

115TH CONGRESS  
1ST SESSION

# S. 183

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

---

## IN THE SENATE OF THE UNITED STATES

JANUARY 20, 2017

Ms. KLOBUCHAR (for herself and Mr. LEE) 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 noncompetitive 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 or the “Short on Com-  
5 petition 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) NONCOMPETITIVE DRUG MARKETS.—Chapter V  
 19          of the Federal Food, Drug, and Cosmetic Act (21 U.S.C.  
 20          351 et seq.) is amended by inserting after section 506C–  
 21          1 the following:

22          **“SEC. 506C–2. NONCOMPETITIVE DRUG MARKETS.**

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

1           “(1) shall treat such noncompetitive market as  
2           creating a drug shortage only for purposes of sub-  
3           sections (g) and (h) of section 506C; and

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

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

9           “(b) DETERMINATION OF NONCOMPETITIVE MAR-  
10          KET.—

11           “(1) IN GENERAL.—The Secretary shall deter-  
12           mine that a noncompetitive market exists with re-  
13           spect to an applicable drug if—

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

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

1           “(C) each patent which claims an active in-  
2           gredient of the applicable listed drug has ex-  
3           pired.

4           “(2) COMMERCIALY AVAILABLE.—

5           “(A) IN GENERAL.—For purposes of para-  
6           graph (1)(A), a drug is not commercially avail-  
7           able in the United States if—

8           “(i) the holder of an application ap-  
9           proved under subsection (c) or (j) of sec-  
10          tion 505 has publicly announced that it  
11          has discontinued the manufacturing of the  
12          drug;

13          “(ii) a drug approved under sub-  
14          section (c) or (j) of section 505 has been  
15          withdrawn or discontinued; or

16          “(iii) the Secretary has any other rea-  
17          sonable basis to conclude that a drug ap-  
18          proved under subsection (c) or (j) of sec-  
19          tion 505 is not competitively relevant.

20          “(B) HOLDER OF APPROVED APPLICA-  
21          TION.—In determining whether 5 drugs are  
22          commercially available under paragraph (1)(A),  
23          in the case of a single person who is the holder  
24          of more than one application approved as de-  
25          scribed 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);”.

○