116TH CONGRESS
2D SESSION

S. 3847

To amend the Public Health Service Act to establish an Emergency Office of Manufacturing for Public Health, and for other purposes.

IN THE SENATE OF THE UNITED STATES

JUNE 1, 2020

Ms. WARREN 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 amend the Public Health Service Act to establish an Emergency Office of Manufacturing for Public Health, 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 ''COVID–19 Emergency Manufacturing Act of 2020''.

SEC. 2. PUBLIC MANUFACTURING OF PHARMACEUTICALS.

Part A of title III of the Public Health Service Act (42 U.S.C. 241 et seq.) is amended by adding at the end the following:

"SEC. 310B. MANUFACTURING OF DRUGS, BIOLOGICAL PRODUCTS, DEVICES, AND PERSONAL PROTECTIVE EQUIPMENT.

''(a) EMERGENCY OFFICE OF MANUFACTURING FOR PUBLIC HEALTH.—

''(1) ESTABLISHMENT.—There is established within the Department of Health and Human Services an office to be known as the Emergency Office of Manufacturing for Public Health (referred to in this section as the 'Office').

''(2) PURPOSE.—The purposes of the Office are—

''(A) to ensure an adequate supply of, and increase access to, prescription drugs, biological products, devices, and other supplies, including personal protective equipment, necessary to, as appropriate, diagnose, mitigate, prevent, or treat COVID–19 and to mitigate the harm the COVID–19 pandemic might otherwise cause for the strategic national stockpile under section 319F–2, Federal, State, local, and Native health programs, and the commercial market;

''(B) to address shortages in the strategic national stockpile and commercial market of prescription drugs, biological products, devices,

and personal protective equipment used to treat conditions other than COVID–19; and

''(C) to provide prescription drugs, biological products, devices, and personal protective equipment necessary to diagnose, mitigate, prevent, and treat COVID–19 and to mitigate the harm the COVID–19 pandemic might otherwise cause, to Federal, State, local, and Native health programs, at no cost, and to consumers in the commercial market and other international entities at cost.

''(3) PERSONNEL.—

''(A) DIRECTOR.—

''(i) IN GENERAL.—The Office shall be headed by a Director, who shall be appointed by the President, not later than 15 days after the date of enactment of the COVID–19 Emergency Manufacturing Act of 2020, by and with the advice and consent of the Senate.

''(ii) ACTING DIRECTOR.—The Assistant Secretary for Preparedness and Response, if in compliance with subparagraph (C), may serve as Director of the Office in an acting capacity until the later of Senate

confirmation of a Director or 3 months after date of enactment of the COVID–19 Emergency Manufacturing Act of 2020.

''(iii) COMPENSATION.—The Director shall be compensated at the rate prescribed for level III of the Executive Schedule under section 5314 of title 5, United States Code.

''(B) EMPLOYEES.—The Director of the Office, in consultation with the Secretary, may fix the number of, and appoint and direct, all employees of the Office.

''(C) BANNED INDIVIDUALS.—

''(i) DRUG COMPANY LOBBYISTS.—No former registered drug manufacturer lobbyist—

''(I) may be appointed to the position of Director of the Office; or

''(II) may be employed by the Office during the 6-year period beginning on the date on which the registered lobbyist terminates its registration in accordance with section 4(d) of the Lobbying Disclosure Act

of 1995 or the agent terminates its status, as applicable.

''(ii) SENIOR EXECUTIVES OF LAW-BREAKING COMPANIES.—No former senior executive of a covered entity—

''(I) may be appointed to the position of Director of the Office; or

''(II) may be employed by the Office during the 6-year period beginning on the later of—

''(aa) the date of the settlement; and

''(bb) the date on which the enforcement action has concluded.

''(iii) COVERED ENTITY.—For purposes of clause (ii), the term 'covered entity' means any entity that is—

''(I) a drug manufacturer; and

''(II)(aa) operating under Federal settlement, including a Federal consent decree; or

''(bb) the subject of an enforcement action in a court of the United States or by an agency.

''(4) DUTIES.—

''(A) IN GENERAL.—The Office shall—

''(i) prepare and submit applications for approval to the Food and Drug Administration, or enter into contracts for such submission, for the manufacture of applicable COVID–19 products and other applicable drugs, biological products, and devices when authorized under this section;

''(ii) obtain rights to manufacture applicable COVID–19 products and applicable drugs, biological products, and devices as authorized under this section;

''(iii) manufacture, or enter into contracts with entities to manufacture, applicable COVID–19 products and other applicable drugs, biological products, and devices as authorized under this section;

''(iv) determine a fair price for each applicable drug, biological product, and device, in accordance with subparagraph (B)(ii);

''(v) sell manufactured applicable drugs, biological products, and devices at a fair price, as authorized under this section;

"(vi) provide, at no cost, applicable COVID–19 products to Federal, State, local, and Native health programs, and other domestic health care providers and suppliers, as determined by the Secretary;

"(vii) sell, at-cost, applicable COVID–19 products to other commercial entities and international entities, in accordance with subparagraph (B)(i); and

"(viii) manufacture, or enter into contracts with entities to manufacture, active pharmaceutical ingredients for use by the Office or for sale to other entities.

"(B) PRICING DETERMINATIONS.—

"(i) AT-COST PRICE.—In determining an at-cost price for an applicable COVID–19 product under subparagraph (A)(vii) the Office shall consider—

"(I) the cost to the Federal Government of manufacturing the applicable COVID–19 product;

"(II) the administrative costs of operating the Office; and

''(III) the cost to acquire or manufacture applicable COVID–19 product under this section.

''(ii) FAIR PRICE.—In determining a fair price for an applicable drug, biological product, or device under subparagraph (A)(iv) the Office shall consider—

''(I) the impact of price on patient access to the applicable drug, biological product, or device;

''(II) the cost of the applicable drug, biological product, or device to Federal or State health care programs;

''(III) the cost to the Federal Government of manufacturing the applicable drug, biological product, or device;

''(IV) the administrative costs of operating the Office;

''(V) the cost to acquire or manufacture the applicable drug, biological product, or device under this section; and

''(VI) the impact of price on market competition for the applicable drug, biological product, or device.

''(iii) TRANSPARENCY.—All prices charged for applicable COVID–19 products and applicable drugs, biological products, or devices shall be made publicly available by the Office.

''(C) OBTAINING RIGHTS TO MANUFACTURE AND MARKET.—

''(i) IN GENERAL.—When necessary to fulfill the Office's duties under this section, the Office shall acquire the rights to manufacture and market applicable COVID–19 products and applicable drugs, biological products, and devices as authorized under this section.

''(ii) LICENSING AUTHORITY.—

''(I) IN GENERAL.—Notwithstanding any other provision of law, the Secretary may issue licenses, as useful for fulfilling the duties under this Act, allowing the Office to practice or have practiced (which may include licensure of retroactive practice)

any invention in the United States or territories of the United States, including making, using, offering to sell or selling, importing, or exporting such invention, to reference or rely upon clinical trial data submitted to a regulatory authority or the grant of marketing approval, and to access and use otherwise confidential information, including know-how, related to the manufacture of an applicable COVID–19 product or applicable drug, biological product, or device.

''(II) NON-VOLUNTARY LICENSING.—For any license that involves a non-voluntary authorization to use patented inventions, regulatory test data, data, know-how or other intellectual property rights, the license shall provide for reasonable remuneration to rights holders such as a reasonable royalty on the sales of product, a 1-time payment, or some combination, provided that the combined royalty payments to all rights holders

shall not exceed the percentage of sales that is the average percent of all royalty payments reported to the Internal Revenue Service by companies in the pharmaceutical and medicines sector, North American Industry Classification System code 325410, provided that when products are distributed for free, the royalty shall be based upon the cost of goods. When there are multiple rights holders, the allocation of the total royalty payments shall be determined by—

"(aa) agreement among the rights holders;

"(bb) allocation by arbitration among the rights holders; or

"(cc) if neither item (aa) nor (bb) applies, by the Office.

"(iii) TRANSPARENCY.—Subject to clause (iv), the Secretary shall post any contract agreement under subparagraph (A) or license issued under clause (ii) on the public internet website of the Department of Health and Human Services, on

the date on which such agreement or license takes effect.

''(iv) PROTECTED INFORMATION.—In carrying out this section, the Secretary shall enforce applicable law concerning the protection of confidential commercial information and trade secrets.

''(D) ACTIVE PHARMACEUTICAL INGREDIENTS.—

''(i) IN GENERAL.—The Office shall manufacture, or enter into contracts with entities to manufacture, an active pharmaceutical ingredient applicable to a drug or biological product that is either an applicable COVID–19 product or an applicable drug or biological product if—

''(I) the Office determines that such ingredient is not readily available from existing suppliers or the existing supply of such ingredient to the domestic market is vulnerable to disruption;

''(II) the manufacture of such ingredient would improve the ability of other entities to enter the market for

the manufacture of applicable COVID–19 products or applicable drugs, biological products, or devices, or otherwise expand the manufacture of applicable COVID–19 products or applicable drugs, biological products, or devices; or

''(III) the manufacture of such ingredient is necessary for the Office to carry out its duties under this section.

''(ii) PRICE DETERMINATIONS.—In determining the price at which to sell an active pharmaceutical ingredient manufactured in accordance with clause (i), the Office shall consider the cost to manufacture the ingredient, the administrative costs of the Office with respect to the ingredient, and the impact of such price on market competition for the ingredient.

''(E) PRIORITY.—In awarding contracts under this paragraph, the Office shall prioritize entities manufacturing applicable COVID–19 products and applicable drugs, biological prod-

ucts, and devices using components originating and manufactured in the United States.

''(F) CONTRACT REQUIREMENTS.—All contracts issued under this paragraph shall include a requirement that the contract recipients reasonably price products produced under the contract.

''(b) MANUFACTURING OF PRODUCTS.—

''(1) IN GENERAL.—As soon as practicable after the date of enactment of this section, but no later than 1 month after such date of enactment, the Office shall begin—

''(A) manufacturing, or entering into contracts with entities for the manufacture of applicable COVID–19 products and applicable drugs, biological products, and devices, prioritizing drugs, biological products, devices or personal protective equipment the manufacture of which would provide the greatest public health impact; and

''(B) constructing, or entering into contracts to construct, manufacturing facilities, including the construction of advanced manufacturing technology, RNA vaccines, DNA vaccines, recombinant protein vaccines, and other

therapeutics, viral vector-based vaccines, live attenuated vaccines, inactivated vaccines, or other therapeutics, after clinical data relating to such products have demonstrated strong positive indications of safety and efficacy, to ensure immediate production at-scale upon Federal approval.

''(2) SUBMISSION OF APPLICATIONS.—For each applicable COVID–19 product, and for each applicable drug, biological product, or device that the Office determines should be manufactured, as provided for under this section, the Secretary shall—

''(A) submit an application under section 505(b), 505(j), or 515 of the Federal Food, Drug, and Cosmetic Act or section 351(a) or 351(k) of this Act or submit a notification under section 510(k) of the Federal Food, Drug, and Cosmetic Act (or enter into a contract with another entity to submit such an application or notification);

''(B) request an emergency use authorization of the product under section 564A of the Federal Food, Drug, and Cosmetic Act (or enter into a contract with another entity to submit an application for such use); or

"(C) obtain from the holder of an application approved under subsection (c) or (j) of section 505 or section 515 of the Federal Food, Drug, and Cosmetic Act or subsection (a) or (k) of section 351 of the Public Health Service Act, or cleared under section 510(k) of the Federal Food, Drug, and Cosmetic Act, rights to manufacture such applicable drug.

"(3) MANUFACTURING TIMELINES.—

"(A) PERSONAL PROTECTIVE EQUIPMENT.—Not later than 1 month after the date of enactment of this section, the Secretary shall begin the public manufacturing of personal protective equipment, including surgical masks, surgical gowns, face shields, and N95 masks, meeting the definition of applicable COVID–19 product and in accordance with this section.

"(B) COVID–19 DIAGNOSTIC TEST MATERIALS.—Not later than 1 month after the date of enactment of this section, the Secretary shall begin the public manufacturing of materials necessary for the development of COVID–19 diagnostic tests, including chemical reagents, test swabs, and materials necessary to develop serological COVID–19 tests, meeting the definition

of applicable COVID–19 product and in accordance with this section.

''(C) COVID–19 TREATMENT DRUGS.—As soon as practicable after the date of enactment of this section, the Secretary shall begin the public manufacturing of drugs and biological products in shortage, and any devices used to administer such drugs and biological products, that are used for treatment of severe COVID–19 cases, including albuterol, drugs used to intubate patients, antibiotics, and antivirals, meeting the definition of applicable COVID–19 product and in accordance with this section.

''(4) PRIORITY MANUFACTURING.—The Office shall prioritize the manufacturing of applicable COVID–19 products and applicable drugs, biological products, and devices that would have the greatest impact on—

''(A) diagnosing, mitigating, preventing, treating, or curing COVID–19;

''(B) limiting the harm the COVID–19 pandemic might otherwise cause to public health and the economy;

''(C) addressing shortages of drugs, biological, products, and devices;

"(D) reducing the cost of combating COVID–19 to Federal, State, local, and Native health programs; and

"(E) alleviating demographic disparities in COVID–19 outcomes or access to diagnosis, mitigation, prevention, and treatment.

"(c) PROVISION OF PRODUCTS.—

"(1) PROVISION OF APPLICABLE COVID–19 PRODUCTS.—The Secretary shall provide applicable COVID–19 products at no cost to Federal, State, local, and Native health programs, and other domestic health care providers and suppliers, including domestic commercial health care providers, as determined by the Secretary, and sell at cost applicable COVID–19 products to other commercial entities and international entities. Amounts received from the sale of such drugs shall be used for the activities of the Office.

"(2) PROVISION OF APPLICABLE DRUGS, BIOLOGICAL PRODUCTS AND DEVICES.—The Secretary shall sell applicable drugs, biological products, and devices produced under this section at a fair price to other entities. Amounts received from the sale of such drugs shall be used to replenish the national strategic stockpile under section 319F–2.

"(d) OVERSIGHT OF CONTRACTS.—In the case of applicable COVID–19 products and applicable drugs, biological products, and devices manufactured via contracts, 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 the Office is issuing contracts under fair and reasonable terms and conditions, including facilitating the procurement by the Federal Government of applicable COVID–19 products and applicable drugs, biological products, and medical 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.

"(e) REPORTS TO CONGRESS.—The Director shall prepare and submit to the President, the Committee on Health, Education, Labor, and Pensions of the Senate, and the Committee on Energy and Commerce of the House of Representatives, a monthly report during the public health emergency declared by the Secretary under section 319 on January 31, 2020, with respect to COVID–

19, and a final report 3 months after the public health emergency has concluded, that includes—

''(1) an assessment of the major supply chain challenges facing hospitals, medical providers, the Federal government, State, local, and tribal governments, and the private sector in procuring drugs, biological products, devices, and personal protective equipment to combat and prevent the spread of COVID–19; and

''(2) a description of the status of all drugs, biological products, devices, active pharmaceutical ingredients, and personal protective equipment for which manufacturing has been authorized under this section, including drugs, biological products, devices, active pharmaceutical ingredients, and personal protective equipment being manufactured, drugs, biological products, devices, active pharmaceutical ingredients, and personal protective equipment for which the Office has submitted an application for approval or a notification for clearance or classification to the Food and Drug Administration but has not yet received approval, clearance, or classification, and drugs, biological products, devices, active pharmaceutical ingredients, and personal protective equipment for which the Office has received ap-

proval, clearance, or classification from the Food and Drug Administration but are not being manufactured.

''(f) DEFINITIONS.—In this section:

''(1) APPLICABLE DRUG, BIOLOGICAL PRODUCT, OR DEVICE DEFINITION.—The term 'applicable drug, biological product, or device' means a drug (as defined in section 201(g) of the Federal Food, Drug, and Cosmetic Act), biological product (as defined in section 351(i) of the Public Health Service Act), combination product (as described in section 503(g) of the Federal Food, Drug, and Cosmetic Act), or device (as defined in section 201(h) of the Federal Food Drug and Cosmetic Act) for which an approved application under section 505 or 515 of the Federal Food, Drug, and Cosmetic Act or section 351 of the Public Health Service Act, or clearance under section 510(k) of the Federal Food, Drug, and Cosmetic Act, is in effect, and—

''(A) is included in the drug shortage list under section 506E of the Federal Food, Drug, and Cosmetic Act; or

''(B) is vulnerable to shortage.

''(2) APPLICABLE COVID–19 PRODUCT DEFINITION.—

''(A) IN GENERAL.—The term 'applicable COVID–19 product' means a product that is included on a list that the Secretary of Health and Human Services, in consultation with the Commissioner of Food and Drugs, the Assistant Secretary for Preparedness and Response, and the Director of the Centers for Disease Control and Prevention, shall compile not later than 2 weeks after the date of enactment of this section and shall review and update, as necessary, every 2 weeks of—

''(i) qualified pandemic or epidemic products, as defined under section 319F–3, that are—

''(I)(aa) drugs, biological products, and devices that are manufactured, used, designed, developed, modified, licensed or procured—

''(AA) to diagnose, mitigate, prevent, treat, or cure COVID–19; or

''(BB) to limit the harm the COVID–19 pandemic might otherwise cause;

''(bb) drugs, biological products, and devices that are manufactured, used, designed, developed, modified, licensed, or procured to diagnose, mitigate, prevent, treat, or cure a serious or life-threatening disease or condition caused by a product described in item (aa); or

''(cc) drugs, biological products, devices or technologies intended to enhance the use or effect of a drug, biological product, or device described in item (aa) or (bb); and

''(ii) personal protective equipment, including protective equipment for eyes, face, head, and extremities, protective clothing, respiratory devices, and protective shields and barriers, used to protect people from COVID–19 infection.

''(B) CONSULTATION.—In developing the list described in subparagraph (A), the Secretary shall consult with the Administrator of the Federal Emergency Management Administration and the Secretary of Defense to ensure that, in instances where the President has en-

acted the Defense Production Act to produce applicable COVID–19 products, the Office does not replicate or overproduce products being developed under the Act.

''(3) NATIVE HEALTH PROGRAM.—The term 'Native health program' shall include—

''(A) a program provided through the Indian Health Service;

''(B) any health program operated by—

''(i) an Indian tribe, or Tribal organization, as such terms are defined in section 4 of the Indian Self-Determination and Education Assistance Act;

''(ii) an inter-tribal consortium, as defined in section 501(a) of the Indian Self-Determination and Education Assistance Act; or

''(iii) an urban Indian organization, as defined in section 4 of the Indian Health Care Improvement Act; and

''(C) any health program provided through a Native Hawaiian health care system, as defined in section 12 of the Native Hawaiian Health Care Improvement Act.

''(4) DOMESTIC HEALTH CARE PROVIDER.—The term 'domestic health care provider' shall include the direct support professional, home health, and personal care attendant workforce.

''(g) AUTHORIZATION OF APPROPRIATIONS.—There are authorized to be appropriated such sums as may be necessary to carry out this section.''.

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