

*Thru* S.L.C. *Smith*

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:

- 1 At the appropriate place in title IV, insert the fol-
- 2 lowing:
- 3 **SEC. 4 \_\_\_\_\_. INCREASED MANUFACTURING CAPACITY FOR**
- 4 **CERTAIN CRITICAL ANTIBIOTIC DRUGS.**
- 5 (a) PROGRAM.—
- 6 (1) IN GENERAL.—The Secretary, in consulta-
- 7 tion with the Assistant Secretary for Preparedness
- 8 and Response and Commissioner of Food and
- 9 Drugs, may award contracts to increase the domes-
- 10 tic manufacturing capacity of certain antibiotic
- 11 drugs with identified supply chain vulnerabilities, or

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

3 (2) ELIGIBLE ENTITIES.—To be eligible to re-  
4 ceive an award under this subsection, an entity  
5 shall—

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

10 (B) prepare and submit to the Secretary  
11 an application at such time, and in such man-  
12 ner, and containing such information as the  
13 Secretary may require, including—

14 (i) a description of proposed activities  
15 to be supported by an award under this  
16 subsection to increase manufacturing ca-  
17 pacity for an antibiotic drug or drugs;

18 (ii) the antibiotic drug or drugs, or re-  
19 lated active pharmaceutical ingredients or  
20 key starting materials for such drug or  
21 drugs, that such entity intends to manu-  
22 facture with any increased manufacturing  
23 capacity supported by an award under this  
24 subsection;

1 (iii) any additional products such in-  
2 creased manufacturing capacity could be  
3 used to manufacture;

4 (iv) a description of the current sup-  
5 ply chain for such antibiotic drugs, includ-  
6 ing any existing and applicable manufac-  
7 turing facilities, known vulnerabilities in  
8 the supply chain, known or potential sup-  
9 ply limitations, such as foreign export re-  
10 strictions, or subsidies from foreign gov-  
11 ernments, as applicable;

12 (v) a description of how such entity  
13 may use advanced or flexible manufac-  
14 turing in carrying out the terms of an  
15 award under this subsection; and

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

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

1 support increased manufacturing capacity of certain  
2 antibiotic drugs for which supply chain  
3 vulnerabilities exist, or the active pharmaceutical in-  
4 gredient or key starting material of such antibiotic  
5 drugs.

6 (4) REPORTS.—An entity in receipt of an  
7 award under this subsection shall submit to the Sec-  
8 retary such reports as the Secretary may require re-  
9 lated to increasing domestic manufacturing capacity  
10 of antibiotic drugs pursuant to a contract under this  
11 subsection, including actions taken to implement the  
12 strategic plan required under paragraph (2)(B)(vi).

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

16 (A) MILESTONE-BASED PAYMENTS.—The  
17 Secretary may provide payment, including ad-  
18 vance payment or partial payment for signifi-  
19 cant milestones, if the Secretary makes a deter-  
20 mination that such payment is necessary and  
21 appropriate.

22 (B) REPAYMENT.—The contract shall pro-  
23 vide that such payment is required to be repaid  
24 if there is a failure to perform by the manufac-  
25 turer under the contract; if the specified mile-

1 stones are reached, an advance or partial pay-  
2 ment shall not be required to be repaid.

3 (C) CONTRACT DURATION.—

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

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

8 (iii) NOTIFICATIONS OF EXTENSIONS  
9 AND TERMINATIONS.—If the Secretary de-  
10 cides to terminate a contract prior to its  
11 expiration, the Secretary shall notify the  
12 manufacturer within 90 days of such de-  
13 termination.

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

16 (i) may specify—

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

21 (II) the amount of manufac-  
22 turing capacity that such eligible enti-  
23 ty must meet; and

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

1           ited to uses related to increasing domestic  
2           manufacturing capacity for antibiotic  
3           drugs to address identified supply chain  
4           vulnerabilities and challenges to estab-  
5           lishing and maintaining domestic manufac-  
6           turing capacity.

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

12          (b) REPORT.—Not later than 2 years after the date  
13 of enactment of this Act and every year thereafter until  
14 the termination or expiration of all such contracts, the  
15 Secretary shall submit to the Committee on Health, Edu-  
16 cation, Labor, and Pensions of the Senate and the Com-  
17 mittee on Energy and Commerce of the House of Rep-  
18 resentatives a report on any activities supported under  
19 subsection (a), including—

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

24           (2) information regarding each contract award-  
25           ed pursuant to subsection (a), including—

1 (A) the recipient of each such contract, in-  
2 cluding any recipients of a subaward;

3 (B) the milestone and performance re-  
4 quirements pursuant to each such contract;

5 (C) the duration of each such contract;

6 (D) the amount of funding provided by the  
7 Secretary pursuant to each such contract, in-  
8 cluding any advanced or partial payments;

9 (E) the antibiotic drugs supported through  
10 each such contract, including a description of  
11 the medical necessity of each such antibiotic  
12 drug and any supply chain vulnerabilities, limi-  
13 tations, and related characteristics identified  
14 pursuant to subsection (a)(2)(B)(iv) for each  
15 such antibiotic drug; and

16 (F) the amount of increased manufac-  
17 turing capacity for such antibiotic drug that  
18 each such contract supports; and

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

23 (4) a description of the strategic plan submitted  
24 pursuant to subsection (a)(2)(B)(vi) by each recipi-  
25 ent of an award under subsection (a).

1 (c) RULE OF CONSTRUCTION.—Nothing in this sec-  
2 tion shall be construed—

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

7 (2) to authorize the Secretary to disclose any  
8 information that is a trade secret, or other privileged  
9 or confidential information subject to section  
10 552(b)(4) of title 5, United States Code, or section  
11 1905 of title 18, United States Code.

12 (d) DEFINITIONS.—For purposes of this section:

13 (1) ACTIVE PHARMACEUTICAL INGREDIENT.—  
14 The term “active pharmaceutical ingredient” has the  
15 meaning given such term in section 744A of the  
16 Federal Food, Drug, and Cosmetic Act (21 U.S.C.  
17 379j-41).

18 (2) ANTIBIOTIC DRUG.—The term “antibiotic  
19 drug” means an antibacterial or antifungal drug ap-  
20 proved by the Food and Drug Administration under  
21 section 505(j) of the Federal Food, Drug, and Cos-  
22 metic Act (21 U.S.C. 355(j)) that is of significant  
23 priority to providing health care and is medically  
24 necessary to have available at all times in an amount  
25 adequate to serve patient needs.



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

5           (4) SECRETARY.—The term “Secretary” means  
6 the Secretary of Health and Human Services.

7           (e) FUNDING.—For purposes of carrying out this sec-  
8 tion, there is appropriated, out of amounts in the Treasury  
9 not otherwise appropriated, such sums for fiscal year  
10 2023, to remain available through September 30, 2025.

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