

119TH CONGRESS
1ST SESSION

S. _____

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

Mr. PETERS (for himself, Mrs. BLACKBURN, Mr. BUDD, and Mr. Kaine) introduced the following bill; which was read twice and referred to the Committee on _____

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.

1 *Be it enacted by the Senate and House of Representa-*
2 *tives of the United States of America in Congress assembled,*

3 **SECTION 1. SHORT TITLE.**

4 This Act may be cited as the “Rolling Active Pharma-
5 ceutical Ingredient and Drug Reserve Act” or the
6 “RAPID Reserve Act”.

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

3 (a) IN GENERAL.—The Secretary of Health and
4 Human Services (referred to in this section as the “Sec-
5 retary”) shall award contracts or cooperative agreements
6 to eligible entities with respect to drugs and active phar-
7 maceutical ingredients of such drugs that the Secretary
8 determines to be critical and to have vulnerable supply
9 chains. The Secretary shall publish the list of such drugs
10 and active pharmaceutical ingredients of such drugs.

11 (b) REQUIREMENTS.—

12 (1) IN GENERAL.—An eligible entity, pursuant
13 to a contract or cooperative agreement under sub-
14 section (a), shall agree to—

15 (A) maintain, in a satisfactory domestic es-
16 tablishment registered under section 510(b) of
17 the Federal Food, Drug, and Cosmetic Act (21
18 U.S.C. 360(b)) or in a satisfactory foreign es-
19 tablishment registered under section 510(i) of
20 such Act that is located in a country that is a
21 member of the Organisation for Economic Co-
22 operation and Development, which may be an
23 establishment owned and operated by the enti-
24 ty, or by a wholesaler, distributor, or other
25 third-party under contract with the entity, a 6-

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

3 (i) the active pharmaceutical ingre-
4 dient of the eligible drug specified in the
5 contract or cooperative agreement, which
6 reserve shall be regularly replenished with
7 a recently manufactured supply of such in-
8 gredient; and

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

14 (B) implement production of the eligible
15 drug or an active pharmaceutical ingredient of
16 the eligible drug, at the direction of the Sec-
17 retary, under the terms of, and in such quan-
18 tities as specified in, the contract or cooperative
19 agreement; and

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

22 (i) agrees to transfer a portion, as de-
23 termined necessary, of the reserve of active
24 pharmaceutical ingredient maintained pur-
25 suant to subparagraph (A)(i) to another

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

8 (ii) permits the Secretary to direct al-
9 location of the reserve of active pharma-
10 ceutical ingredient so maintained in the
11 event of a public health emergency, natural
12 disaster, or chemical, biological, radio-
13 logical, or nuclear threat.

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

18 (A) the factors the Secretary will use to
19 determine which eligible drugs, or active phar-
20 maceutical ingredient of such drugs, have vul-
21 nerable supply chains and how a contract or co-
22 operative agreement would help minimize the
23 vulnerability or vulnerabilities identified;

24 (B) the factors the Secretary will consider
25 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—

(A) give preference to eligible entities that will—

(i) 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; or

1 (ii) source key starting materials or
2 excipients for eligible drugs domestically or
3 from a country that is a member of the
4 Organisation for Economic Cooperation
5 and Development; and

6 (B) to the greatest extent practicable,
7 award such contracts and cooperative agree-
8 ments in a manner that strengthens domestic
9 manufacturing, resiliency, and capacity of eligi-
10 ble drugs and their active pharmaceutical ingre-
11 dients.

12 (c) ADDITIONAL CONTRACT AND COOPERATIVE
13 AGREEMENT TERMS.—

14 (1) IN GENERAL.—Each contract or cooperative
15 agreement under subsection (a) shall be subject to
16 such terms and conditions as the Secretary may
17 specify, including terms and conditions with respect
18 to procurement, maintenance, storage, testing, and
19 delivery of drugs, in alignment with inventory man-
20 agement and other applicable best practices, under
21 such contract or cooperative agreement, which may
22 consider, as appropriate, costs of transporting and
23 handling such drugs.

24 (2) TERMS CONCERNING THE ACQUISITION,
25 CONSTRUCTION, ALTERATION, OR RENOVATION OF

1 ESTABLISHMENTS.—Notwithstanding section 6303
2 of title 41, United States Code, the Secretary may
3 award a contract or cooperative agreement under
4 this section to support the acquisition, construction,
5 alteration, or renovation of non-Federally owned es-
6 tablishments—

7 (A) as determined necessary to carry out
8 or improve preparedness and response capa-
9 bility at the State and local level; or

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

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

19 (1) maximizes quality, minimizes cost, mini-
20 mizes vulnerability of the United States to severe
21 shortages or disruptions for eligible drugs and their
22 active pharmaceutical ingredients, gives preference
23 to domestic manufacturers, and encourages competi-
24 tion in the marketplace; and

1 (2) increases domestic production surge capac-
2 ity and reserves of domestic-based manufacturing es-
3 tablishments for critical drugs and active pharma-
4 ceutical ingredients of such drugs.

5 (e) DEFINITIONS.—In this section:

6 (1) ACTIVE PHARMACEUTICAL INGREDIENT.—
7 The term “active pharmaceutical ingredient” has the
8 meaning given such term in section 744A of the
9 Federal Food, Drug, and Cosmetic Act (21 U.S.C.
10 379j–41).

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

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

18 (4) ELIGIBLE DRUG.—The term “eligible drug”
19 means a drug, as determined by the Secretary, in
20 coordination with the Assistant Secretary for Pre-
21 paredness and Response, the Director of the Centers
22 for Disease Control and Prevention, and the Com-
23 missioner of Food and Drugs—

24 (A) that is approved under section 505(j)
25 of the Federal Food, Drug, and Cosmetic Act

1 (21 U.S.C. 355(j)) or licensed under section
2 351(k) of the Public Health Service Act (42
3 U.S.C. 262(k));

4 (B)(i) that is reasonably likely to be re-
5 quired to respond to a public health emergency
6 or to a chemical, biological, radiological, or nu-
7 clear threat; or

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

11 (C) that has a vulnerable supply chain,
12 such as a geographic concentration of manufac-
13 turing, poor quality or safety issues, complex
14 manufacturing or chemistry, or few manufac-
15 turers.

16 (5) ELIGIBLE ENTITY.—The term “eligible enti-
17 ty” means a person that—

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

24 (ii) maintains at least one domestic estab-
25 lishment registered under section 510(b) of the

1 Federal Food, Drug, and Cosmetic Act (21
2 U.S.C. 360(b)) or one foreign establishment
3 registered under section 510(i) of such Act that
4 is located in a country that is a member of the
5 Organisation for Economic Cooperation and
6 Development that is capable of manufacturing
7 the eligible drug; and

8 (iii) has a strong record of good manufac-
9 turing practices of drugs;

10 (B)(i) is a manufacturer of an active phar-
11 maceutical ingredient for an eligible drug, in
12 partnership with an entity that meets the re-
13 quirements of subparagraph (A);

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

23 (iii) has a strong record of good manufac-
24 turing practices of active pharmaceutical ingre-
25 dients; or

1 (C) is a distributor or wholesaler of an eli-
2 gible drug, in partnership with an entity that
3 meets the requirements of subparagraph (A).

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

8 (1) the list of drugs determined to be eligible
9 drugs, as described in subsection (e)(2), and the ra-
10 tionale behind selecting each such drug; and

11 (2) an update on the effectiveness of the pro-
12 gram under this section, in a manner that does not
13 compromise national security.

14 (g) AUTHORIZATION OF APPROPRIATIONS.—To carry
15 out this section, there is authorized to be appropriated
16 \$500,000,000 for fiscal year 2026.