

115TH CONGRESS  
2D SESSION

# S. 3775

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

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IN THE SENATE OF THE UNITED STATES

DECEMBER 18, 2018

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 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 2018”.

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;

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

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

17 “(3) PERSONNEL.—

18 “(A) DIRECTOR.—

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

23 “(ii) COMPENSATION.—The Director  
24 shall be compensated at the rate prescribed  
25 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                         redient 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; and

14          “(C) an analysis of how the public manu-  
15          facture of drugs meeting the conditions de-  
16          scribed in paragraph (6) would impact, or has  
17          already impacted, competition, access to such  
18          drugs, the costs of such drugs, the costs of pre-  
19          scription drugs to Federal and State health pro-  
20          grams, and public health.

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

24                 “(A) lowering drug costs to patients;



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

3           “(C) improving public health; or

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

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

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

18                 “(1) submit an application under section 505(j)  
19                 or 515 of the Federal Food, Drug, and Cosmetic Act  
20                 or section 351(k) of the Public Health Service Act  
21                 or submit a notification under section 510(k) of the  
22                 Federal Food, Drug, and Cosmetic Act (or enter  
23                 into a contract with another entity to submit such  
24                 an application or notification); or

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

8           “(c) USE.—

9           “(1) IN GENERAL.—The Secretary shall sell a  
10 drug produced under this section at a fair price to  
11 other entities. Amounts received from the sale of  
12 such drugs shall be used for the activities of the Of-  
13 fice.

14           “(2) SALE OF APPROVED APPLICATION.—

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

23           “(B) FAILURE TO USE.—If a person pur-  
24 chasing an approved application under subpara-  
25 graph (A)—

1                   “(i) fails to market the applicable  
2                   drug within 6 months of the date of such  
3                   purchase; or

4                   “(ii) increases the average manufac-  
5                   turer price for the applicable drug above  
6                   the fair price (increased by the consumer  
7                   price index for all urban consumers (as  
8                   published by the Bureau of Labor Statis-  
9                   tics) for that year);

10                  the Secretary shall revoke the purchaser’s ap-  
11                  proved application and resume production of  
12                  the applicable drug.

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

17                  “(e) APPLICABLE DRUG.—In this section, the term  
18 ‘applicable drug’ means a drug (as defined in section 201  
19 of the Federal Food, Drug, and Cosmetic Act), biological  
20 product (as defined in section 351 of the Public Health  
21 Service Act), or combination product (as described in sec-  
22 tion 503(g) of the Federal Food, Drug, and Cosmetic Act)  
23 for which an approved application under section 505 or  
24 515 of the Federal Food, Drug, and Cosmetic Act or sec-  
25 tion 351 of the Public Health Service Act, or clearance

1 under section 510(k) of the Federal Food, Drug, and Cos-  
2 metic Act, is in effect, and—

3 “(1)(A) for which, with respect to a drug in-  
4 cluded in the list described in section 505(j)(7) of  
5 the Federal Food, Drug, and Cosmetic Act, each  
6 patent included with respect to such drug in such  
7 list has expired, or each patent that claims a biologi-  
8 cal product has expired;

9 “(B) any period of regulatory exclusivity grant-  
10 ed under—

11 “(i) clause (ii), (iii), or (iv) of section  
12 505(c)(3)(E) of the Federal Food, Drug, and  
13 Cosmetic Act, section 505(j)(5)(B)(iv) of such  
14 Act, clause (ii), (iii), or (iv) of section  
15 505(j)(5)(F) of such Act, section 527 of such  
16 Act, and any extension of such a period granted  
17 under section 505A or 505E of such Act, has  
18 expired; or

19 “(ii) paragraph (6) or (7) of section 351(k)  
20 of the Public Health Service Act, and any ex-  
21 tension of such a period granted under para-  
22 graph (2) or (3) of section 351(m) of such Act,  
23 has expired; and

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

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

3           “(I) in the previous 1-year period, has ex-  
4 perience a price increase that is greater than  
5 the medical component of the consumer price  
6 index for the same period;

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

10           “(III)(aa) has an average manufacturer  
11 price that the Secretary determines to be a bar-  
12 rier to patient access; and

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

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

17           “(A) section 1498 of title 28, United  
18 States Code;

19           “(B) section 202 of title 35, United States  
20 Code;

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

23           “(D) section 209 of title 35, United States  
24 Code; or

1                   “(E) any other licensing authority of the  
2                   Federal Government.

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

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