

118TH CONGRESS
1ST SESSION

S. 3398

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

IN THE SENATE OF THE UNITED STATES

DECEMBER 5, 2023

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

A BILL

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

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 “Affordable Drug Man-
5 ufacturing Act of 2023”.

6 **SEC. 2. PUBLIC MANUFACTURING OF PHARMACEUTICALS.**

7 Part A of title III of the Public Health Service Act
8 (42 U.S.C. 241 et seq.) is amended by adding at the end
9 the following:

1 **“SEC. 310C. MANUFACTURING OF DRUGS.**

2 “(a) ESTABLISHMENT OF OFFICE OF DRUG MANU-
3 FACTURING.—

4 “(1) IN GENERAL.—There is established within
5 the Department of Health and Human Services an
6 office to be known as the Office of Drug Manufac-
7 turing (referred to in this section as the ‘Office’).

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

9 “(A) to increase competition, lower prices,
10 and address shortages in the market for pre-
11 scription drugs, including insulin, asthma and
12 chronic obstructive pulmonary disease (COPD)
13 inhalers, naloxone, epinephrine auto-injectors,
14 and antibiotics;

15 “(B) to reduce the cost of prescription
16 drugs to Federal and State health programs,
17 taxpayers, and consumers; and

18 “(C) to increase patient access to afford-
19 able drugs and associated devices.

20 “(3) PERSONNEL.—

21 “(A) DIRECTOR.—

22 “(i) IN GENERAL.—The Office shall
23 be headed by a Director, who shall be ap-
24 pointed by the President.

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

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

8 “(C) BANNED INDIVIDUALS.—

9 “(i) DRUG COMPANY LOBBYISTS.—No
10 former registered drug industry lobbyist—

11 “(I) may be appointed to the po-
12 sition of Director of the Office; or

13 “(II) may be employed by the Of-
14 fice during the 6-year period begin-
15 ning on the date on which the reg-
16 istered lobbyist terminates its reg-
17 istration in accordance with section
18 4(d) of the Lobbying Disclosure Act
19 of 1995 (2 U.S.C. 1603(d)) or the
20 agent terminates its status, as appli-
21 cable.

22 “(ii) SENIOR EXECUTIVES OF LAW-
23 BREAKING COMPANIES.—No former senior
24 executive of a covered entity (as defined in
25 clause (iii)) who was employed by such en-

1 tity on any date on which wrongful con-
2 duct is the subject of a settlement, decree
3 or enforcement action described in clause
4 (iii)(III) occurred—

5 “(I) may be appointed to the po-
6 sition of Director of the Office; or

7 “(II) may be employed by the Of-
8 fice during the 6-year period begin-
9 ning on the later of—

10 “(aa) the date of the settle-
11 ment; and

12 “(bb) the date on which the
13 enforcement action has con-
14 cluded.

15 “(iii) COVERED ENTITY.—The term
16 ‘covered entity’ means any entity that is
17 currently—

18 “(I) a drug manufacturer;

19 “(II) a wholesaler; and

20 “(III)(aa) operating under Fed-
21 eral settlement, including a Federal
22 consent decree; or

23 “(bb) the subject of an enforce-
24 ment action in a court of the United
25 States or by an agency.

1 “(4) DUTIES.—

2 “(A) IN GENERAL.—The Office shall—

3 “(i) prepare and submit applications
4 for approval to the Food and Drug Admin-
5 istration, or enter into contracts for such
6 submission, for the manufacture of appli-
7 cable drugs when authorized under this
8 section, and in accordance with subpara-
9 graph (G);

10 “(ii) acquire rights to manufacture
11 applicable drugs as authorized under this
12 section;

13 “(iii) manufacture, or enter into con-
14 tracts with entities, with preference for
15 nonprofit entities and public partners, to
16 manufacture, applicable drugs as author-
17 ized under this section;

18 “(iv) determine a fair price for each
19 applicable drug, in accordance with sub-
20 paragraph (B);

21 “(v) sell manufactured applicable
22 drugs at a fair price as authorized under
23 this section; and

24 “(vi) manufacture, or enter into con-
25 tracts with entities, with preference for

1 nonprofit entities and public partners, to
2 manufacture active pharmaceutical ingredi-
3 ents for use by the Office or for sale to
4 other entities.

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

8 “(C) FAIR PRICE.—In determining a fair
9 price (the price at which the Office sells an ap-
10 plicable drug to a wholesaler or direct pur-
11 chaser) for an applicable drug under subpara-
12 graph (A)(iv) the Office shall consider—

13 “(i) the impact of price on patient ac-
14 cess to the applicable drug;

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

17 “(iii) the cost to the Federal Govern-
18 ment of manufacturing the applicable
19 drug;

20 “(iv) the administrative costs of oper-
21 ating the Office;

22 “(v) the cost to acquire or manufac-
23 ture applicable drugs under this section;

24 “(vi) the impact of price on market
25 competition for the applicable drug;

1 “(vii) the impact of formulary design
 2 on patient access to the applicable drug;
 3 and

4 “(viii) the cost to acquire the applica-
 5 ble drug at the National Average Drug Ac-
 6 quisition Cost.

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

11 “(E) ACTIVE PHARMACEUTICAL INGREDI-
 12 ENTS.—

13 “(i) IN GENERAL.—The Office shall
 14 manufacture, or enter into contracts with
 15 entities to manufacture, an active pharma-
 16 ceutical ingredient if—

17 “(I) the Office determines that
 18 such ingredient is not readily available
 19 from existing suppliers;

20 “(II) such ingredient is supplied
 21 by a single manufacturing facility;

22 “(III) such ingredient is nec-
 23 essary for the manufacture of medical
 24 countermeasures or medicines deemed

1 essential from a public health perspec-
2 tive;

3 “(IV) the manufacture of such
4 ingredient would improve the ability
5 of other entities to enter the market
6 for the manufacture of applicable
7 drugs or otherwise expand the manu-
8 facture of applicable drugs; or

9 “(V) the manufacture of such in-
10 gredient is necessary for, or would im-
11 prove the ability of, the Office to
12 carry out its duties under this section.

13 “(ii) PRICE DETERMINATIONS.—In
14 determining what price at which to sell an
15 active pharmaceutical ingredient under
16 clause (i), the Office shall consider the cost
17 to manufacture the ingredient, the admin-
18 istrative costs of the Office with respect to
19 the ingredient, and the impact of such
20 price on market competition for the ingre-
21 dient.

22 “(F) PURCHASE REQUIREMENTS.—Not-
23 withstanding applicable laws relating to the
24 procurement of prescription drugs, the Office
25 shall establish minimum purchase requirements

1 for the Department of Veterans Affairs, the De-
 2 partment of Defense, the Public Health Service,
 3 and the Coast Guard to purchase drugs manu-
 4 factured by or as a result of the Office.

5 “(G) LIMITATION ON UNDUE INFLU-
 6 ENCE.—The Food and Drug Administration
 7 shall consider an application submitted by the
 8 Office under subparagraph (A)(i) in the same
 9 manner in which the Administration considers
 10 applications submitted by other manufacturers.
 11 Nothing in this paragraph shall be construed to
 12 require the Food and Drug Administration to
 13 give special deference to any determination
 14 made, or application submitted, by the Office.

15 “(5) PRIORITY MANUFACTURING.—The Office
 16 shall prioritize the manufacturing of those applicable
 17 drugs that would have the greatest impact on—

18 “(A) lowering drug costs to patients;

19 “(B) increasing competition and address-
 20 ing drug shortages in the pharmaceutical mar-
 21 ket;

22 “(C) improving public health;

23 “(D) addressing health disparities;

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

1 “(F) addressing public health emergencies
2 as defined in this Act, the National Emer-
3 gencies Act, and the Robert T. Stafford Dis-
4 aster Relief and Emergency Assistance Act, in
5 coordination with the Biomedical Advanced Re-
6 search and Development Authority, the Admin-
7 istration for Strategic Preparedness and Re-
8 sponse, the Centers for Disease Control and
9 Prevention, and any other Federal agency that
10 the Office determines necessary, to enable effi-
11 cient procurement, including contracting, for
12 the Federal emergency response.

13 “(6) MANUFACTURING LEVELS.—Not later
14 than 1 year after the date of enactment of this sec-
15 tion, the Office shall manufacture, or enter into con-
16 tracts with entities for the manufacture of, not less
17 than 15 applicable drugs. Not later than 3 years
18 after such date of enactment, the Office shall manu-
19 facture, or enter into contracts with entities for the
20 manufacture of, not less than 25 applicable drugs.

21 “(7) REPORTS TO CONGRESS.—The Director
22 shall prepare and submit to the President, the Com-
23 mittee on Health, Education, Labor, and Pensions
24 of the Senate, and the Committee on Energy and

1 Commerce of the House of Representatives, an an-
2 nual report that includes—

3 “(A) an assessment of the major problems
4 faced by patients in accessing affordable appli-
5 cable drugs;

6 “(B) a description of the status of all
7 medications for which manufacturing has been
8 authorized under this section, including medica-
9 tions being manufactured, medications for
10 which the Office has submitted an application
11 to the Food and Drug Administration but has
12 not yet received approval, and medications for
13 which the Office has received approval from the
14 Food and Drug Administration but are not
15 being manufactured;

16 “(C) in the case of antibiotics manufac-
17 tured under this section, an assessment from
18 the Centers for Disease Control and Prevention
19 and the Food and Drug Administration on the
20 impact of the manufacturing of antibiotics on
21 antimicrobial resistance;

22 “(D) an accounting of funds received from
23 the sale of all medications for which manufac-
24 turing has been authorized under this section
25 and the use of such funds;

1 “(E) an analysis of how the public manu-
2 facture of drugs meeting the conditions de-
3 scribed in paragraph (5) would impact, or has
4 already impacted, competition, access to such
5 drugs, the costs of such drugs, the costs of pre-
6 scription drugs to Federal and State health pro-
7 grams, and public health; and

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

11 “(b) SUBMISSION OF APPLICATIONS.—For each ap-
12 plicable drug that the Office determines should be manu-
13 factured, as provided for under this section, the Office
14 shall—

15 “(1) submit an application under section
16 505(b)(2), 505(j), or 515 of the Federal Food,
17 Drug, and Cosmetic Act or section 351(a) or 351(k)
18 of this Act or submit a notification under section
19 510(k) of the Federal Food, Drug, and Cosmetic
20 Act (or enter into a contract with another entity to
21 submit such an application);

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

1 into a contract with another entity to submit an ap-
2 plication for such use); or

3 “(3) acquire from the holder of an application
4 approved under subsection (c) or (j) of section 505
5 or section 515 of the Federal Food, Drug, and Cos-
6 metic Act or section 351 of this Act, or cleared
7 under section 510(k) of the Federal Food, Drug,
8 and Cosmetic Act, rights to manufacture such appli-
9 cable drug.

10 “(c) USE.—

11 “(1) IN GENERAL.—The Office shall sell a drug
12 produced under this section at a fair price to other
13 entities. Amounts received by the Office from the
14 sale of such drugs shall be used for the activities of
15 the Office.

16 “(2) SALE OF APPROVED APPLICATION.—

17 “(A) AVAILABILITY.—

18 “(i) IN GENERAL.—For any applicable
19 drug that the Office is manufacturing, the
20 Office shall, beginning 3 years after the
21 date on which the Office first undertakes
22 manufacturing of such drug and annually
23 thereafter, make available for sale, to any
24 person who commits to manufacturing and

1 marketing the applicable drug, the ap-
2 proved application for the drug.

3 “(ii) CONTINUED COMPLIANCE WITH
4 FDA REQUIREMENTS.—The Office shall en-
5 sure that any application purchased under
6 clause (i) is consistent with existing stand-
7 ards applied by the Food and Drug Ad-
8 ministration related to the transfer of own-
9 ership rights for an approved application,
10 including any additional filing require-
11 ments that the purchaser would need to be
12 in compliance with due to material changes
13 in information provided in the approved
14 application.

15 “(B) FAILURE TO USE.—If the Office
16 makes a determination that a person pur-
17 chasing an approved application under subpara-
18 graph (A)—

19 “(i) fails to market the applicable
20 drug within 6 months of the date of such
21 purchase; or

22 “(ii) increases the average manufac-
23 turer price for the applicable drug above
24 the fair price (increased by the consumer
25 price index for all urban consumers (as

1 published by the Bureau of Labor Statis-
2 tics) for that year),
3 the Office shall revoke the purchaser's approved
4 application and resume production of the appli-
5 cable drug. The Office may waive the applica-
6 tion of this subparagraph in the case of a Na-
7 tional Emergency or in any other case deter-
8 mined appropriate by the Office.

9 “(d) ENSURING PATIENT ACCESS.—

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

15 “(2) ADVISORY COUNCIL.—The Office shall es-
16 tablish an advisory council to inform the Office on
17 the identification of applicable drugs, market land-
18 scape, and supply chain considerations to ensure de-
19 livery of applicable drugs to consumers. The advi-
20 sory committee shall include representatives from
21 community and retail pharmacies, pharmacy benefit
22 managers, drug wholesalers, hospitals, health plans,
23 independent patient groups, clinicians, and consumer
24 advocacy organizations.

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

9 “(f) ASTHMA AND COPD INHALERS.—Not later than
10 1 year after the date of enactment of this section, the Of-
11 fice shall begin the public manufacturing of at least 1 in-
12 haler, meeting the definition of applicable drug and in ac-
13 cordance with this section.

14 “(g) EPINEPHRINE AUTO-INJECTOR.—Not later
15 than 1 year after the date of enactment of this section,
16 the Office shall begin the public manufacturing of an epi-
17 nephrine auto-injector, meeting the definition of applicable
18 drug and in accordance with this section.

19 “(h) NALOXONE.—Not later than 1 year after the
20 date of enactment of this section, the Office shall begin
21 the public manufacturing of naloxone, including naloxone
22 indicated for community use, meeting the definition of ap-
23 plicable drug and in accordance with this section.

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

1 the Centers for Disease Control and Prevention and the
 2 Food and Drug Administration to ensure the appropriate
 3 use of manufactured antibiotics, the Office shall begin the
 4 public manufacturing of no fewer than three discrete anti-
 5 biotics meeting the definition of applicable drug in accord-
 6 ance with this section.

7 “(j) APPLICABLE DRUG.—In this section, the term
 8 ‘applicable drug’ means a drug (as defined in section 201
 9 of the Federal Food, Drug, and Cosmetic Act), biological
 10 product (as defined in section 351 of the Public Health
 11 Service Act), or combination product (as described in sec-
 12 tion 503(g) of the Federal Food, Drug, and Cosmetic Act)
 13 for which an approved application under section 505 or
 14 515 of the Federal Food, Drug, and Cosmetic Act or sec-
 15 tion 351 of the Public Health Service Act, or clearance
 16 under section 510(k) of the Federal Food, Drug, and Cos-
 17 metic Act, is in effect, and—

18 “(1)(A) for which, with respect to a drug in-
 19 cluded in the list described in section 505(j)(7) of
 20 the Federal Food, Drug, and Cosmetic Act, each
 21 patent included with respect to such drug in such
 22 list has expired, or each patent that claims a biologi-
 23 cal product has expired;

24 “(B) any period of regulatory exclusivity grant-
 25 ed under—

1 “(i) clause (ii), (iii), or (iv) of section
2 505(c)(3)(E) of the Federal Food, Drug, and
3 Cosmetic Act, section 505(j)(5)(B)(iv) of such
4 Act, clause (ii), (iii), or (iv) of section
5 505(j)(5)(F) of such Act, section 527 of such
6 Act, and any extension of such a period granted
7 under section 505A or 505E of such Act, has
8 expired; or

9 “(ii) paragraph (6) or (7) of section 351(k)
10 of the Public Health Service Act, and any ex-
11 tension of such a period granted under para-
12 graph (2) or (3) of section 351(m) of such Act,
13 has expired; and

14 “(C)(i) that is not being marketed in the
15 United States; or

16 “(ii) that is being marketed in the United
17 States by 3 or fewer manufacturers with an ap-
18 proved abbreviated new drug application or bio-
19 similar (not including manufacturers of authorized
20 generics under a new drug application or biosimilar),
21 and that—

22 “(I) in the previous 5-year period, has ex-
23perienced an increase in the wholesale acquisi-
24tion cost by at least 1 of its manufacturers that
25is greater than the consumer price index for all

1 urban consumers (as published by the Bureau
 2 of Labor Statistics) for 1 of the years in that
 3 the same period;

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

7 “(III)(aa) has an average wholesale acqui-
 8 sition cost that the Office determines to be a
 9 barrier to patient access; and

10 “(bb) is listed by the World Health Orga-
 11 nization as an essential medicine; or

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

14 “(A) section 1498 of title 28, United
 15 States Code;

16 “(B) section 202 of title 35, United States
 17 Code;

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

20 “(D) section 209 of title 35, United States
 21 Code; or

22 “(E) any other licensing authority of the
 23 Federal Government.

1 “(k) AUTHORIZATION OF APPROPRIATIONS.—There
2 are authorized to be appropriated such sums as may be
3 necessary to carry out this section.”.

○