

115TH CONGRESS
2D SESSION

S. 3775

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

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

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 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; 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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