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2D SESSION

S. 4175

To secure the supply of drugs in the United States, and for other purposes.

IN THE SENATE OF THE UNITED STATES

JULY 2, 2020

Ms. WARREN (for herself and Ms. SMITH) introduced the following bill; which was read twice and referred to the Committee on Health, Education, Labor, and Pensions

A BILL

To secure the supply of drugs in the United States, and
for other purposes.

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 “Pharmaceutical Supply
5 Chain Defense and Enhancement Act”.

6 **SEC. 2. LISTING OF CRITICAL DRUGS.**

7 (a) IN GENERAL.—Not later than 1 year after the
8 date of enactment of this Act, the Secretary, acting
9 through the Commissioner of Food and Drugs and in con-
10 sultation with the Secretary of Defense, shall develop a

1 confidential list of drugs such Secretary determines to be
2 critical to the public health or national security. Such list
3 shall include the name of each such drug, as well as all
4 active pharmaceutical ingredients and starting materials
5 required for the manufacture of the drug. In developing
6 the list, the Secretary may consider the role of shortages
7 in impeding access to drugs.

8 (b) UPDATES.—The Secretary shall update the list
9 described in subsection (a) not less frequently than once
10 every 2 years.

11 (c) SUBMISSION OF LIST.—The Secretary shall sub-
12 mit the list described in subsection (a), including any up-
13 dates to such list under subsection (b), as a classified mat-
14 ter, to the Committee on Health, Education, Labor, and
15 Pensions, the Committee on Armed Services, the Com-
16 mittee on Foreign Relations, and the Committee on Bank-
17 ing, Housing, and Urban Affairs of the Senate, and to
18 the Committee on Energy and Commerce, the Committee
19 on Armed Services, the Committee on Foreign Affairs,
20 and the Committee on Financial Services of the House of
21 Representatives.

22 (d) INTERIM LIST.—During the period between the
23 date of enactment of this Act and the date on which the
24 Secretary issues the first list under subsection (a), the
25 Secretary, in consultation with the Commissioner of Food

1 and Drugs, the Secretary of Defense, and the Assistant
2 Secretary for Preparedness and Response, shall establish
3 an interim list of drugs that will be deemed the list under
4 subsection (a) until the Secretary develops the first list
5 under subsection (a). Such interim list shall include not
6 fewer than 30 drugs, as well as the active pharmaceutical
7 ingredients and starting materials required for the manu-
8 facture of such drugs, that are—

9 (1) included on the most recent list of essential
10 medicines issued by the World Health Organization;

11 or

12 (2) countermeasures and products that could
13 replenish the strategic national stockpile.

14 (e) COMMENT PERIOD.—Not later than 60 days prior
15 to the submission of the list described in subsection (a),
16 the Secretary shall establish a comment period during
17 which the public may comment on which drugs should be
18 included on the list under subsection (a).

19 **SEC. 3. BOOSTING DOMESTIC DRUG AND ACTIVE INGRE-**
20 **DIENT MANUFACTURING CAPACITY.**

21 (a) IN GENERAL.—The Secretary, acting through the
22 Director of the Biomedical Advanced Research and Devel-
23 opment Authority, shall increase the domestic capacity to
24 manufacture active pharmaceutical ingredients and start-
25 ing materials for drugs critical to the public health and

1 national security by entering into the contracts described
2 in subsection (b).

3 (b) CONTRACTS.—

4 (1) IN GENERAL.—To carry out subsection (a),
5 the Secretary shall enter into contracts, not later
6 than 6 months after the date of enactment of this
7 Act, as follows:

8 (A) The Secretary shall enter into con-
9 tracts with companies and nonprofit entities
10 headquartered in the United States, under
11 which such companies use manufacturing estab-
12 lishments located in the United States to manu-
13 facture the drugs included on the list under sec-
14 tion 2, and the requisite active pharmaceutical
15 ingredients and starting materials of such
16 drugs, using advanced manufacturing, including
17 continuous manufacturing where applicable.

18 (B) As a condition for entering into con-
19 tracts with the Secretary to manufacture drugs,
20 companies and nonprofit entities shall—

21 (i) develop and maintain a redun-
22 dancy risk management and continuity of
23 business plan (reviewed and approved by
24 the Secretary) that identifies and evaluates
25 risks to the supply of the drug, as applica-

1 ble, for each establishment in which such
2 drug, and the requisite active pharma-
3 ceutical ingredients and starting materials
4 of such drug, is manufactured;

5 (ii) commit to implementing, as ap-
6 propriate, risk management and other
7 strategies to ensure that, in the case of po-
8 tential supply chain disruptions, the entity
9 can continue normal production of the
10 drug, and the requisite active pharma-
11 ceutical ingredients and starting materials
12 of such drug, for 18 months;

13 (iii) commit to maintaining, to the ex-
14 tent practicable (as determined by the Sec-
15 retary) for each drug, and the requisite ac-
16 tive pharmaceutical ingredients and start-
17 ing materials of such drug, a 3-month sup-
18 ply in order to mitigate the impact of sup-
19 ply chain disruptions and shortages;

20 (iv) commit to selling drugs, or the
21 requisite active pharmaceutical ingredients
22 and starting materials of such drugs, de-
23 veloped under contract with the Secretary
24 at fair and reasonable prices, as deter-

1 mined by the Secretary, taking into consid-
2 eration—

3 (I) the impact of price on patient
4 access to the drug;

5 (II) the cost of the drug to Fed-
6 eral or State health programs;

7 (III) the cost of manufacturing
8 the drug; and

9 (IV) the impact of price on mar-
10 ket competition for the drug; and

11 (v) commit to making the prices de-
12 scribed in clause (iv) public.

13 (C) The contracts described in this para-
14 graph shall contain continuity of business
15 agreements demonstrating, in advance of receiv-
16 ing a contract, the company's ability to rapidly
17 begin production.

18 (D) The Secretary shall enter into con-
19 tracts only with companies headquartered in the
20 United States that use manufacturing establish-
21 ments located in the United States, under
22 which such companies expand the capabilities of
23 continuous manufacturing and other advanced
24 manufacturing for the production of the active
25 pharmaceutical ingredients and starting mate-

1 rials for the drugs included on the list under
2 section 2.

3 (E) In issuing contracts under this section,
4 the Secretary shall prioritize—

5 (i) contracts designed to enhance the
6 supply of generic drugs and biosimilar bio-
7 logical products and the requisite active
8 pharmaceutical ingredients and starting
9 materials of such generic drugs and bio-
10 similar products; and

11 (ii) contracts designed to enhance the
12 supply of drugs, and the requisite active
13 pharmaceutical ingredients and starting
14 materials of such drugs, that are not cur-
15 rently manufactured in the United States.

16 (2) INSPECTOR GENERAL REVIEW.—The In-
17 specter General of the Department of Health and
18 Human Services shall conduct a review of not fewer
19 than 1 of every 3 contracts entered into under this
20 section, and of the entities entering into such con-
21 tracts, to ensure that contracts are being issued
22 under fair and reasonable terms and conditions, in-
23 cluding facilitating the procurement by the Federal
24 Government of applicable products under section 2
25 and applicable drugs, biological products, and med-

1 ical devices at fair and reasonable prices. The In-
2 spector General shall make each such review public
3 and, in cases where such a review identifies unrea-
4 sonable prices, submit recommendations to Congress
5 on how the Office should improve its contracting
6 systems to ensure reasonable pricing.

7 (3) FUNDING.—To carry out this section, there
8 are authorized to be appropriated \$5,000,000,000
9 for the period of fiscal years 2020 and 2024. Not
10 later than April 1, 2024, the Secretary shall report
11 to the congressional committees listed under section
12 2(c) of this Act, and provide a recommendation for
13 renewal of funding under this paragraph.

14 (c) FEDERAL PROCUREMENT OF DOMESTICALLY
15 MANUFACTURED DRUGS.—

16 (1) PROCUREMENT OF DRUGS.—

17 (A) IN GENERAL.—Beginning in fiscal year
18 2024, when purchasing any drug included on
19 the list under section 2, the Secretary of De-
20 fense, the Secretary of Veterans Affairs, the Di-
21 rector of the Bureau of Prisons, and, for pur-
22 poses of maintaining the strategic national
23 stockpile, the Secretary of Health and Human
24 Services, shall give priority to supplies of the
25 drug manufactured in the United States (in-

1 including all active pharmaceutical ingredient and
2 starting materials of the drug) that is of high
3 quality.

4 (B) USE OF REMAINING FUNDS.—In the
5 case that a Federal agency described in this
6 paragraph that, after purchasing all drugs on
7 the list under section 2 needed by such agency
8 for a fiscal year, has funds appropriated under
9 paragraph (2) for that fiscal year remaining,
10 such Federal agency may use the remaining
11 funds to purchase drugs wholly manufactured
12 in the United States that are not included on
13 the list under section 2.

14 (2) FUNDING.—

15 (A) IN GENERAL.—There are authorized to
16 be appropriated to each of the Secretary of De-
17 fense, the Secretary of Veterans Affairs, the
18 Bureau of Prisons, and the Secretary of Health
19 and Human Services, \$1,000,000,000 for the
20 period of fiscal years 2024 and 2028, to be
21 used to purchase drugs manufactured in the
22 United States, as described in paragraph (1).

23 (B) REVERSION.—All funds that are ap-
24 propriated under this paragraph for a fiscal
25 year, but not expended by the end of the fiscal

1 year, shall revert to the General Fund of the
2 Treasury.

3 (C) NO DIVERSION OR TRANSFER OF
4 FUNDS.—No funding appropriated under this
5 section shall be diverted, transferred, or other-
6 wise made available for purposes beyond what
7 is described in this Act.

8 (3) NIH AUTHORIZATION.—There are author-
9 ized to be appropriated to the Director of the Na-
10 tional Institutes of Health, for each fiscal year for
11 which amounts are appropriated under paragraph
12 (2) but not expended in full, an amount equal to the
13 amount that reverts to the Treasury for such year,
14 as described in paragraph (2). Such amounts shall
15 be used by the Director of the National Institutes of
16 Health to carry out biomedical research.

17 **SEC. 4. SUPPLY CHAIN TRANSPARENCY.**

18 (a) DOMESTIC SUPPLIERS TO FEDERAL PRO-
19 GRAMS.—Each domestic manufacturer of a drug that sup-
20 plies such drug to the Department of Defense, the Depart-
21 ment of Veterans Affairs, the Department of Health and
22 Human Services, or the Bureau of Prisons, or a domestic
23 manufacturer of an active ingredient of a drug so supplied,
24 shall—

1 (1) report annually to the Secretary and the
2 agency receiving such drug on—

3 (A) whether any ingredients of such drug
4 is sourced, either wholly or in part, from a for-
5 eign country;

6 (B) in the case of an active pharmaceutical
7 ingredient or key starting material that the
8 manufacturer procures from a single source in
9 a single foreign country, as applicable—

10 (i) not less than 2 alternative sources
11 of any active pharmaceutical ingredient or
12 key starting material;

13 (ii) 1 such alternative source, if only
14 1 such alternative source is available; or

15 (iii) a statement that no such alter-
16 native sources are available; and

17 (C) an assessment of the resilience and ca-
18 pacity of the alternate sources identified under
19 subparagraph (B); and

20 (2) develop continuity of business plans to pre-
21 vent the disruption of any drug listed under section
22 2, including any active or inactive ingredients of
23 such drug, which the Secretary may audit.

24 (b) FOREIGN DRUG SUPPLIERS.—

1 (1) ESTABLISHMENTS IN A FOREIGN COUN-
2 TRY.—Section 510(i) of the Federal Food, Drug,
3 and Cosmetic Act (21 U.S.C. 360(i)) is amended by
4 inserting at the end the following:

5 “(5) The requirements of paragraphs (1) and (2)
6 shall apply to establishments within a foreign country en-
7 gaged in the manufacture, preparation, propagation,
8 compounding, or processing of any drug that is required
9 to be listed pursuant to subsection (j), or of any active
10 pharmaceutical ingredient of such a drug. Such require-
11 ments shall apply regardless of whether the drug or active
12 pharmaceutical ingredient undergoes further manufacture,
13 preparation, propagation, compounding, or processing at
14 a separate establishment or establishments outside the
15 United States prior to being imported or offered for im-
16 port into the United States.”.

17 (2) LISTING OF DRUGS.—Section 510(j)(1) of
18 the Federal Food, Drug, and Cosmetic Act (21
19 U.S.C. 360(j)(1)) is amended—

20 (A) in subparagraph (D), by striking
21 “and” at the end;

22 (B) in subparagraph (E), by striking the
23 period at the end and inserting “; and”; and

24 (C) by adding at the end the following new
25 subparagraph:

1 “(F) in the case of a drug contained in the ap-
2 plicable list, a certification that the registrant has—

3 “(i) identified every other establishment
4 where manufacturing is performed for the drug
5 by the registrant; and

6 “(ii) notified each known foreign establish-
7 ment engaged in the manufacture, preparation,
8 propagation, compounding, or processing of the
9 drug or the active pharmaceutical ingredient of
10 the drug of the inclusion of the drug in the list
11 and the obligation to register pursuant to sub-
12 section (i)(5).”.

13 (c) REPORTS TO CONGRESS AND THE PUBLIC.—

14 (1) CLASSIFIED REPORT TO CONGRESS.—Not
15 later than 1 year after the date of enactment of this
16 Act and annually thereafter, the Secretary, in con-
17 sultation with the Secretary of Defense, shall submit
18 a classified report to Congress on the Nation’s reli-
19 ance on importation of active and inactive ingredi-
20 ents of drugs included on the list under section 2.

21 (2) PUBLIC REPORTS.—Not later than 1 year
22 after the date of enactment of this Act and annually
23 thereafter, the Secretary, in consultation with the
24 Secretary of Defense, shall prepare an unclassified
25 summary of the report described in paragraph (1),

1 and shall make such summary publicly available on
2 the internet websites of the Department of Health
3 and Human Services and the Department of De-
4 fense for purposes of understanding the Nation's de-
5 pendency on foreign manufacturers of drugs. Such
6 summaries shall not include the names of any drugs,
7 active pharmaceutical ingredients, or starting mate-
8 rials.

9 (3) CONTENT.—The reports under paragraph
10 (1) shall include—

11 (A) all brand name and generic drugs, and
12 the active and inactive ingredients of such
13 drugs that—

14 (i) are not wholly produced in the
15 United States;

16 (ii) are exclusively produced, or utilize
17 active or inactive ingredients produced
18 abroad;

19 (iii) are critical to the public health
20 and national security of the people of the
21 United States, as determined by the Sec-
22 retary, in consultation with the Secretary
23 of Defense, and including any drugs in-
24 cluded in the list under section 2; or

1 (iv) are procured in any quantity by
2 the Department of Defense for use by serv-
3 ice members or veterans or by the Depart-
4 ment of Health and Human Services for
5 the strategic national stockpile;

6 (B) a list of potential, alternative sources
7 for any finished drug or active or inactive ingre-
8 dient of a drug, that is sourced from a single
9 manufacturer with establishments in the United
10 States; and

11 (C) assess the resiliency and capacity of al-
12 ternative sources of any drug described in sub-
13 paragraph (A), and whether any such alter-
14 native source could be relied on to support do-
15 mestic demand for such drug.

16 (d) MANUFACTURER COMPLIANCE.—

17 (1) FAILURE TO NOTIFY OF A PERMANENT DIS-
18 CONTINUANCE OR AN INTERRUPTION.—Section 301
19 of the Federal Food, Drug, and Cosmetic Act (21
20 U.S.C. 331) is amended by adding at the end the
21 following:

22 “(fff) The failure of a manufacturer of a drug de-
23 scribed in section 506C(a), or an active pharmaceutical
24 ingredient of such a drug, to notify the Secretary of a per-
25 manent discontinuance or an interruption, and the reasons

1 for such discontinuance or interruption, as required by
2 section 506C.”.

3 (2) EXEMPTION FROM PENALTY.—Section
4 303(c) of the Federal Food, Drug, and Cosmetic Act
5 (21 U.S.C. 333(c)) is amended by inserting before
6 the period at the end the following: or “(6) for hav-
7 ing violated section 301(fff) if such person made a
8 good faith determination that the discontinuance or
9 interruption was not likely to lead to a meaningful
10 disruption in the supply of that drug in the United
11 States”.

12 (e) REGISTRY OF ACTIVE INGREDIENTS.—There is
13 authorized to be appropriated to the Secretary of Health
14 and Human Services \$20,000,000 for fiscal year 2021, for
15 purposes of establishing, in consultation with the Commis-
16 sioner of Food and Drugs, an online registry of active
17 pharmaceutical ingredients and key starting materials
18 using information reported under subsection (a) and pur-
19 suant to a registration under section 510(i) of the Federal
20 Food, Drug, and Cosmetic Act (21 U.S.C. 360(i)).

21 (f) FOOD AND DRUG ADMINISTRATION INSPEC-
22 TIONS.—There are authorized to be appropriated such
23 funds as may be necessary to ensure that the Commis-
24 sioner of Food and Drugs is able to conduct inspections

1 and evaluations of new establishments established using
2 funds made available under this Act.

3 **SEC. 5. OVERSIGHT OF FOREIGN PHARMACEUTICAL IN-**
4 **VESTMENT.**

5 (a) IN GENERAL.—Not later than 1 year after the
6 date of the enactment of this Act, and annually thereafter,
7 the Federal Trade Commission, in consultation with the
8 Secretary of the Treasury acting through the Committee
9 on Foreign Investment in the United States (referred to
10 in this section as the “Committee”), shall submit to the
11 appropriate congressional committees, the Secretary of
12 Health and Human Services, and the Commissioner of
13 Food and Drugs, a report on foreign investment in the
14 pharmaceutical industry of the United States.

15 (b) ELEMENTS.—The report required by subsection
16 (a) shall include the following:

17 (1) An assessment of—

18 (A) the supply chain of the pharmaceutical
19 industry of the United States and the effect of
20 concentration and reliance on foreign manufac-
21 turing within that industry;

22 (B) the effect of foreign investment in the
23 pharmaceutical industry of the United States
24 on domestic capacity to produce drugs and ac-
25 tive and inactive ingredients of drugs; and

1 (C) the effect of foreign investment in
2 technologies or other products for sequencing or
3 storage of DNA, including genome and exome
4 analysis, in the United States, including the ef-
5 fect of such investment on the capacity to se-
6 quence or store DNA in the United States.

7 (2) The number of reviews and investigations
8 conducted by the Committee, in each of the 10 fiscal
9 years preceding the year in which the study is con-
10 ducted, with respect to covered transactions (as de-
11 fined in section 721(a) of the Defense Production
12 Act of 1950 (50 U.S.C. 4565(a))—

13 (A) in the pharmaceutical industry of the
14 United States; or

15 (B) relating to the sequencing or storage
16 of DNA in the United States.

17 (3) A short description of each such review or
18 investigation, including whether the transaction was
19 approved or prohibited.

20 (c) AUTHORITY.—The Federal Trade Commission
21 shall have authority under section 6 of the Federal Trade
22 Commission Act (15 U.S.C. 46) to conduct the studies re-
23 quired to prepare the report required by subsection (a).

24 (d) PUBLICATION.—The Federal Trade Commission
25 shall publish an unclassified summary of the report re-

1 quired by subsection (a) on a publicly available internet
2 website of the Commission.

3 (e) APPROPRIATE CONGRESSIONAL COMMITTEES DE-
4 FINED.—In this section, the term “appropriate congress-
5 sional committees” means—

6 (1) the Committee on Banking, Housing, and
7 Urban Affairs, the Committee on Health, Education,
8 Labor, and Pensions, the Committee on Armed
9 Services, the Committee on Foreign Relations, the
10 Committee on Commerce, Science, and Transpor-
11 tation, and the Committee on Appropriations of the
12 Senate; and

13 (2) the Committee on Financial Services, the
14 Committee on Energy and Commerce, the Com-
15 mittee on Armed Services, the Committee on For-
16 eign Affairs, and the Committee on Appropriations
17 of the House of Representatives.

18 **SEC. 6. DEFINITIONS.**

19 In this Act—

20 (1) “advanced manufacturing” means an ap-
21 proach for the manufacturing of pharmaceuticals
22 that incorporates novel technology, or uses an estab-
23 lished technique or technology in a new or innovative
24 way (such as continuous manufacturing where the
25 input materials are continuously transformed within

1 the process by 2 or more unit operations), that en-
2 hances drug quality or improves the manufacturing
3 process;

4 (2) the term “continuous manufacturing”—

5 (A) means a process where the input mate-
6 rials are continuously fed into and transformed
7 within the process, and the processed output
8 materials are continuously removed from the
9 system; and

10 (B) consists of an integrated process that
11 consists of a series of 2 or more unit oper-
12 ations;

13 (3) the term “drug” has the meaning given
14 such term in section 201(g) of the Federal Food,
15 Drug, and Cosmetic Act (21 U.S.C. 321(g));

16 (4) the term “Secretary”, unless otherwise
17 specified, means the Secretary of Health and
18 Human Services;

19 (5) the term “starting material” means a raw
20 material, intermediate, or a drug substance that is
21 used in the production of a drug substance and that
22 is incorporated as a significant structural fragment
23 into the structure of the drug substance; and

24 (6) the term “strategic national stockpile”
25 means the stockpile maintained by the Secretary

1 under section 319F-2 of the Public Health Service
2 Act (42 U.S.C. 247d-6b).

○