114TH CONGRESS
2D SESSION

S. 3455

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

SEPTEMBER 28, 2016

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

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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.

Be it enacted by the Senate and House of Representatives of the United States of America in Congress assembled,

SECTION 1. SHORT TITLE.

This Act may be cited as the ''Pharmaceutical Supply and Value Enhancement Act'' or the ''Pharmaceutical SAVE Act''.

SEC. 2. TEMPORARY IMPORTATION OF PRESCRIPTION DRUGS.

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

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

(2) by inserting after subsection (g) the following:

''(h) TEMPORARY IMPORTATION AUTHORITY.—

''(1) IN GENERAL.—If, based on notifications described in subsection (a) or any other relevant information, the Secretary concludes that there is, or is likely to be, a drug shortage of a drug described in subsection (a), except as provided in paragraph (3), the Secretary shall authorize importation of such drug for a period of up to 3 years if—

''(A) the drug is a drug subject to section 503(b)(1), other than a drug described in subparagraphs (A) through (F) of section 804(a)(3);

''(B) the drug is authorized to be lawfully marketed in one or more of the countries included in the list under section 802(b)(1);

''(C) the imported drug has the same active ingredient as the drug for which there is a

shortage described in subsection (i)(2)(B) with respect to manufacturers in the United States;

''(D) the manufacturer certifies to the Secretary that it intends to seek approval of the drug under section 505(j); and

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

''(i) attesting that the requirements under subparagraphs (A) through (D) are satisfied;

''(ii) identifying the drug the importer proposes to import and the manufacturer from whom the importer proposes to import such drug; and

''(iii) requesting authority to import the drug.

''(2) BEGINNING DATE OF IMPORTATION.—If all of the conditions under paragraph (1) are met, the Secretary shall authorize importation of a drug in accordance with such paragraph beginning not later than 60 days after receipt of the information under paragraph (1)(E).

''(3) DISCRETIONARY DENIAL OF IMPORTATION.—The Secretary may deny importation of a

drug otherwise qualified for importation under paragraph (1) if the Secretary determines that—

"(A) the drug is not safe and effective;

"(B) the drug is used in conjunction with a device for which there is no reasonable assurance of safety and effectiveness; or

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

"(4) TERMINATION OF AUTHORITY.—The authority to import a drug pursuant to paragraph (1) shall terminate after 3 years, or when the drug shortage no longer applies, whichever occurs first.".

(b) NONCOMPETITIVE DRUG MARKETS.—Chapter V of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 351 et seq.) is amended by inserting after section 506C–1 the following:

"SEC. 506C–2. NONCOMPETITIVE DRUG MARKETS.

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

"(1) shall treat such noncompetitive market as creating a drug shortage for purposes of section

506C(g), and may expedite the review of applications and inspections in accordance with such subsection; and

''(2) shall treat such noncompetitive market as creating a drug shortage for purposes of section 506C(h), and shall authorize importation of the drug in accordance with such subsection.

''(b) DETERMINATION OF NONCOMPETITIVE MARKET.—

''(1) IN GENERAL.—The Secretary shall determine that a noncompetitive market exists with respect to an applicable drug if—

''(A) for at least 2 consecutive months prior to the determination, fewer than 5 drugs approved under section 505(c) (referred to in this paragraph as the 'applicable listed drug') or under section 505(j) that reference the applicable listed drug were commercially available in the United States;

''(B) the applicable listed drug was approved at least 10 years before such determination; and

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

"(2) COMMERCIALLY 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 1 application approved as described in paragraph (1)(A) with respect to an applicable drug, only 1 such drug shall be considered to be commercially available.

''(c) APPLICABLE DRUG.—In this section, the term 'applicable drug' means a drug that is not a radio pharmaceutical drug product or any other product as designated by the Secretary.''.

(c) ANNUAL REPORTING ON DRUG SHORTAGES.—Section 506C–1(a)(3)(B) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 356c–1(a)(3)(B)) is amended—

(1) in clause (i), by striking ''; and'' and inserting '';'';

(2) in clause (ii), by adding ''and'' after the semicolon; and

(3) by inserting after clause (ii) the following:

''(iii) the number of drugs authorized for temporary importation under section 506C(h);''.

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