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(Original Signature of Member)

118TH CONGRESS
1ST SESSION

H. R. _____

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

IN THE HOUSE OF REPRESENTATIVES

Ms. SCHAKOWSKY introduced the following bill; which was 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 2023''.

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. 310C. 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, asthma and chronic obstructive pulmonary disease (COPD) inhalers, naloxone, epinephrine auto-injectors, and antibiotics;

"(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 and associated devices.

"(3) PERSONNEL.—

"(A) DIRECTOR.—

"(i) IN GENERAL.—The Office shall be headed by a Director, who shall be appointed by the President.

''(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 industry 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)) who was employed by such en-

tity on any date on which wrongful conduct is the subject of a settlement, decree or enforcement action described in clause (iii)(III) occurred—

''(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 currently—

''(I) a drug manufacturer;

''(II) a wholesaler; and

''(III)(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, and in accordance with subparagraph (G);

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

''(iii) manufacture, or enter into contracts with entities, with preference for nonprofit entities and public partners, to manufacture, applicable drugs as authorized under this section;

''(iv) determine a fair price for each applicable drug, 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, with preference for

nonprofit entities and public partners, to manufacture active pharmaceutical ingredients for use by the Office or for sale to other entities.

''(B) TRANSPARENCY.—All prices paid and charged for applicable drugs and their inputs shall be made publicly available by the Office.

''(C) FAIR PRICE.—In determining a fair price (the price at which the Office sells an applicable drug to a wholesaler or direct purchaser) 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;

''(vi) the impact of price on market competition for the applicable drug;

''(vii) the impact of formulary design on patient access to the applicable drug; and

''(viii) the cost to acquire the applicable drug at the National Average Drug Acquisition Cost.

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

''(E) 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) such ingredient is supplied by a single manufacturing facility;

''(III) such ingredient is necessary for the manufacture of medical countermeasures or medicines deemed

essential from a public health perspective;

''(IV) the manufacture of such ingredient would improve the ability of other entities to enter the market for the manufacture of applicable drugs or otherwise expand the manufacture of applicable drugs; or

''(V) the manufacture of such ingredient is necessary for, or would improve the ability of, 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.

''(F) PURCHASE REQUIREMENTS.—Notwithstanding applicable laws relating to the procurement of prescription drugs, the Office shall establish minimum purchase requirements

for the Department of Veterans Affairs, the Department of Defense, the Public Health Service, and the Coast Guard to purchase drugs manufactured by or as a result of the Office.

''(G) LIMITATION ON UNDUE INFLUENCE.—The Food and Drug Administration shall consider an application submitted by the Office under subparagraph (A)(i) in the same manner in which the Administration considers applications submitted by other manufacturers. Nothing in this paragraph shall be construed to require the Food and Drug Administration to give special deference to any determination made, or application submitted, by the Office.

''(5) 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 drug shortages in the pharmaceutical market;

''(C) improving public health;

''(D) addressing health disparities;

''(E) reducing the cost of prescription drugs to Federal and State health programs; or

''(F) addressing public health emergencies as defined in this Act, the National Emergencies Act, and the Robert T. Stafford Disaster Relief and Emergency Assistance Act, in coordination with the Biomedical Advanced Research and Development Authority, the Administration for Strategic Preparedness and Response, the Centers for Disease Control and Prevention, and any other Federal agency that the Office determines necessary, to enable efficient procurement, including contracting, for the Federal emergency response.

''(6) 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.

''(7) 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 applicable drugs;

"(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;

"(C) in the case of antibiotics manufactured under this section, an assessment from the Centers for Disease Control and Prevention and the Food and Drug Administration on the impact of the manufacturing of antibiotics on antimicrobial resistance;

"(D) an accounting of funds received from the sale of all medications for which manufacturing has been authorized under this section and the use of such funds;

''(E) an analysis of how the public manufacture of drugs meeting the conditions described in paragraph (5) 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; and

''(F) a description of the challenges faced by the Office in carrying out its duties under paragraph (4).

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

''(1) submit an application under section 505(b)(2), 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);

''(2) request an emergency use authorization of the product, as appropriate, under section 564 of the Federal Food, Drug, and Cosmetic Act (or enter

into a contract with another entity to submit an application for such use); or

''(3) 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 this 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 Office shall sell a drug produced under this section at a fair price to other entities. Amounts received by the Office from the sale of such drugs shall be used for the activities of the Office.

''(2) SALE OF APPROVED APPLICATION.—

''(A) AVAILABILITY.—

''(i) IN GENERAL.—For any applicable drug that the Office is manufacturing, the Office 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.

''(ii) CONTINUED COMPLIANCE WITH FDA REQUIREMENTS.—The Office shall ensure that any application purchased under clause (i) is consistent with existing standards applied by the Food and Drug Administration related to the transfer of ownership rights for an approved application, including any additional filing requirements that the purchaser would need to be in compliance with due to material changes in information provided in the approved application.

''(B) FAILURE TO USE.—If the Office makes a determination that 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 Office shall revoke the purchaser's approved application and resume production of the applicable drug. The Office may waive the application of this subparagraph in the case of a National Emergency or in any other case determined appropriate by the Office.

''(d) ENSURING PATIENT ACCESS.—

''(1) IN GENERAL.—The Office shall carry out appropriate activities to ensure the distribution and coverage of all applicable drugs that the Office is manufacturing or has entered into a contract to manufacture under this section.

''(2) ADVISORY COUNCIL.—The Office shall establish an advisory council to inform the Office on the identification of applicable drugs, market landscape, and supply chain considerations to ensure delivery of applicable drugs to consumers. The advisory committee shall include representatives from community and retail pharmacies, pharmacy benefit managers, drug wholesalers, hospitals, health plans, independent patient groups, clinicians, and consumer advocacy organizations.

''(e) INSULIN.—Not later than 1 year after the date of enactment of this section, the Office shall begin the public manufacturing of at least 1 insulin product of each dosage form (such as vial, pump, or pen dosage forms) and of each different type of insulin (such as rapid-acting, short-acting, intermediate-acting, long-acting, ultra-long acting, and premixed), meeting the definition of applicable drug and in accordance with this section.

''(f) ASTHMA AND COPD INHALERS.—Not later than 1 year after the date of enactment of this section, the Office shall begin the public manufacturing of at least 1 inhaler, meeting the definition of applicable drug and in accordance with this section.

''(g) EPINEPHRINE AUTO-INJECTOR.—Not later than 1 year after the date of enactment of this section, the Office shall begin the public manufacturing of an epinephrine auto-injector, meeting the definition of applicable drug and in accordance with this section.

''(h) NALOXONE.—Not later than 1 year after the date of enactment of this section, the Office shall begin the public manufacturing of naloxone, including naloxone indicated for community use, meeting the definition of applicable drug and in accordance with this section.

''(i) ANTIBIOTICS.—Not later than 1 year after the date of enactment of this section, and in consultation with

the Centers for Disease Control and Prevention and the Food and Drug Administration to ensure the appropriate use of manufactured antibiotics, the Office shall begin the public manufacturing of no fewer than three discrete antibiotics meeting the definition of applicable drug in accordance with this section.

''(j) 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 3 or fewer manufacturers with an approved abbreviated new drug application or biosimilar (not including manufacturers of authorized generics under a new drug application or biosimilar), and that—

''(I) in the previous 5-year period, has experienced an increase in the wholesale acquisition cost by at least 1 of its manufacturers that is greater than the consumer price index for all

urban consumers (as published by the Bureau of Labor Statistics) for 1 of the years in that 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 wholesale acquisition cost that the Office 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.

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