114TH CONGRESS
1ST SESSION

S. 1790

To amend the Federal Food, Drug, and Cosmetic Act to allow for the personal importation of safe and affordable prescription drugs from approved pharmacies.

IN THE SENATE OF THE UNITED STATES

JULY 16, 2015

Mr. VITTER 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 Federal Food, Drug, and Cosmetic Act to allow for the personal importation of safe and affordable prescription drugs from approved pharmacies.

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 ''Safe and Affordable Prescription Drugs Act of 2015''.

SEC. 2. SAFE AND AFFORDABLE PRESCRIPTION DRUGS.

Chapter VIII of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 381 et seq.) is amended by adding at the end the following:

"SEC. 810. IMPORTATION BY INDIVIDUALS OF PRESCRIPTION DRUGS.

"(a) IN GENERAL.—Notwithstanding any other provision of this Act, not later than 180 days after the date of enactment of this section, the Secretary shall promulgate regulations permitting individuals to safely import into the United States a prescription drug described in subsection (b).

"(b) PRESCRIPTION DRUG.—A prescription drug described in this subsection—

"(1) is a prescription drug that—

"(A) is purchased from an approved pharmacy;

"(B) is dispensed by a pharmacist licensed to practice pharmacy and dispense prescription drugs in the country in which the pharmacy is located;

"(C) is purchased for personal use by the individual, not for resale, in quantities that do not exceed a 90-day supply;

"(D) is filled using a valid prescription issued by a physician licensed to practice in a State in the United States; and

"(E) has the same active ingredient or ingredients, route of administration, dosage form,

and strength as a prescription drug approved by the Secretary under chapter V; and

''(2) does not include—

''(A) a controlled substance (as defined in section 102 of the Controlled Substances Act (21 U.S.C. 802));

''(B) a biological product (as defined in section 351 of the Public Health Service Act (42 U.S.C. 262));

''(C) an infused drug (including a peritoneal dialysis solution);

''(D) an intravenously injected drug;

''(E) a drug that is inhaled during surgery;

''(F) a parenteral drug;

''(G) a drug manufactured through 1 or more biotechnology processes, including—

''(i) a therapeutic DNA plasmid product;

''(ii) a therapeutic synthetic peptide product of not more than 40 amino acids;

''(iii) a monoclonal antibody product for in vivo use; and

''(iv) a therapeutic recombinant DNA-derived product;

"(H) a drug required to be refrigerated at any time during manufacturing, packing, processing, or holding; or

"(I) a photoreactive drug.

"(c) APPROVED PHARMACY.—

"(1) IN GENERAL.—In this section, an approved pharmacy is a pharmacy that—

"(A) is located in a country listed or described in section 802(b)(1)(A); and

"(B) the Secretary certifies—

"(i) is licensed to operate and dispense prescription drugs to individuals in the country in which such pharmacy is located; and

"(ii) meets the criteria under paragraph (3).

"(2) PUBLICATION OF APPROVED PHARMACIES.—The Secretary shall publish on the Internet Web site of the Food and Drug Administration a list of approved pharmacies, including the Internet Web site address of each such approved pharmacy, from which individuals may purchase prescription drugs in accordance with subsection (a).

''(3) ADDITIONAL CRITERIA.—To be an approved pharmacy, the Secretary shall certify that the pharmacy—

''(A) has been in existence for a period of at least 5 years preceding the date of such certification and has a purpose other than to participate in the program established under this section;

''(B) operates in accordance with pharmacy standards set forth by the pharmacy rules and regulations enacted in the country in which it is located;

''(C) has processes established by the pharmacy, or participates in another established process, to certify that the physical premises and data reporting procedures and licenses are in compliance with all applicable laws and regulations, and has implemented policies designed to monitor ongoing compliance with such laws and regulations;

''(D) conducts or commits to participate in ongoing and comprehensive quality assurance programs and implements such quality assurance measures, including blind testing, to en-

sure the veracity and reliability of the findings of the quality assurance program;

''(E) agrees that laboratories approved by the Secretary shall be used to conduct product testing to determine the safety and efficacy of sample pharmaceutical products;

''(F) has established, or will establish or participate in, a process for resolving grievances and will be held accountable for violations of established guidelines and rules;

''(G) does not resell products from online pharmacies located outside the country in which the pharmacy is located to customers in the United States; and

''(H) meets any other criteria established by the Secretary.''.

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