118TH CONGRESS
1ST SESSION

S. 2510

To improve supply chain resiliency for critical drug products with vulnerable supply chains and ensure that reserves of critical drugs and active pharmaceutical ingredients are maintained to prevent supply disruptions in the event of drug shortages or public health emergencies.

IN THE SENATE OF THE UNITED STATES

JULY 26, 2023

Mr. PETERS (for himself, Mr. BROWN, and Mrs. BLACKBURN) 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 supply chain resiliency for critical drug products with vulnerable supply chains and ensure that reserves of critical drugs and active pharmaceutical ingredients are maintained to prevent supply disruptions in the event of drug shortages or public health emergencies.

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 ''Rolling Active Pharmaceutical Ingredient and Drug Reserve Act'' or the ''RAPID Reserve Act''.

SEC. 2. ROLLING ACTIVE PHARMACEUTICAL INGREDIENT AND DRUG RESERVE.

(a) IN GENERAL.—The Secretary of Health and Human Services (referred to in this section as the ''Secretary'') shall award contracts or cooperative agreements to eligible entities with respect to drugs and active pharmaceutical ingredients of such drugs that the Secretary determines to be critical and to have vulnerable supply chains. The Secretary shall publish the list of such drugs and active pharmaceutical ingredients of such drugs.

(b) REQUIREMENTS.—

(1) IN GENERAL.—An eligible entity, pursuant to a contract or cooperative agreement under subsection (a), shall agree to—

(A) maintain, in a satisfactory domestic establishment registered under section 510(b) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360(b)) or in a satisfactory foreign establishment registered under section 510(i) of such Act that is located in a country that is a member of the Organisation for Economic Cooperation and Development, which may be an establishment owned and operated by the entity, or by a wholesaler, distributor, or other third-party under contract with the entity, a 6-

month reserve, or other reasonable quantity, as determined by the Secretary, of—

(i) the active pharmaceutical ingredient of the eligible drug specified in the contract or cooperative agreement, which reserve shall be regularly replenished with a recently manufactured supply of such ingredient; and

(ii) the finished eligible drug product specified in the contract or cooperative agreement, which reserve shall be regularly replenished with a recently manufactured supply of such product;

(B) implement production of the eligible drug or an active pharmaceutical ingredient of the eligible drug, at the direction of the Secretary, under the terms of, and in such quantities as specified in, the contract or cooperative agreement; and

(C) enter into an arrangement with the Secretary under which the eligible entity—

(i) agrees to transfer a portion, as determined necessary, of the reserve of active pharmaceutical ingredient maintained pursuant to subparagraph (A)(i) to another

drug manufacturer in the event that the Secretary determines there to be a need for additional finished eligible drug product and such eligible entity is unable to use the reserve of active pharmaceutical ingredient to manufacture a sufficient supply of such drug product; and

(ii) permits the Secretary to direct allocation of the reserve of active pharmaceutical ingredient so maintained in the event of a public health emergency or chemical, biological, radiological, or nuclear threat.

(2) GUIDANCE.—Not later than 180 days after the date of enactment of this Act, the Secretary, in coordination with the Commissioner of Food and Drugs, shall issue guidance on—

(A) the factors the Secretary will use to determine which eligible drugs, or active pharmaceutical ingredient of such drugs, have vulnerable supply chains and how a contract or cooperative agreement would help minimize the vulnerability or vulnerabilities identified;

(B) the factors the Secretary will consider in determining eligibility of an entity to partici-

pate in the program under this section, which shall include an entity's commitment to quality systems, including strong manufacturing infrastructure, reliable processes, and trained staff, as well as the entity's commitment to domestic manufacturing capacity and surge capacity, as appropriate; and

(C) requirements for entities receiving an award under this section, including the extent of excess manufacturing capacity the manufacturers will be required to generate, the amount of redundancy required, and requirements relating to advanced quality systems.

(3) PREFERENCE.—In awarding contracts and cooperative agreements under subsection (a), the Secretary shall give preference to eligible entities that will carry out the requirements of paragraph (1) through one or more domestic establishments registered under section 510(b) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360(b)) capable of manufacturing the eligible drug. To the greatest extent practicable, the Secretary shall award contracts and cooperative agreements with manufacturers in a manner that strengthens domestic manufac-

turing, resiliency, and capacity of eligible drugs and their active pharmaceutical ingredients.

(c) ADDITIONAL CONTRACT AND COOPERATIVE AGREEMENT TERMS.—

(1) IN GENERAL.—Each contract or cooperative agreement under subsection (a) shall be subject to such terms and conditions as the Secretary may specify, including terms and conditions with respect to procurement, maintenance, storage, testing, and delivery of drugs, in alignment with inventory management and other applicable best practices, under such contract or cooperative agreement, which may consider, as appropriate, costs of transporting and handling such drugs.

(2) TERMS CONCERNING THE ACQUISITION, CONSTRUCTION, ALTERATION, OR RENOVATION OF ESTABLISHMENTS.—Notwithstanding section 6303 of title 41, United States Code, the Secretary may award a contract or cooperative agreement under this section to support the acquisition, construction, alteration, or renovation of non-Federally owned establishments—

(A) as determined necessary to carry out or improve preparedness and response capability at the State and local level; or

(B) for the production of drugs, devices, and supplies where the Secretary determines that such a contract or cooperative agreement is necessary to ensure sufficient amounts of such drugs, devices, and supplies.

(d) REQUIREMENTS IN AWARDING CONTRACTS.—To the greatest extent practicable, the Secretary shall award contracts and cooperative agreements under this section in a manner that—

(1) maximizes quality, minimizes cost, minimizes vulnerability of the United States to severe shortages or disruptions for eligible drugs and their active pharmaceutical ingredients, gives preference to domestic manufacturers, and encourages competition in the marketplace; and

(2) increases domestic production surge capacity and reserves of domestic-based manufacturing establishments for critical drugs and active pharmaceutical ingredients of such drugs.

(e) DEFINITIONS.—In this section:

(1) ACTIVE PHARMACEUTICAL INGREDIENT.—The term ''active pharmaceutical ingredient'' has the meaning given such term in section 744A of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 379j–41).

(2) DRUG.—The term ''drug'' has the meaning given such term in section 201(g) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 321(g)).

(3) DRUG SHORTAGE; SHORTAGE.—The term ''drug shortage'' or ''shortage'' has the meaning given such term in section 506C of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 356c).

(4) ELIGIBLE DRUG.—The term ''eligible drug'' means a drug, as determined by the Secretary, in coordination with the with Assistant Secretary for Preparedness and Response, the Director of the Centers for Disease Control and Prevention, and the Commissioner of Food and Drugs—

(A) that is approved under section 505(j) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355(j)) or licensed under section 351(k) of the Public Health Service Act (42 U.S.C. 262(k));

(B)(i) that is reasonably likely to be required to respond to a public health emergency or to a chemical, biological, radiological, or nuclear threat; or

(ii) the shortage of which would pose a significant threat to the United States health care system or at-risk populations; and

(C) that has a vulnerable supply chain, such as a geographic concentration of manufacturing, poor quality or safety issues, complex manufacturing or chemistry, or few manufacturers.

(5) ELIGIBLE ENTITY.—The term ''eligible entity'' means a person that—

(A)(i) is the holder of an approved application under subsection (j) of section 505 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355) or subsection (k) of section 351 of the Public Health Service Act (42 U.S.C. 262) for an eligible drug;

(ii) maintains at least one domestic establishment registered under section 510(b) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360(b)) or one foreign establishment registered under section 510(i) of such Act that is located in a country that is a member of the Organisation for Economic Cooperation and Development that is capable of manufacturing the eligible drug; and

(iii) has a strong record of good manufacturing practices of drugs;

(B)(i) is a manufacturer of an active pharmaceutical ingredient for an eligible drug, in partnership with an entity that meets the requirements of subparagraph (A);

(ii) maintains at least one domestic establishment registered under section 510(b) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360(b)) or one foreign establishment registered under section 510(i) of such Act that is located in a country that is a member of the Organisation for Economic Cooperation and Development that is capable of manufacturing the active pharmaceutical ingredient; and

(iii) has a strong record of good manufacturing practices of active pharmaceutical ingredients; or

(C) is a distributor or wholesaler of an eligible drug, in partnership with an entity that meets the requirements of subparagraph (A).

(f) REPORTS TO CONGRESS.—Not later than 2 years after the date on which the first award is made under this section, and every 2 years thereafter, the Secretary shall submit a report to Congress detailing—

(1) the list of drugs determined to be eligible drugs, as described in subsection (e)(2), and the rationale behind selecting each such drug; and

(2) an update on the effectiveness of the program under this section, in a manner that does not compromise national security.

(g) AUTHORIZATION OF APPROPRIATIONS.—To carry out this section, there is authorized to be appropriated $500,000,000 for fiscal year 2024.

SEC. 3. GAO REPORT.

Not later than 18 months after the date of enactment of this Act, the Comptroller General of the United States shall—

(1) examine, such as through a survey or other means, excess or underutilized domestic manufacturing capacity for critical drugs and active pharmaceutical ingredients of such drugs, including capacity to manufacture different dosage forms, such as oral tablets and sterile injectable drugs, and the capacity to manufacture drugs with various characteristics, such as cytotoxic drugs and drugs requiring lyophilization; and

(2) prepare and submit a report to the Committee on Homeland Security and Governmental Affairs and the Committee on Health, Education,

Labor, and Pensions of the Senate and the Committee on Homeland Security and the Committee on Energy and Commerce of the House of Representatives that—

(A) includes—

(i) the results of the survey under paragraph (1);

(ii) an assessment of projected costs of utilizing and expanding existing domestic manufacturing capabilities and policies, as of the date of the report, that may help establish or strengthen domestic manufacturing capacity for key starting materials, excipients, active pharmaceutical ingredients, and finished dosage manufacturing establishments; and

(iii) an evaluation of policies designed to invest in advanced domestic manufacturing capabilities and capacity for critical active pharmaceutical ingredients and drug products; and

(B) shall be publicly available in an unclassified form, but may include a classified annex

containing any information that the Comptroller General determines to be sensitive.

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