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AMENDMENT NO._____ Calendar No._____

Purpose: To provide for increased manufacturing capacity for certain critical antibiotic drugs.

IN THE SENATE OF THE UNITED STATES—117th Cong., 2d Sess.

S. 3799

To prepare for, and respond to, existing viruses, emerging new threats, and pandemics.

Referred to the Committee on _____ and ordered to be printed

Ordered to lie on the table and to be printed

AMENDMENT intended to be proposed by Ms. SMITH (for herself and Mr. CASSIDY)

Viz:

At the appropriate place in title IV, insert the following:

SEC. 4_____. INCREASED MANUFACTURING CAPACITY FOR CERTAIN CRITICAL ANTIBIOTIC DRUGS.

(a) PROGRAM.—

(1) IN GENERAL.—The Secretary, in consultation with the Assistant Secretary for Preparedness and Response and Commissioner of Food and Drugs, may award contracts to increase the domestic manufacturing capacity of certain antibiotic drugs with identified supply chain vulnerabilities, or

the active pharmaceutical ingredient or key starting material of such antibiotic drugs.

(2) ELIGIBLE ENTITIES.—To be eligible to receive an award under this subsection, an entity shall—

(A) be a manufacturer and in compliance with the relevant requirements of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 301 et seq.); and

(B) prepare and submit to the Secretary an application at such time, and in such manner, and containing such information as the Secretary may require, including—

(i) a description of proposed activities to be supported by an award under this subsection to increase manufacturing capacity for an antibiotic drug or drugs;

(ii) the antibiotic drug or drugs, or related active pharmaceutical ingredients or key starting materials for such drug or drugs, that such entity intends to manufacture with any increased manufacturing capacity supported by an award under this subsection;

(iii) any additional products such increased manufacturing capacity could be used to manufacture;

(iv) a description of the current supply chain for such antibiotic drugs, including any existing and applicable manufacturing facilities, known vulnerabilities in the supply chain, known or potential supply limitations, such as foreign export restrictions, or subsidies from foreign governments, as applicable;

(v) a description of how such entity may use advanced or flexible manufacturing in carrying out the terms of an award under this subsection; and

(vi) a strategic plan regarding the maintenance, operation, and sustainment of such increased manufacturing capacity following the expiration of a contract under this subsection.

(3) USE OF FUNDS.—A recipient of an award under this subsection shall use such funds to build, expand, upgrade, modify, or recommission a facility located in the United States, which may include the purchase or upgrade of equipment, as applicable, to

support increased manufacturing capacity of certain antibiotic drugs for which supply chain vulnerabilities exist, or the active pharmaceutical ingredient or key starting material of such antibiotic drugs.

(4) REPORTS.—An entity in receipt of an award under this subsection shall submit to the Secretary such reports as the Secretary may require related to increasing domestic manufacturing capacity of antibiotic drugs pursuant to a contract under this subsection, including actions taken to implement the strategic plan required under paragraph (2)(B)(vi).

(5) CONTRACT TERMS.—The following shall apply to a contract to support increased domestic manufacturing capacity under this subsection:

(A) MILESTONE-BASED PAYMENTS.—The Secretary may provide payment, including advance payment or partial payment for significant milestones, if the Secretary makes a determination that such payment is necessary and appropriate.

(B) REPAYMENT.—The contract shall provide that such payment is required to be repaid if there is a failure to perform by the manufacturer under the contract; if the specified mile-

stones are reached, an advance or partial payment shall not be required to be repaid.

(C) CONTRACT DURATION.—

(i) IN GENERAL.—Each contract shall be for a period not to exceed 5 years.

(ii) NON-RENEWABILITY.—A contract shall not be renewable.

(iii) NOTIFICATIONS OF EXTENSIONS AND TERMINATIONS.—If the Secretary decides to terminate a contract prior to its expiration, the Secretary shall notify the manufacturer within 90 days of such determination.

(D) ADDITIONAL TERMS.—The Secretary, in any contract under this subsection—

(i) may specify—

(I) the amount of funding that will be dedicated by the Secretary for supporting increased manufacturing capacity under such contract; and

(II) the amount of manufacturing capacity that such eligible entity must meet; and

(ii) shall provide a clear statement of defined Federal Government purpose lim-

ited to uses related to increasing domestic manufacturing capacity for antibiotic drugs to address identified supply chain vulnerabilities and challenges to establishing and maintaining domestic manufacturing capacity.

(E) SUSTAINMENT.—Each contract shall provide for the eligible entity to update the strategic plan required under paragraph (2)(B)(vi) throughout the duration of such contract, as required by the Secretary.

(b) REPORT.—Not later than 2 years after the date of enactment of this Act and every year thereafter until the termination or expiration of all such contracts, the Secretary shall submit to the Committee on Health, Education, Labor, and Pensions of the Senate and the Committee on Energy and Commerce of the House of Representatives a report on any activities supported under subsection (a), including—

(1) the antibiotic drugs for which the Secretary prioritized awards under subsection (a), including a description of how the Secretary consulted with stakeholders to inform such prioritization;

(2) information regarding each contract awarded pursuant to subsection (a), including—

(A) the recipient of each such contract, including any recipients of a subaward;

(B) the milestone and performance requirements pursuant to each such contract;

(C) the duration of each such contract;

(D) the amount of funding provided by the Secretary pursuant to each such contract, including any advanced or partial payments;

(E) the antibiotic drugs supported through each such contract, including a description of the medical necessity of each such antibiotic drug and any supply chain vulnerabilities, limitations, and related characteristics identified pursuant to subsection (a)(2)(B)(iv) for each such antibiotic drug; and

(F) the amount of increased manufacturing capacity for such antibiotic drug that each such contract supports; and

(3) a description of how such contracts address supply chain vulnerabilities, including increasing manufacturing capacity of antibiotic drugs in the United States; and

(4) a description of the strategic plan submitted pursuant to subsection (a)(2)(B)(vi) by each recipient of an award under subsection (a).

(c) RULE OF CONSTRUCTION.—Nothing in this section shall be construed—

(1) to limit, directly or indirectly, or otherwise impact the private distribution, purchase, or sale of antibiotic drugs or active pharmaceutical ingredients or key starting materials; or

(2) to authorize the Secretary to disclose any information that is a trade secret, or other privileged or confidential information subject to section 552(b)(4) of title 5, United States Code, or section 1905 of title 18, United States Code.

(d) DEFINITIONS.—For purposes of 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) ANTIBIOTIC DRUG.—The term " antibiotic drug" means an antibacterial or antifungal drug approved by the Food and Drug Administration under section 505(j) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355(j)) that is of significant priority to providing health care and is medically necessary to have available at all times in an amount adequate to serve patient needs.

(3) KEY STARTING MATERIAL.—The term "key starting material" means any component of a drug that the Secretary determines to be necessary to the safety and effectiveness of the drug.

(4) SECRETARY.—The term "Secretary" means the Secretary of Health and Human Services.

(e) FUNDING.—For purposes of carrying out this section, there is appropriated, out of amounts in the Treasury not otherwise appropriated, such sums for fiscal year 2023, to remain available through September 30, 2025.

(f) SUNSET.—The authority to enter into new contracts under this section shall cease to be effective 3 years after the date of enactment of this Act, and, beginning on the date that is 8 years after the date of enactment of this Act, this section shall have no force or effect.