

116TH CONGRESS  
1ST SESSION

# H. R. 5501

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

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IN THE HOUSE OF REPRESENTATIVES

DECEMBER 19, 2019

Ms. SCHAKOWSKY introduced the following bill; which was referred to the Committee on Energy and Commerce

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## 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 2019”.

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. 310B. 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, naloxone, and  
12 antibiotics;

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

16 “(C) to increase patient access to afford-  
17 able drugs.

18 “(3) PERSONNEL.—

19 “(A) DIRECTOR.—

20 “(i) IN GENERAL.—The Office shall  
21 be headed by a Director, who shall be ap-  
22 pointed by the President, by and with the  
23 advice and consent of the Senate.

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

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

5           “(C) BANNED INDIVIDUALS.—

6           “(i) DRUG COMPANY LOBBYISTS.—No  
7 former registered drug manufacturer lob-  
8 byist—

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

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

20           “(ii) SENIOR EXECUTIVES OF LAW-  
21 BREAKING COMPANIES.—No former senior  
22 executive of a covered entity (as defined in  
23 clause (iii))—

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

1 “(II) may be employed by the Of-  
2 fice during the 6-year period begin-  
3 ning on the later of—

4 “(aa) the date of the settle-  
5 ment; and

6 “(bb) the date on which the  
7 enforcement action has con-  
8 cluded.

9 “(iii) COVERED ENTITY.—The term  
10 ‘covered entity’ means any entity that is—

11 “(I) a drug manufacturer; and

12 “(II)(aa) operating under Fed-  
13 eral settlement, including a Federal  
14 consent decree; or

15 “(bb) the subject of an enforce-  
16 ment action in a court of the United  
17 States or by an agency.

18 “(4) DUTIES.—

19 “(A) IN GENERAL.—The Office shall—

20 “(i) prepare and submit applications  
21 for approval to the Food and Drug Admin-  
22 istration, or enter into contracts for such  
23 submission, for the manufacture of appli-  
24 cable drugs when authorized under this  
25 section;

1           “(ii) acquire rights to manufacture  
2 applicable drugs as authorized under this  
3 section;

4           “(iii) manufacture, or enter into con-  
5 tracts with entities to manufacture, appli-  
6 cable drugs as authorized under this sec-  
7 tion;

8           “(iv) determine a fair price for each  
9 applicable drugs, in accordance with sub-  
10 paragraph (B);

11           “(v) sell manufactured applicable  
12 drugs at a fair price as authorized under  
13 this section; and

14           “(vi) manufacture, or enter into con-  
15 tracts with entities to manufacture, active  
16 pharmaceutical ingredients for use by the  
17 Office or for sale to other entities.

18           “(B) FAIR PRICE.—In determining a fair  
19 price for an applicable drug under subpara-  
20 graph (A)(iv) the Office shall consider—

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

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

1           “(iii) the cost to the Federal Govern-  
2           ment of manufacturing the applicable  
3           drug;

4           “(iv) the administrative costs of oper-  
5           ating the Office;

6           “(v) the cost to acquire or manufac-  
7           ture applicable drugs under this section;  
8           and

9           “(vi) the impact of price on market  
10          competition for the applicable drug.

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

15          “(D) ACTIVE PHARMACEUTICAL INGREDI-  
16          ENTS.—

17                 “(i) IN GENERAL.—The Office shall  
18                 manufacture, or enter into contracts with  
19                 entities to manufacture, an active pharma-  
20                 ceutical ingredient if—

21                         “(I) the Office determines that  
22                         such ingredient is not readily available  
23                         from existing suppliers;

24                         “(II) the manufacture of such in-  
25                         gredient would improve the ability of

1 other entities to enter the market for  
2 the manufacture of generic drugs or  
3 otherwise expand the manufacture of  
4 generic drugs; or

5 “(III) the manufacture of such  
6 ingredient is necessary for the Office  
7 to carry out its duties under this sec-  
8 tion.

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

18 “(5) REPORTS TO CONGRESS.—The Director  
19 shall prepare and submit to the President, the Com-  
20 mittee on Health, Education, Labor, and Pensions  
21 of the Senate, and the Committee on Energy and  
22 Commerce of the House of Representatives, an an-  
23 nual report that includes—

1           “(A) an assessment of the major problems  
2           faced by patients in accessing affordable generic  
3           medications;

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

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

20          “(D) an analysis of how the public manu-  
21          facture of drugs meeting the conditions de-  
22          scribed in paragraph (6) would impact, or has  
23          already impacted, competition, access to such  
24          drugs, the costs of such drugs, the costs of pre-



1            prescription drugs to Federal and State health pro-  
2            grams, and public health.

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

6                    “(A) lowering drug costs to patients;

7                    “(B) increasing competition and address-  
8            ing shortages in the prescription drug market;

9                    “(C) improving public health; or

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

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

20            “(b) SUBMISSION OF APPLICATIONS.—For each ap-  
21            plicable drug that the Office determines should be manu-  
22            factured, as provided for under this section, the Secretary  
23            shall—

24                    “(1) submit an application under section 505(j)  
25            or 515 of the Federal Food, Drug, and Cosmetic Act

1 or section 351(k) of the Public Health Service Act  
2 or submit a notification under section 510(k) of the  
3 Federal Food, Drug, and Cosmetic Act (or enter  
4 into a contract with another entity to submit such  
5 an application or notification); or

6 “(2) acquire from the holder of an application  
7 approved under subsection (c) or (j) of section 505  
8 or section 515 of the Federal Food, Drug, and Cos-  
9 metic Act or section 351 of the Public Health Serv-  
10 ice Act, or cleared under section 510(k) of the Fed-  
11 eral Food, Drug, and Cosmetic Act, rights to manu-  
12 facture such applicable drug.

13 “(c) USE.—

14 “(1) IN GENERAL.—The Secretary shall sell a  
15 drug produced under this section at a fair price to  
16 other entities. Amounts received from the sale of  
17 such drugs shall be used for the activities of the Of-  
18 fice.

19 “(2) SALE OF APPROVED APPLICATION.—

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

1 manufacturing and marketing the applicable  
2 drug, the approved application for the drug.

3 “(B) FAILURE TO USE.—If a person pur-  
4 chasing an approved application under subpara-  
5 graph (A)—

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

9 “(ii) increases the average manufac-  
10 turer price for the applicable drug above  
11 the fair price (increased by the consumer  
12 price index for all urban consumers (as  
13 published by the Bureau of Labor Statis-  
14 tics) for that year);

15 the Secretary shall revoke the purchaser’s ap-  
16 proved application and resume production of  
17 the applicable drug.

18 “(d) INSULIN.—Not later than 1 year after the date  
19 of enactment of this section, the Secretary shall begin the  
20 public manufacturing of insulin within a delivery device  
21 that does not violate active patents, meeting the definition  
22 of applicable drug and in accordance with this section.

23 “(e) NALOXONE.—Not later than 1 year after the  
24 date of enactment of this section, the Secretary shall begin  
25 the public manufacturing of naloxone, including naloxone

1 indicated for community use, meeting the definition of ap-  
2 plicable drug and in accordance with this section.

3 “(f) ANTIBIOTICS.—Not later than 1 year after the  
4 date of enactment of this section, and in consultation with  
5 the Centers for Disease Control and Prevention and the  
6 Food and Drug Administration to ensure the appropriate  
7 use of manufactured antibiotics, the Secretary shall begin  
8 the public manufacturing of no fewer than three discrete  
9 antibiotics meeting the definition of applicable drug in ac-  
10 cordance with this section.

11 “(g) APPLICABLE DRUG.—In this section, the term  
12 ‘applicable drug’ means a drug (as defined in section 201  
13 of the Federal Food, Drug, and Cosmetic Act), biological  
14 product (as defined in section 351 of the Public Health  
15 Service Act), or combination product (as described in sec-  
16 tion 503(g) of the Federal Food, Drug, and Cosmetic Act)  
17 for which an approved application under section 505 or  
18 515 of the Federal Food, Drug, and Cosmetic Act or sec-  
19 tion 351 of the Public Health Service Act, or clearance  
20 under section 510(k) of the Federal Food, Drug, and Cos-  
21 metic Act, is in effect, and—

22 “(1)(A) for which, with respect to a drug in-  
23 cluded in the list described in section 505(j)(7) of  
24 the Federal Food, Drug, and Cosmetic Act, each  
25 patent included with respect to such drug in such

1 list has expired, or each patent that claims a biological  
2 product has expired;

3 “(B) any period of regulatory exclusivity granted  
4 ed under—

5 “(i) clause (ii), (iii), or (iv) of section  
6 505(c)(3)(E) of the Federal Food, Drug, and  
7 Cosmetic Act, section 505(j)(5)(B)(iv) of such  
8 Act, clause (ii), (iii), or (iv) of section  
9 505(j)(5)(F) of such Act, section 527 of such  
10 Act, and any extension of such a period granted  
11 under section 505A or 505E of such Act, has  
12 expired; or

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

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

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

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

1 for all urban consumers (as published by the  
2 Bureau of Labor Statistics) for one of the years  
3 in that 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 Secretary determines to be  
9 a 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       “(h) AUTHORIZATION OF APPROPRIATIONS.—There  
2 are authorized to be appropriated such sums as may be  
3 necessary to carry out this section.”.

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