115TH CONGRESS
2D SESSION

S. _____

To amend the Public Health Service Act to establish an Office of Drug Manufacturing.

IN THE SENATE OF THE UNITED STATES

Ms. WARREN introduced the following bill; which was read twice and referred to the Committee on _____

A BILL

To amend the Public Health Service Act to establish an Office of Drug Manufacturing.

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 ''Affordable Drug Manufacturing Act of 2018''.

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.

''(a) ESTABLISHMENT OF OFFICE OF DRUG MANUFACTURING.—

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

''(2) PURPOSE.—The purpose of the Office is—

''(A) to increase competition, lower prices, and address shortages in the market for prescription drugs, including insulin;

''(B) to reduce the cost of prescription drugs to Federal and State health programs, taxpayers, and consumers; and

''(C) to increase patient access to affordable drugs.

''(3) PERSONNEL.—

''(A) DIRECTOR.—

''(i) IN GENERAL.—The Office shall be headed by a Director, who shall be appointed by the President, by and with the advice and consent of the Senate.

''(ii) COMPENSATION.—The Director shall be compensated at the rate prescribed for level III of the Executive Schedule.

''(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 (2 U.S.C. 1603(d)) or the agent terminates its status, as applicable.

''(ii) SENIOR EXECUTIVES OF LAWBREAKING COMPANIES.—No former senior executive of a covered entity (as defined in clause (iii))—

''(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.—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 drugs when authorized under this section;

"(ii) acquire rights to manufacture applicable drugs as authorized under this section;

"(iii) manufacture, or enter into contracts with entities to manufacture, applicable drugs as authorized under this section;

"(iv) determine a fair price for each applicable drugs, in accordance with subparagraph (B);

"(v) sell manufactured applicable drugs at a fair price as authorized under this section; and

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

"(B) FAIR PRICE.—In determining a fair price for an applicable drug under subparagraph (A)(iv) the Office shall consider—

"(i) the impact of price on patient access to the applicable drug;

"(ii) the cost of the applicable drug to Federal or State health care programs;

"(iii) the cost to the Federal Government of manufacturing the applicable drug;

"(iv) the administrative costs of operating the Office;

"(v) the cost to acquire or manufacture applicable drugs under this section; and

"(vi) the impact of price on market competition for the applicable drug.

"(C) ACQUIRING RIGHT TO MANUFACTURE AND MARKET.—The Office may acquire the rights to manufacture and market applicable drugs as authorized under this section.

"(D) ACTIVE PHARMACEUTICAL INGREDIENTS.—

"(i) IN GENERAL.—The Office shall manufacture, or enter into contracts with entities to manufacture, an active pharmaceutical ingredient if—

"(I) the Office determines that such ingredient is not readily available from existing suppliers;

"(II) the manufacture of such ingredient would improve the ability of

other entities to enter the market for the manufacture of generic drugs or otherwise expand the manufacture of generic drugs; 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 what price at which to sell an active pharmaceutical ingredient under 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.

"(5) 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, an annual report that includes—

"(A) an assessment of the major problems faced by patients in accessing affordable generic medications;

"(B) a description of the status of all medications for which manufacturing has been authorized under this section, including medications being manufactured, medications for which the Office has submitted an application to the Food and Drug Administration but has not yet received approval, and medications for which the Office has received approval from the Food and Drug Administration but are not being manufactured; and

"(C) an analysis of how the public manufacture of drugs meeting the conditions described in paragraph (6) would impact, or has already impacted, competition, access to such drugs, the costs of such drugs, the costs of prescription drugs to Federal and State health programs, and public health.

"(6) PRIORITY MANUFACTURING.—The Office shall prioritize the manufacturing of those applicable drugs that would have the greatest impact on—

"(A) lowering drug costs to patients;

"(B) increasing competition and addressing shortages in the prescription drug market;

"(C) improving public health; or

"(D) reducing the cost of prescription drugs to Federal and State health programs.

"(7) MANUFACTURING LEVELS.—Not later than 1 year after the date of enactment of this section, the Office shall manufacture, or enter into contracts with entities for the manufacture, of not less than 15 applicable drugs. Not later than 3 years after such date of enactment, the Office shall manufacture, or enter into contracts with entities for the manufacture, of not less than 25 applicable drugs.

"(b) SUBMISSION OF APPLICATIONS.—For each applicable drug that the Office determines should be manufactured, as provided for under this section, the Secretary shall—

"(1) submit an application under section 505(j) or 515 of the Federal Food, Drug, and Cosmetic Act or section 351(k) of the Public Health Service 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); or

''(2) acquire 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 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.

''(c) USE.—

''(1) IN GENERAL.—The Secretary shall sell a drug produced under this section at a fair price to other entities. Amounts received from the sale of such drugs shall be used for the activities of the Office.

''(2) SALE OF APPROVED APPLICATION.—

''(A) IN GENERAL.—For any applicable drug that the Office is manufacturing, the Secretary shall, beginning 3 years after the date on which the Office first undertakes manufacturing of such drug and annually thereafter, make available for sale, to any person who commits to manufacturing and marketing the applicable drug, the approved application for the drug.

''(B) FAILURE TO USE.—If a person purchasing an approved application under subparagraph (A)—

"(i) fails to market the applicable drug within 6 months of the date of such purchase; or

"(ii) increases the average manufacturer price for the applicable drug above the fair price (increased by the consumer price index for all urban consumers (as published by the Bureau of Labor Statistics) for that year);

the Secretary shall revoke the purchaser's approved application and resume production of the applicable drug.

"(d) INSULIN.—Not later than 1 year after the date of enactment of this section, the Secretary shall begin the public manufacturing of insulin meeting the definition of applicable drug and in accordance with this section.

"(e) APPLICABLE DRUG.—In this section, the term 'applicable drug' means a drug (as defined in section 201 of the Federal Food, Drug, and Cosmetic Act), biological product (as defined in section 351 of the Public Health Service Act), or combination product (as described in section 503(g) 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—

''(1)(A) for which, with respect to a drug included in the list described in section 505(j)(7) of the Federal Food, Drug, and Cosmetic Act, each patent included with respect to such drug in such list has expired, or each patent that claims a biological product has expired;

''(B) any period of regulatory exclusivity granted under—

''(i) clause (ii), (iii), or (iv) of section 505(c)(3)(E) of the Federal Food, Drug, and Cosmetic Act, section 505(j)(5)(B)(iv) of such Act, clause (ii), (iii), or (iv) of section 505(j)(5)(F) of such Act, section 527 of such Act, and any extension of such a period granted under section 505A or 505E of such Act, has expired; or

''(ii) paragraph (6) or (7) of section 351(k) of the Public Health Service Act, and any extension of such a period granted under paragraph (2) or (3) of section 351(m) of such Act, has expired; and

''(C)(i) that is not being marketed in the United States; or

"(ii) that is being marketed in the United States by fewer than 3 manufacturers, and that—

"(I) in the previous 1-year period, has experienced a price increase that is greater than the medical component of the consumer price index for the same period;

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

"(III)(aa) has an average manufacturer price that the Secretary determines to be a barrier to patient access; and

"(bb) is listed by the World Health Organization as an essential medicine; or

"(2) for which there is in effect a license, or patent use is authorized, under—

"(A) section 1498 of title 28, United States Code;

"(B) section 202 of title 35, United States Code;

"(C) section 203 of title 35, United States Code (march-in rights);

"(D) section 209 of title 35, United States Code; or

"(E) any other licensing authority of the Federal Government.

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