECTOR.—The Center shall be headed by a Director (referred to in this section as the 'Director') who shall be appointed by the Secretary and to whom the Secretary shall delegate such functions and authorities as may be necessary to implement this section.

''(d) PROGRAM.—

''(1) IN GENERAL.—The Center for Domestic Advanced Manufacturing of Critical Drugs and Devices shall—

''(A) not later than 18 months after the date of enactment of this section—

''(i) establish an advisory board of experts from governmental entities, manufacturers, other private industry entities, nonprofit entities, and institutions of higher education, and any other entity as determined by the Center; and

''(ii) compile a list of critical drugs and devices that should be prioritized for domestic advanced manufacturing and increased domestic production under the program described in paragraph (2), based on reports to the Secretary under sections 506C and 506J of the Federal Food, Drug, and Cosmetic Act, the drug shortage list under section 506E of such Act, the device shortage list under section 506J(g) of such Act, and the annual risk assessments described in section 5 of the HOME Act, if available, and update such list quarterly;

''(B) establish and oversee the grant and forgivable loan program described in paragraph (2), including by establishing requirements for participation in such program, including—

''(i) target goals to substantially increase advanced manufacturing production for critical drugs and devices within the United States; and

''(ii) conditioning the receipt of funding under such program on an entity's agreement to commercially distribute the drug or device in the United States; and

''(C) review the effects of the program described in paragraph (2) on the percentage change in domestic manufacturing of critical drugs, devices, and active pharmaceutical ingredients.

''(2) GRANT AND FORGIVABLE LOAN PROGRAM.—

''(A) IN GENERAL.—The Center for Domestic Advanced Manufacturing of Critical Drugs and Devices shall establish a grant and forgivable loan program in order to support investment in—

"(i) advanced manufacturing and facilities upgrades for the domestic production of critical drugs, devices, and active pharmaceutical ingredients; and

"(ii) increased domestic production and diversification of critical drugs, devices, and active pharmaceutical ingredients.

"(B) ELIGIBLE ENTITIES.—

"(i) IN GENERAL.—To be eligible to receive a grant or forgivable loan under this paragraph, an entity shall meet the requirements established under paragraphs (1)(A)(ii) and (1)(B) and such criteria as the Center shall develop and, as applicable—

"(I) with respect to a critical drug, shall be the holder of an application approved under section 505 of the Federal Food, Drug, and Cosmetic Act or section 351 of this Act, or a contract manufacturer of the drug for such holder of an approved application;

"(II) with respect to an active pharmaceutical ingredient, shall be the manufacturer of an active pharmaceutical ingredient of a drug approved under section 505 of the Federal Food, Drug, and Cosmetic Act or section 351 of this Act;

"(III) with respect to a critical device, shall have received approval under section 515 of the Federal Food, Drug, and Cosmetic Act, clearance under section 510(k) of such Act (or be exempt from the requirements of such section 510(k)), or authorization under section 513(f)(2) of such Act, or shall be a contract manufacturer of the device for such an entity; or

"(IV) with respect to a drug or device, shall have submitted an application under section 505 or 515 of the Federal Food, Drug, and Cosmetic Act or under section 351 of this Act, a report under section 510(k), or a request under section 513(f)(2).

"(ii) PRIORITY.—In awarding grants and forgivable loans under this paragraph the Center for Domestic Advanced Manufacturing of Critical Drugs and Devices shall give priority—

"(I) in the case of manufacturers of drugs or active pharmaceutical ingredients, to entities—

"(aa) described in subclauses (I) and (II) of clause (i); and

"(bb) whose application for an award under this paragraph relates to a drug that was approved under section 505(j) of the Federal Food, Drug, and Cosmetic Act; and

"(II) in the case of manufacturers of devices, to entities described in clause (i)(III).

"(C) USE OF FUNDS.—Awards received under this paragraph shall be used for the advanced manufacturing and increased production of critical drugs and devices in the United States.

"(D) FORGIVABLE LOANS.—The Center may award forgivable loans under this paragraph under which a recipient shall receive a loan and be eligible for forgiveness of indebtedness on such loan, under such conditions for receipt and forgiveness as the Center may establish.

"(E) GRANTS.—The Center may award grants under this section, which shall be conditioned upon the recipient matching Federal funds so awarded.

"(F) FUNDING.—Out of amounts made available to carry out this section, the Secretary shall allocate $500,000,000 toward awards of forgivable loans and grants under this paragraph.

"(e) ANNUAL REPORTING.—The Secretary shall submit to the relevant committees of Congress annual reports on the program under this section. At a minimum, each such report shall—

"(1) identify the list of critical drugs and devices under subsection (d)(1)(A)(ii) and account for any alterations in the list;

''(2) describe the participants in the program under subsection (d)(2) and criteria for eligibility for such participation;

''(3) address target goals for substantially increased advanced manufacturing production for critical drugs and devices; and

''(4) review the percentage change in domestic manufacturing of critical drugs, devices, and active pharmaceutical ingredients since the most recent report.

''(f) INTERAGENCY COOPERATION.—

''(1) IN GENERAL.—In carrying out activities under this section, the Center is authorized, subject to paragraph (2), to enter into interagency agreements and other collaborative undertakings with other Federal agencies.

''(2) LIMITATION.—An agreement or undertaking under this subsection shall not authorize another agency to exercise the authorities provided by this section.

''(g) AUTHORIZATION OF APPROPRIATIONS.—To carry out this section, there is authorized to be appropriated such funds as may be necessary, for each of fiscal years 2021 through 2031.

''(h) DEFINITIONS.—In this section—

''(1) the terms 'drug' and 'device' have the meanings given such terms in section 201 of the Federal Food, Drug, and Cosmetic Act;

''(2) the term 'institution of higher education' has the meaning given such term in section 101(a) of the Higher Education Act of 1965; and

''(3) the term 'relevant committees of Congress' means the Committee on Homeland Security and Governmental Affairs, the Committee on Health, Education, Labor, and Pensions, and the Committee on Armed Services of the Senate and the Committee on Homeland Security, the Committee on Energy and Commerce, and the Committee on Armed Services of the House of Representatives.''.

SEC. 3. EXPEDITED REVIEW OF CERTAIN SUPPLEMENTAL APPLICATIONS.

Section 506 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 356) is amended by adding at the end the following:

''(i) EXPEDITED REVIEW OF CERTAIN SUPPLEMENTAL APPLICATIONS.—

''(1) IN GENERAL.—The holder of an application approved under section 505 of this Act or license under section 351 of the Public Health Service Act who submits a supplemental application with re-

spect to such application or license may request an expedited review of such supplemental application under this subsection.

''(2) APPLICATION.—To be eligible for expedited review under this subsection, the holder of the approved application or license with respect to a drug included on the most recent list of critical drugs and devices compiled under section 310B(d)(1)(A)(ii) of the Public Health Service Act, shall demonstrate in the supplemental application that—

''(A) approval of such supplemental application would enable the incorporation of a manufacturing change that is intended to enhance drug quality, increase domestic manufacturing of the drug, or incorporate the use of advanced manufacturing; and

''(B) the applicant's plan for producing the drug domestically after approval of the supplemental application.

''(3) REVIEW BY SECRETARY.—If the Secretary determines, after preliminary evaluation of a supplemental application, that the application demonstrates that the manufacturing change would enhance the ability of the holder of the application to

domestically manufacture a drug on the list of critical drugs and devices described in paragraph (2), the Secretary shall evaluate for filing, and may commence review of portions of, such supplemental application before the sponsor submits a complete application. The Secretary shall commence such review only if the applicant provides a schedule for submission of information necessary to make the application complete.''.

SEC. 4. LONG-TERM, HIGH-VOLUME CONTRACTS TO PURCHASE CRITICAL DRUGS AND DEVICES.

(a) CONTRACTING GOALS.— In order to further the needs of the Department of Health and Human Services and the Department of Defense, invest in preparedness and the strategic national stockpile, and mitigate drug and device shortages, each of the Secretary of Health and Human Services and the Assistant Secretary of Defense for Health Affairs may enter into contracts to purchase a drug or device included on the list of critical drugs and devices compiled under section 310B(d)(1)(A)(ii) of the Public Health Service Act (as added by section 2), including multi-year, high-volume contracts, as set forth in subsection (b), and otherwise in accordance with procurement laws and regulations.

(b) RESPONSIBILITY DETERMINATIONS.—For purposes of meeting the goals under subsection (a), a contracting officer of the Department of Health and Human Services or the Department of Defense may give preference and award a contract to a program participant under section 310B(d)(2) of the Public Health Service Act (as added by section 2), if—

(1) the program participant is determined by the contracting officer, in consultation with the Center for Domestic Advanced Manufacturing of Critical Drugs and Devices with respect to the participant's performance in the program under section 310B(d)(2) of the Public Health Service Act, to be a responsible source with respect to performance of the contract; and

(2) in the estimation of the contracting officer, the contract award can be made at a fair and reasonable price that offers best value to the United States.

SEC. 5. ANNUAL RISK ASSESSMENT.

(a) IN GENERAL.—Not later than 1 year after the date of enactment of this Act, and annually thereafter, the Secretary of Homeland Security, the Secretary of Health and Human Services, and the Secretary of Defense shall each conduct separate independent risk assessments

of the medical supply chain and report to the relevant committees of Congress on the findings of such assessments. At a minimum, each risk assessment shall—

(1) identify drugs and devices critical to each agency in responding to a public health emergency, biological or chemical threat, or other national security threat;

(2) identify the drugs and devices identified under paragraph (1) for which there is a single manufacturer or distributer in the United States;

(3) list the drugs and devices identified under paragraph (1) that are sourced exclusively from foreign sources;

(4) assess current domestic manufacturing capability with respect to drugs and devices identified under paragraph (1), including advanced manufacturing capabilities; and

(5) identify critical vulnerabilities and establish contingency plans in the event of a public health emergency, biological or chemical threat, or other national security threat.

(b) RISK ASSESSMENT REPORT CONCLUSIONS.—Each risk assessment of each secretary under subsection (a) shall indicate, at a minimum—

(1) the existing statutory authorities the department has to address public health or national security risks that may arise as a result of vulnerabilities in the medical supply chain;

(2) any deficiencies, lack of authorities, or limitations in policy or process that limit the department's ability to address vulnerabilities identified in the applicable risk assessment; and

(3) the secretary's plans to address drug and device shortages, control costs, and prepare for public health emergencies, biological or chemical threats, and other national security threats.

(c) REVIEW BY SECRETARIES.—The Secretary of Homeland Security, the Secretary of Health and Human Services, and the Secretary of Defense, in providing the risk assessments under subsection (a) may consult with each other, as appropriate, regarding any similarities in vulnerabilities experienced by each such secretary and any coordination among the secretaries that may address such vulnerabilities.

(d) DEFINITIONS.—In this section—

(1) the terms ''device'' and ''drug'' have the meanings given such terms in section 201 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 321); and

(2) the term ''relevant committees of Congress'' means the Committee on Homeland Security and Governmental Affairs, the Committee on Health, Education, Labor, and Pensions, and the Committee on Armed Services of the Senate and the Committee on Homeland Security, the Committee on Energy and Commerce, and the Committee on Armed Services of the House of Representatives.

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