

116TH CONGRESS
1ST SESSION

S. 844

To allow for expedited approval of generic prescription drugs and temporary importation of prescription drugs in the case of marginally competitive drug markets and drug shortages.

IN THE SENATE OF THE UNITED STATES

MARCH 14, 2019

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

A BILL

To allow for expedited approval of generic prescription drugs and temporary importation of prescription drugs in the case of marginally competitive drug markets and drug shortages.

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 “Short on Competition
5 Act”.

1 **SEC. 2. TEMPORARY IMPORTATION OF PRESCRIPTION**
2 **DRUGS.**

3 (a) TEMPORARY IMPORTATION.—Section 506C of the
4 Federal Food, Drug, and Cosmetic Act (21 U.S.C. 356c)
5 is amended—

6 (1) by redesignating subsections (h) and (i) as
7 subsections (i) and (j), respectively; and

8 (2) by inserting after subsection (g) the fol-
9 lowing:

10 “(h) TEMPORARY IMPORTATION AUTHORITY.—

11 “(1) IN GENERAL.—If, based on notifications
12 described in subsection (a) or any other relevant in-
13 formation, the Secretary concludes that there is, or
14 is likely to be, a drug shortage of a drug described
15 in subsection (a), except as provided in paragraph
16 (3), the Secretary shall authorize importation of
17 such drug for a period of up to 3 years if—

18 “(A) the drug is a drug subject to section
19 503(b)(1), including a combination product
20 whose primary mode of action is that of a drug
21 as determined under section 503(g)(1)(D)(i),
22 other than a drug described in subparagraphs
23 (A) through (F) of section 804(a)(3);

24 “(B) the drug is authorized to be lawfully
25 marketed in one or more of the countries in-
26 cluded in the list under section 802(b)(1);

1 “(C) the imported drug has the same ac-
2 tive ingredient as the drug for which there is a
3 shortage with respect to manufacturers in the
4 United States;

5 “(D) the manufacturer certifies to the Sec-
6 retary that it intends to seek approval of the
7 drug under section 505(j); and

8 “(E) an importer (as defined in section
9 804(a)) files with the Secretary information—

10 “(i) attesting that the requirements
11 under subparagraphs (A) through (D) are
12 satisfied;

13 “(ii) identifying the drug the importer
14 proposes to import and the manufacturer
15 from whom the importer proposes to im-
16 port such drug; and

17 “(iii) requesting authority to import
18 the drug.

19 “(2) BEGINNING DATE OF IMPORTATION.—Ex-
20 cept as provided in paragraph (3), if all of the condi-
21 tions under paragraph (1) are met, the Secretary
22 shall authorize importation of a drug in accordance
23 with such paragraph beginning not later than 60
24 days after receipt of the information under para-
25 graph (1)(E).

1 “(3) DISCRETIONARY DENIAL OF IMPORTA-
 2 TION.—The Secretary may deny importation of a
 3 drug otherwise qualified for importation under para-
 4 graph (1) if the Secretary determines that—

5 “(A) the drug is not safe and effective;

6 “(B) the drug is used in conjunction with
 7 a device for which there is no reasonable assur-
 8 ance of safety and effectiveness; or

9 “(C) the authorization to market the drug
 10 in one or more of the countries included in the
 11 list under section 802(b)(1) has been rescinded
 12 or withdrawn because of any concern relating to
 13 the safety or effectiveness of the drug.

14 “(4) TERMINATION OF AUTHORITY.—The au-
 15 thority to import a drug pursuant to paragraph (1)
 16 shall terminate after 3 years, or when the drug
 17 shortage no longer applies, whichever occurs first.”.

18 (b) **MARGINALLY COMPETITIVE DRUG MARKETS.**—
 19 Chapter V of the Federal Food, Drug, and Cosmetic Act
 20 (21 U.S.C. 351 et seq.) is amended by inserting after sec-
 21 tion 506C–1 the following:

22 **“SEC. 506C-2. MARGINALLY COMPETITIVE DRUG MARKETS.**

23 “(a) **IN GENERAL.**—If the Secretary determines
 24 under subsection (b) that a marginally competitive market
 25 exists with respect to an applicable drug, the Secretary—

1 “(1) shall treat such marginally competitive
2 market as creating a drug shortage only for pur-
3 poses of subsections (g) and (h) of section 506C;
4 and

5 “(2)(A) may expedite the review of applications
6 and inspections with respect to the drug in accord-
7 ance with section 506C(g); and

8 “(B) shall authorize importation of the drug in
9 accordance with section 506C(h).

10 “(b) DETERMINATION OF MARGINALLY COMPETI-
11 TIVE MARKET.—

12 “(1) IN GENERAL.—The Secretary shall deter-
13 mine that a marginally competitive market exists
14 with respect to an applicable drug if—

15 “(A) for at least 2 consecutive months
16 prior to the determination, fewer than 5 drugs
17 approved under section 505(c) (referred to in
18 this paragraph as the ‘applicable listed drug’)
19 or under section 505(j) that reference the appli-
20 cable listed drug were commercially available in
21 the United States;

22 “(B) the applicable listed drug was ap-
23 proved at least 10 years before such determina-
24 tion; and

“(C) each patent which claims an active ingredient of the applicable listed drug has expired.

“(2) COMMERCIALY AVAILABLE.—

“(A) IN GENERAL.—For purposes of paragraph (1)(A), a drug is not commercially available in the United States if—

“(i) the holder of an application approved under subsection (c) or (j) of section 505 has publicly announced that it has discontinued the manufacturing of the drug;

“(ii) a drug approved under subsection (c) or (j) of section 505 has been withdrawn or discontinued; or

“(iii) the Secretary has any other reasonable basis to conclude that a drug approved under subsection (c) or (j) of section 505 is not competitively relevant.

“(B) HOLDER OF APPROVED APPLICATION.—In determining whether 5 drugs are commercially available under paragraph (1)(A), in the case of a single person who is the holder of more than one application approved as described in paragraph (1)(A) with respect to an

1 applicable drug, only one such drug shall be
 2 considered to be commercially available.

3 “(c) APPLICABLE DRUG.—In this section, the term
 4 ‘applicable drug’ means a drug that is not a radio pharma-
 5 ceutical drug product or any other product as designated
 6 by the Secretary.”.

7 (c) ANNUAL REPORTING ON DRUG SHORTAGES.—
 8 Section 506C–1(a)(3)(B) of the Federal Food, Drug, and
 9 Cosmetic Act (21 U.S.C. 356c–1(a)(3)(B)) is amended—
 10 (1) in clause (i), by striking “; and” and insert-
 11 ing “;”;
 12 (2) in clause (ii), by adding “and” after the
 13 semicolon; and
 14 (3) by inserting after clause (ii) the following:
 15 “(iii) the number of drugs authorized for
 16 temporary importation under section 506C(h);”.

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