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S. 1366

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

IN THE SENATE OF THE UNITED STATES

APRIL 26, 2021

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

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A BILL

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

Be it enacted by the Senate and House of Representatives of the United States of America in Congress assembled,

SECTION 1. SHORT TITLE.

This Act may be cited as the ''Pharmaceutical Supply Chain Defense and Enhancement Act''.

SEC. 2. LISTING OF CRITICAL DRUGS.

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

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

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

(c) SUBMISSION OF LIST.—The Secretary shall submit the list described in subsection (a), including any updates to such list under subsection (b), as a classified matter, to the Committee on Health, Education, Labor, and Pensions, the Committee on Armed Services, the Committee on Foreign Relations, and the Committee on Banking, Housing, and Urban Affairs of the Senate, and to the Committee on Energy and Commerce, the Committee on Armed Services, the Committee on Foreign Affairs, and the Committee on Financial Services of the House of Representatives.

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

and Drugs, the Secretary of Defense, and the Assistant Secretary for Preparedness and Response, shall establish an interim list of drugs that will be deemed the list under subsection (a) until the Secretary develops the first list under subsection (a). Such interim list shall include not fewer than 30 drugs, as well as the active pharmaceutical ingredients and starting materials required for the manufacture of such drugs, that are—

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

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

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

SEC. 3. BOOSTING DOMESTIC DRUG AND ACTIVE INGREDIENT MANUFACTURING CAPACITY.

(a) IN GENERAL.—The Secretary, acting through the Director of the Biomedical Advanced Research and Development Authority, shall increase the domestic capacity to manufacture active pharmaceutical ingredients and starting materials for drugs critical to the public health and

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

(b) CONTRACTS.—

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

(A) The Secretary shall enter into contracts with companies and nonprofit entities headquartered in the United States, under which such companies use manufacturing establishments located in the United States to manufacture the drugs included on the list under section 2, and the requisite active pharmaceutical ingredients and starting materials of such drugs, using advanced manufacturing, including continuous manufacturing where applicable.

(B) As a condition for entering into contracts with the Secretary to manufacture drugs, companies and nonprofit entities shall—

(i) develop and maintain a redundancy risk management and continuity of business plan (reviewed and approved by the Secretary) that identifies and evaluates risks to the supply of the drug, as applica-

ble, for each establishment in which such drug, and the requisite active pharmaceutical ingredients and starting materials of such drug, is manufactured;

(ii) commit to implementing, as appropriate, risk management and other strategies to ensure that, in the case of potential supply chain disruptions, the entity can continue normal production of the drug, and the requisite active pharmaceutical ingredients and starting materials of such drug, for 18 months;

(iii) commit to maintaining, to the extent practicable (as determined by the Secretary) for each drug, and the requisite active pharmaceutical ingredients and starting materials of such drug, a 3-month supply in order to mitigate the impact of supply chain disruptions and shortages;

(iv) commit to selling drugs, or the requisite active pharmaceutical ingredients and starting materials of such drugs, developed under contract with the Secretary at fair and reasonable prices, as deter-

mined by the Secretary, taking into consideration—

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

(II) the cost of the drug to Federal or State health programs;

(III) the cost of manufacturing the drug; and

(IV) the impact of price on market competition for the drug; and

(v) commit to making the prices described in clause (iv) public.

(C) The contracts described in this paragraph shall contain continuity of business agreements demonstrating, in advance of receiving a contract, the company's ability to rapidly begin production.

(D) The Secretary shall enter into contracts only with companies headquartered in the United States that use manufacturing establishments located in the United States, under which such companies expand the capabilities of continuous manufacturing and other advanced manufacturing for the production of the active pharmaceutical ingredients and starting mate-

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

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

(i) contracts designed to enhance the supply of generic drugs and biosimilar biological products and the requisite active pharmaceutical ingredients and starting materials of such generic drugs and biosimilar products; and

(ii) contracts designed to enhance the supply of drugs, and the requisite active pharmaceutical ingredients and starting materials of such drugs, that are not currently manufactured in the United States.

(2) INSPECTOR GENERAL REVIEW.—The Inspector General of the Department of Health and Human Services shall conduct a review of not fewer than 1 of every 3 contracts entered into under this section, and of the entities entering into such contracts, to ensure that contracts are being issued under fair and reasonable terms and conditions, including facilitating the procurement by the Federal Government of applicable products under section 2 and applicable drugs, biological products, and med-

ical devices at fair and reasonable prices. The Inspector General shall make each such review public and, in cases where such a review identifies unreasonable prices, submit recommendations to Congress on how the Office should improve its contracting systems to ensure reasonable pricing.

(3) FUNDING.—To carry out this section, there are authorized to be appropriated $5,000,000,000 for the period of fiscal years 2021 and 2025. Not later than April 1, 2025, the Secretary shall report to the congressional committees listed under section 2(c) of this Act, and provide a recommendation for renewal of funding under this paragraph.

(c) FEDERAL PROCUREMENT OF DOMESTICALLY MANUFACTURED DRUGS.—

(1) PROCUREMENT OF DRUGS.—

(A) IN GENERAL.—Beginning in fiscal year 2025, when purchasing any drug included on the list under section 2, the Secretary of Defense, the Secretary of Veterans Affairs, the Director of the Bureau of Prisons, and, for purposes of maintaining the strategic national stockpile, the Secretary of Health and Human Services, shall give priority to supplies of the drug manufactured in the United States (in-

cluding all active pharmaceutical ingredient and starting materials of the drug) that is of high quality.

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

(2) FUNDING.—

(A) IN GENERAL.—There are authorized to be appropriated to each of the Secretary of Defense, the Secretary of Veterans Affairs, the Bureau of Prisons, and the Secretary of Health and Human Services, $1,000,000,000 for the period of fiscal years 2025 and 2029, to be used to purchase drugs manufactured in the United States, as described in paragraph (1).

(B) REVERSION.—All funds that are appropriated under this paragraph for a fiscal year, but not expended by the end of the fiscal

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

(C) NO DIVERSION OR TRANSFER OF FUNDS.—No funding appropriated under this section shall be diverted, transferred, or otherwise made available for purposes beyond what is described in this Act.

(3) NIH AUTHORIZATION.—There are authorized to be appropriated to the Director of the National Institutes of Health, for each fiscal year for which amounts are appropriated under paragraph (2) but not expended in full, an amount equal to the amount that reverts to the Treasury for such year, as described in paragraph (2). Such amounts shall be used by the Director of the National Institutes of Health to carry out biomedical research.

SEC. 4. SUPPLY CHAIN TRANSPARENCY.

(a) DOMESTIC SUPPLIERS TO FEDERAL PROGRAMS.—Each domestic manufacturer of a drug that supplies such drug to the Department of Defense, the Department of Veterans Affairs, the Department of Health and Human Services, or the Bureau of Prisons, or a domestic manufacturer of an active ingredient of a drug so supplied, shall—

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

(A) whether any ingredients of such drug is sourced, either wholly or in part, from a foreign country;

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

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

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

(iii) a statement that no such alternative sources are available; and

(C) an assessment of the resilience and capacity of the alternate sources identified under subparagraph (B); and

(2) develop continuity of business plans to prevent the disruption of any drug listed under section 2, including any active or inactive ingredients of such drug, which the Secretary may audit.

(b) FOREIGN DRUG SUPPLIERS.—

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

''(5) The requirements of paragraphs (1) and (2) shall apply to establishments within a foreign country engaged in the manufacture, preparation, propagation, compounding, or processing of any drug that is required to be listed pursuant to subsection (j), or of any active pharmaceutical ingredient of such a drug. Such requirements shall apply regardless of whether the drug or active pharmaceutical ingredient undergoes further manufacture, preparation, propagation, compounding, or processing at a separate establishment or establishments outside the United States prior to being imported or offered for import into the United States.''.

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

(A) in subparagraph (D), by striking ''and'' at the end;

(B) in subparagraph (E), by striking the period at the end and inserting ''; and''; and

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

''(F) in the case of a drug contained in the applicable list, a certification that the registrant has—

''(i) identified every other establishment where manufacturing is performed for the drug by the registrant; and

''(ii) notified each known foreign establishment engaged in the manufacture, preparation, propagation, compounding, or processing of the drug or the active pharmaceutical ingredient of the drug of the inclusion of the drug in the list and the obligation to register pursuant to subsection (i)(5).''.

(c) REPORTS TO CONGRESS AND THE PUBLIC.—

(1) CLASSIFIED REPORT TO CONGRESS.—Not later than 1 year after the date of enactment of this Act and annually thereafter, the Secretary, in consultation with the Secretary of Defense, shall submit a classified report to Congress on the Nation's reliance on importation of active and inactive ingredients of drugs included on the list under section 2.

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

and shall make such summary publicly available on the internet websites of the Department of Health and Human Services and the Department of Defense for purposes of understanding the Nation's dependency on foreign manufacturers of drugs. Such summaries shall not include the names of any drugs, active pharmaceutical ingredients, or starting materials.

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

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

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

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

(iii) are critical to the public health and national security of the people of the United States, as determined by the Secretary, in consultation with the Secretary of Defense, and including any drugs included in the list under section 2; or

(iv) are procured in any quantity by the Department of Defense for use by service members or veterans or by the Department of Health and Human Services for the strategic national stockpile;

(B) a list of potential, alternative sources for any finished drug or active or inactive ingredient of a drug, that is sourced from a single manufacturer with establishments in the United States; and

(C) assess the resiliency and capacity of alternative sources of any drug described in subparagraph (A), and whether any such alternative source could be relied on to support domestic demand for such drug.

(d) MANUFACTURER COMPLIANCE.—

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

''(fff) The failure of a manufacturer of a drug described in section 506C(a), or an active pharmaceutical ingredient of such a drug, to notify the Secretary of a permanent discontinuance or an interruption, and the reasons

for such discontinuance or interruption, as required by section 506C.''.

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

(e) REGISTRY OF ACTIVE INGREDIENTS.—There is authorized to be appropriated to the Secretary of Health and Human Services $20,000,000 for fiscal year 2022, for purposes of establishing, in consultation with the Commissioner of Food and Drugs, an online registry of active pharmaceutical ingredients and key starting materials using information reported under subsection (a) and pursuant to a registration under section 510(i) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360(i)).

(f) FOOD AND DRUG ADMINISTRATION INSPECTIONS.—There are authorized to be appropriated such funds as may be necessary to ensure that the Commissioner of Food and Drugs is able to conduct inspections

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

SEC. 5. OVERSIGHT OF FOREIGN PHARMACEUTICAL INVESTMENT.

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

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

(1) An assessment of—

(A) the supply chain of the pharmaceutical industry of the United States and the effect of concentration and reliance on foreign manufacturing within that industry;

(B) the effect of foreign investment in the pharmaceutical industry of the United States on domestic capacity to produce drugs and active and inactive ingredients of drugs; and

(C) the effect of foreign investment in technologies or other products for sequencing or storage of DNA, including genome and exome analysis, in the United States, including the effect of such investment on the capacity to sequence or store DNA in the United States.

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

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

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

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

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

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

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

(e) APPROPRIATE CONGRESSIONAL COMMITTEES DEFINED.—In this section, the term ''appropriate congressional committees'' means—

(1) the Committee on Banking, Housing, and Urban Affairs, the Committee on Health, Education, Labor, and Pensions, the Committee on Armed Services, the Committee on Foreign Relations, the Committee on Commerce, Science, and Transportation, and the Committee on Appropriations of the Senate; and

(2) the Committee on Financial Services, the Committee on Energy and Commerce, the Committee on Armed Services, the Committee on Foreign Affairs, and the Committee on Appropriations of the House of Representatives.

SEC. 6. DEFINITIONS.

In this Act—

(1) ''advanced manufacturing'' means an approach for the manufacturing of pharmaceuticals that incorporates novel technology, or uses an established technique or technology in a new or innovative way (such as continuous manufacturing where the input materials are continuously transformed within

the process by 2 or more unit operations), that enhances drug quality or improves the manufacturing process;

(2) the term ''continuous manufacturing''—

(A) means a process where the input materials are continuously fed into and transformed within the process, and the processed output materials are continuously removed from the system; and

(B) consists of an integrated process that consists of a series of 2 or more unit operations;

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

(4) the term ''Secretary'', unless otherwise specified, means the Secretary of Health and Human Services;

(5) the term ''starting material'' means a raw material, intermediate, or a drug substance that is used in the production of a drug substance and that is incorporated as a significant structural fragment into the structure of the drug substance; and

(6) the term ''strategic national stockpile'' means the stockpile maintained by the Secretary

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

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