AMENDMENT TO RULES COMMITTEE PRINT 114-22

OFFERED BY MS. PINGREE OF MAINE

Showing text based on H.R. 6, as ordered reported by the Committee on Energy and Commerce

Page 174, after line 13, insert the following new section:

SEC. 2163. SAFE AND AFFORDABLE DRUGS FROM CANADA.

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 FROM CANADA.

''(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 Canadian pharmacy;

''(B) is dispensed by a pharmacist licensed to practice pharmacy and dispense prescription drugs in Canada;

''(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 CANADIAN PHARMACY.—

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

''(A) is located in Canada; and

''(B) that the Secretary certifies—

''(i) is licensed to operate and dispense prescription drugs to individuals in Canada; and

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

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

''(3) ADDITIONAL CRITERIA.—To be an approved Canadian 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 provincial pharmacy rules and regulations enacted in Canada;

''(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 ensure 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 Canada to customers in the United States; and

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