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108TH CONGRESS
1ST SESSION

H. R. 2717

To amend the Federal Food, Drug, and Cosmetic Act to establish a program to provide for the voluntary certification of Internet and mail-order pharmacies, to amend such Act to authorize, subject to certain conditions, the importation by individuals of prescription drugs from Canada for personal use, and for other purposes.

IN THE HOUSE OF REPRESENTATIVES

JULY 14, 2003

Mr. BROWN of Ohio (for himself, Mr. STARK, and Mr. HINCHEY) introduced the following bill; which was referred to the Committee on Energy and Commerce

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A BILL

To amend the Federal Food, Drug, and Cosmetic Act to establish a program to provide for the voluntary certification of Internet and mail-order pharmacies, to amend such Act to authorize, subject to certain conditions, the importation by individuals of prescription drugs from Canada for personal use, and for other purposes.

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 ''Affordable Medicine Safety and Access Act''.

TITLE I—INTERNET AND MAIL-ORDER PHARMACIES

SEC. 101. VOLUNTARY CERTIFICATIONS REGARDING INTERNET AND MAIL-ORDER PHARMACIES.

(a) IN GENERAL.—Chapter 5 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 351 et seq.) is amended by inserting after section 503A the following section:

''SEC. 503B. VOLUNTARY CERTIFICATIONS REGARDING INTERNET AND MAIL-ORDER PHARMACIES.

''(a) IN GENERAL.—The Secretary, directly or through contract with one or more public or nonprofit private entities, shall establish a program under which Internet and mail-order pharmacies, on a voluntary basis, are certified by the Secretary as meeting the requirements of this section for certification.

''(b) SEAL.—The Secretary shall provide for a seal that Internet and mail-order pharmacies certified under subsection (a) are authorized to display for purposes of indicating to the public the fact of such certification.

''(c) CONDITIONS FOR CERTIFICATION.—As a condition of certifying an Internet or mail-order pharmacy under subsection (a), the Secretary shall require the following with respect to such pharmacy:

''(1) Verification that, in each State in which the pharmacy engages in pharmaceutical activities, the pharmacy, and all the employees and agents of the pharmacy, are in compliance with applicable laws regarding—

''(A) the practice of pharmacy, including licensing laws; and

''(B) the manufacturing and distribution of controlled substances, including with respect to mailing or shipping such substances to consumers.

''(2) Controls to ensure that a prescription drug is dispensed by the pharmacy only pursuant to a valid prescription, including circumstance in which the drug is shipped or mailed from a country under whose laws the drug is not a prescription drug.

''(3) The prominent display of contact information for the pharmacy, including a telephone number, an electronic mail address, a mailing address, and (if different from the mailing address) the address for the physical location of the principal place of business of the pharmacy.

''(4) The prominent display of complete and accurate information concerning the ownership and

management of the pharmacy, including addresses and contact information.

''(5) A certification from the person who owns or manages the pharmacy that a certification under subsection (a) for the pharmacy has not previously been terminated by the Secretary, and that no other Internet or mail-order pharmacy owned or managed by such person has received a certification under subsection (a) that has been terminated by the Secretary.

''(6) An agreement by the pharmacy that, upon certification under subsection (a), the facilities and business practices of the pharmacy will be subject to inspection by the Secretary to the extent appropriate to determine whether the pharmacy is in compliance with conditions under this subsection.

''(7) Meaningful and accessible opportunities for a consumer to consult with a licensed pharmacist regarding a drug prior to the time at which the pharmacy dispenses the drug to the consumer.

''(8) Controls to ensure that, prior to dispensing a drug to a consumer, a prospective review of the use of the drug by the consumer is completed, based on accurate information about the consumer

and the medication profiles of the consumer and other pertinent medical information.

''(9) Effective, accessible systems for communication with consumers, including systems for consumer reporting of adverse drug reactions and errors, systems by which consumers can effectively track and report problems with unfulfilled orders, systems for the investigation and redress of consumer complaints, and systems facilitating effective communication between the pharmacy and consumers concerning drug recalls.

''(10) Controls to ensure the protection of patient privacy and confidentiality, including but not limited to the prevention of unauthorized internal and external use of personally-identifiable patient information.

''(11) An agreement by the pharmacy that the pharmacy will notify the Secretary within 10 days concerning any change in information submitted under this subsection as a condition of certification under subsection (a).

''(12) Such additional criteria as the Secretary determines, after notice and opportunity for comment, to be appropriate for the sound operation of certified pharmacies or the protection of consumers.

''(d) ANNUAL APPLICATION; DURATION OF CERTIFICATION.—

''(1) IN GENERAL.—The Secretary may certify an Internet or mail-order pharmacy under subsection (a) only if the pharmacy submits to the Secretary an application for such certification that demonstrates compliance with the conditions under subsection (c) and is in such form, and is made in such manner, as the Secretary may require. The Secretary shall establish an application form for purposes of the preceding sentence, including an electronic application form.

''(2) DURATION OF CERTIFICATION; RENEWAL.—

''(A) IN GENERAL.—A certification under subsection (a) is effective for the one-year period beginning on the date on which the application under paragraph (1) for such certification is approved by the Secretary. The Secretary may renew the certification, pursuant to the submission of an additional application under paragraph (1), and the number of renewals of the certification is not limited. The Secretary may establish an abbreviated process for such renewal applications.

"(B) RENEWAL EVALUATION.—Before renewing a certification under subsection (a), the Secretary shall conduct an evaluation to determine whether the pharmacy involved is in compliance with the conditions under subsection (c). The evaluation, at the Secretary's discretion and as applicable, may include testing of the Internet site of the pharmacy or other systems through which the pharmacy communicates with consumers, and may include physical inspection of the records and premises of the pharmacy pursuant to subsection (c)(6).

"(e) FEES.—The Secretary may impose a fee on the submission of an application under subsection (d). Any such fee is due upon the submission of the application. To the extent provided in appropriations Acts, such fees are available to the Secretary for carrying out this section.

"(f) INFORMATION CAMPAIGN.—The Secretary shall carry out activities to inform the public of the program under subsection (a), including information on the significance of the seal under subsection (b) when displayed by an Internet or mail-order pharmacy, and including information on the benefits of doing business with a pharmacy certified under subsection (a) as compared to a pharmacy that is not so certified.

''(g) TERMINATION OF CERTIFICATION.—The Secretary, upon the own initiative of the Secretary or a petition by an interested person, may terminate a certification under subsection (a), after notice to the Internet or mail-order pharmacy involved and an opportunity for a hearing.

''(h) CONTRACT FOR OPERATION OF PROGRAM.—

''(1) DETERMINATION REGARDING USE OF CONTRACT AUTHORITY.—The Secretary may award a contract under subsection (a) for the operation of the program under such subsection only if the Secretary determines that the administration by the contractor of such program would be as protective or more protective of the public than direct administration of the program by the Secretary.

''(2) CERTAIN REQUIREMENTS.—With respect to a contract under subsection (a):

''(A) The duration of the contract may not exceed two years.

''(B) The Secretary may renew the contract, subject to compliance with subparagraph (A).

''(C) The Secretary shall annually review performance under the contract.

''(D) The contract shall specify that the Secretary may terminate the contract for unsatisfactory performance under the contract.

''(i) DEFINITIONS.—For purposes of this section:

''(1) The term 'Internet pharmacy' means a pharmacy that, by shipping, mailing, or transporting a prescription drug, dispenses such drug pursuant to a sale of the drug by the pharmacy in circumstances in which the purchaser of the drug submitted the purchase order for the drug, or conducted any other part of the sales transaction for the drug, through an Internet site.

''(2) The term 'mail-order pharmacy' means a pharmacy that, by shipping, mailing, or transporting a prescription drug, dispenses such drug pursuant to a sale of the drug by the pharmacy in circumstances in which the purchaser of the drug submitted the purchase order for the drug, or conducted any other part of the sales transaction for the drug, through the mail or through any telecommunications means other than an Internet site.

''(3)(A) Subject to subparagraph (B), the term 'pharmacy' means an organization licensed by a State to practice pharmacy, including the dispensing and selling of prescription drugs.

''(B) The Secretary shall consider an organization as meeting the definition established in subparagraph (A) if the Secretary determines that the organization would qualify for licensure in at least one of the States but for a policy of such State that denies licensure as a pharmacy on the basis that the organization dispenses prescription drugs from locations in Canada or dispenses prescription drugs obtained by such organization from an entity in Canada.

''(4) The term 'prescription drug' means a drug subject to section 503(b).''.

(b) UNAUTHORIZED DISPLAY OF SEAL; FALSE CLAIMS.—Section 301 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 331) is amended by adding at the end the following:

''(hh) The display by an Internet or mail-order pharmacy of the seal under section 503B without a certification in effect under such section for the pharmacy, or the making by such a pharmacy of a false claim that such a certification is in effect for the pharmacy.''.

TITLE II—PERSONAL IMPORTATION OF PRESCRIPTION DRUGS FROM CANADA

Subtitle A—Waiver Requirement

SEC. 201. WAIVER REQUIREMENT FOR PERSONAL IMPORTATION OF PRESCRIPTION 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 section:

''WAIVER REQUIREMENT FOR PERSONAL IMPORTATION OF PRESCRIPTION DRUGS FROM CANADA

''SEC. 805. With respect to the importation by individuals of prescription drugs from Canada, the Secretary shall in accordance with this section establish by regulation a waiver of prohibitions under this Act that apply to the importation of drugs. Such a waiver shall permit an individual to import into the United States any prescription drug that—

''(1) is imported from Canada for personal use by the individual (not for resale);

''(2) is approved by the Secretary under section 505, is manufactured in an establishment registered with the Secretary under section 510, and is not a

controlled substance in schedule I, II, or III under section 202(c) of the Controlled Substances Act;

''(3) is imported from a Canadian pharmacy that has submitted to the Secretary a registration that identifies the pharmacy and provides documentation that the pharmacy is licensed in Canada;

''(4) is imported in a quantity that does not (for that instance of importation) exceed a 90-day supply;

''(5) at the time of importation, is accompanied by a copy of a valid prescription for the drug for the individual, issued in the United States by a practitioner in accordance with section 503(b), or is accompanied by documentation that verifies the issuance of such a prescription for the individual;

''(6) is in the form of a final finished dosage; and

''(7) is imported under such other conditions as the Secretary determines to be necessary to ensure public safety.''.

Subtitle B—Studies

SEC. 211. STUDY REGARDING IN-PERSON PERSONAL IMPORTATION FROM CANADA.

(a) IN GENERAL.—The Secretary of Health and Human Services (referred to in this subtitle as the ''Sec-

retary''), acting through the Commissioner of Food and Drugs, shall conduct a study for the purpose of developing recommendations regarding any legislative or administrative changes that may be necessary to provide reasonable assurance concerning the safety and effectiveness of prescription drugs that are purchased in-person at a licensed pharmacy in Canada and imported from Canada into the United States for personal use by individuals who are not in the business of importing such drugs (referred to in this section with respect to such drugs as ''in-person personal importation''). Not later than 18 months after the date of the enactment of this Act, the Secretary shall submit to the Congress a report describing the findings of such study.

(b) CERTAIN REQUIREMENTS.—The activities of the Secretary in carrying out the study under subsection (a) shall include the following:

(1) With respect to prescription drugs that are commonly purchased from Canadian pharmacies for in-person personal importation, the purchase of a representative sample of such drugs at randomly-selected Canadian pharmacies that are representative of Canadian pharmacies from which prescription drugs are purchased for personal importation.

(2) Determining, for purposes of laws and regulations administered by the Food and Drug Administration, the safety and effectiveness of the prescription drugs that are purchased under paragraph (1).

(3) Making a comparison of laws and regulations referred to in paragraph (2) with the Canadian system for the regulation of the safety and effectiveness of prescription drugs.

(c) ADVISORY BOARD.—The Secretary shall establish an advisory board for the purpose of providing advice to the Secretary regarding the design of the study under subsection (a) and regarding the development of recommendations in the study. The membership of the advisory board shall include representatives of the Directorate of Border and Transportation Security (Department of Homeland Security); the comparable agency or agencies of the Canadian government; health officials of State and local governments; pharmacists in the United States; and physicians and patients in the United States.

SEC. 212. STUDY REGARDING INTERNET AND MAIL-ORDER PHARMACIES CLAIMING CANADIAN SOURCES FOR PRESCRIPTION DRUGS.

With respect to prescription drugs that are commonly prescribed in the United States, the Secretary, acting

through the Commissioner of Food and Drugs, shall conduct a study through which the Secretary—

(1) makes purchases of such drugs from Internet pharmacies and mail-order pharmacies that make sales to consumers in the United States and claim such drugs are obtained from Canadian pharmacies or wholesalers, which purchases are a representative sample of such drugs purchased from such pharmacies; and

(2) determines whether the drugs purchased under paragraph (1) are approved for commercial distribution in Canada and are obtained from Canadian pharmacies or wholesalers.

The Secretary shall seek the cooperation of the Government of Canada in making the determination under paragraph (2). Not later than 18 months after the date of the enactment of this Act, the Secretary shall submit to the Congress a report describing the findings of such study.

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