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H. R. 6802

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 HOUSE OF REPRESENTATIVES

DECEMBER 14, 2023

Ms. CRAIG (for herself, Mr. VAN DREW, and Ms. SPANBERGER) introduced the following bill; which was referred to the Committee on Energy and Commerce

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 or
12 chemical, biological, radiological, or nuclear
13 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-

1 pate in the program under this section, which
2 shall include an entity's commitment to quality
3 systems, including strong manufacturing infra-
4 structure, reliable processes, and trained staff,
5 as well as the entity's commitment to domestic
6 manufacturing capacity and surge capacity, as
7 appropriate; and

8 (C) requirements for entities receiving an
9 award under this section, including the extent
10 of excess manufacturing capacity the manufac-
11 turers will be required to generate, the amount
12 of redundancy required, and requirements relat-
13 ing to advanced quality systems.

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

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

3 (c) ADDITIONAL CONTRACT AND COOPERATIVE
4 AGREEMENT TERMS.—

5 (1) IN GENERAL.—Each contract or cooperative
6 agreement under subsection (a) shall be subject to
7 such terms and conditions as the Secretary may
8 specify, including terms and conditions with respect
9 to procurement, maintenance, storage, testing, and
10 delivery of drugs, in alignment with inventory man-
11 agement and other applicable best practices, under
12 such contract or cooperative agreement, which may
13 consider, as appropriate, costs of transporting and
14 handling such drugs.

15 (2) TERMS CONCERNING THE ACQUISITION,
16 CONSTRUCTION, ALTERATION, OR RENOVATION OF
17 ESTABLISHMENTS.—Notwithstanding section 6303
18 of title 41, United States Code, the Secretary may
19 award a contract or cooperative agreement under
20 this section to support the acquisition, construction,
21 alteration, or renovation of non-federally owned es-
22 tablishments—

23 (A) as determined necessary to carry out
24 or improve preparedness and response capa-
25 bility at the State and local level; or

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

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

10 (1) maximizes quality, minimizes cost, mini-
11 mizes vulnerability of the United States to severe
12 shortages or disruptions for eligible drugs and their
13 active pharmaceutical ingredients, gives preference
14 to domestic manufacturers, and encourages competi-
15 tion in the marketplace; and

16 (2) increases domestic production surge capac-
17 ity and reserves of domestic-based manufacturing es-
18 tablishments for critical drugs and active pharma-
19 ceutical ingredients of such drugs.

20 (e) DEFINITIONS.—In this section:

21 (1) ACTIVE PHARMACEUTICAL INGREDIENT.—
22 The term “active pharmaceutical ingredient” has the
23 meaning given such term in section 744A of the
24 Federal Food, Drug, and Cosmetic Act (21 U.S.C.
25 379j–41).

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

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

8 (4) ELIGIBLE DRUG.—The term “eligible drug”
9 means a drug, as determined by the Secretary, in
10 coordination with the Assistant Secretary for Pre-
11 paredness and Response, the Director of the Centers
12 for Disease Control and Prevention, and the Com-
13 missioner of Food and Drugs—

14 (A) that is approved under section 505(j)
15 of the Federal Food, Drug, and Cosmetic Act
16 (21 U.S.C. 355(j)) or licensed under section
17 351(k) of the Public Health Service Act (42
18 U.S.C. 262(k));

19 (B)(i) that is reasonably likely to be re-
20 quired to respond to a public health emergency
21 or to a chemical, biological, radiological, or nu-
22 clear threat; or

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

1 (C) that has a vulnerable supply chain,
2 such as a geographic concentration of manufac-
3 turing, poor quality or safety issues, complex
4 manufacturing or chemistry, or few manufac-
5 turers.

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

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

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 eligible drug; and

23 (iii) has a strong record of good manufac-
24 turing practices of drugs;

1 (B)(i) is a manufacturer of an active phar-
2 maceutical ingredient for an eligible drug, in
3 partnership with an entity that meets the re-
4 quirements of subparagraph (A);

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

14 (iii) has a strong record of good manufac-
15 turing practices of active pharmaceutical ingre-
16 dients; or

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

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

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

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

7 (g) AUTHORIZATION OF APPROPRIATIONS.—To carry
8 out this section, there is authorized to be appropriated
9 \$500,000,000 for fiscal year 2024.

10 **SEC. 3. GAO REPORT.**

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

14 (1) examine, such as through a survey or other
15 means, excess or underutilized domestic manufac-
16 turing capacity for critical drugs and active pharma-
17 ceutical ingredients of such drugs, including capacity
18 to manufacture different dosage forms, such as oral
19 tablets and sterile injectable drugs, and the capacity
20 to manufacture drugs with various characteristics,
21 such as cytotoxic drugs and drugs requiring
22 lyophilization; and

23 (2) prepare and submit a report to the Com-
24 mittee on Homeland Security and Governmental Af-
25 fairs and the Committee on Health, Education,

1 Labor, and Pensions of the Senate and the Com-
2 mittee on Homeland Security and the Committee on
3 Energy and Commerce of the House of Representa-
4 tives that—

5 (A) includes—

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

8 (ii) an assessment of projected costs
9 of utilizing and expanding existing domes-
10 tic manufacturing capabilities and policies,
11 as of the date of the report, that may help
12 establish or strengthen domestic manufac-
13 turing capacity for key starting materials,
14 excipients, active pharmaceutical ingredi-
15 ents, and finished dosage manufacturing
16 establishments; and

17 (iii) an evaluation of policies designed
18 to invest in advanced domestic manufac-
19 turing capabilities and capacity for critical
20 active pharmaceutical ingredients and drug
21 products; and

22 (B) shall be publicly available in an unclas-
23 sified form, but may include a classified annex

1 containing any information that the Comp-
2 troller General determines to be sensitive.

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