I

107TH CONGRESS
2D SESSION

H. R. 5217

To amend the Federal Food, Drug, and Cosmetic Act to authorize the Secretary of Health and Human Services to grant waivers permitting individuals to import prescription drugs from Canada, to amend such Act with respect to the sale of prescription drugs through the Internet, and for other purposes.

IN THE HOUSE OF REPRESENTATIVES

JULY 25, 2002

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

---

A BILL

To amend the Federal Food, Drug, and Cosmetic Act to authorize the Secretary of Health and Human Services to grant waivers permitting individuals to import prescription drugs from Canada, to amend such Act with respect to the sale of prescription drugs through the Internet, 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 Drugs Access Act''.

SEC. 2. WAIVER REQUIREMENT FOR PERSONAL IMPORTATION OF PRESCRIPTION DRUGS FROM CANADA.

(a) IN GENERAL.—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. (a) IN GENERAL.—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.

''(b) STUDY; LIMITATION ON WAIVER REQUIREMENT.—

''(1) STUDY.—During the one-year period beginning on the effective date of this section, the Secretary shall conduct a study of prescription drugs imported from Canada under subsection (a), and of prescription drugs that are imported into the United States from other countries for personal use, in order to determine the authenticity and quality of such drugs.

''(2) LIMITATION.—If through the study under paragraph (1) the Secretary determines that drugs imported under subsection (a) present a significant threat to the public health, the following applies:

''(A) The Secretary may, in order to protect the public health, establish one or more conditions for the importation from Canada of prescription drugs for personal use that are different than the conditions described in such subsection, in which case any conflicting condition described in such subsection ceases to apply.

''(B) The Secretary may publish in the Federal Register a statement that, pursuant to this section, the Secretary has determined that waivers under this section should be terminated in order to protect the public health. Effective on the date on which such a statement is so published, this section ceases to have any legal effect.

''(c) AUTHORITY REGARDING OTHER COUNTRIES.—If through the study under subsection (b)(1) the Secretary determines that drugs imported under subsection (a) do not present a significant threat to the public health, or if under authority of subsection (b)(2)(A) the Secretary

establishes conditions in order to protect the public health, the Secretary may, in the case of such countries in addition to Canada as the Secretary determines to be appropriate, establish by regulation a waiver of prohibitions under this Act that apply to the importation of drugs, under which waiver individuals are permitted to import into the United States prescription drugs that meet the conditions that apply under subsection (a) (or under subsection (b)(2)(A), as the case may be). Such regulations may establish country-specific conditions, as determined appropriate by the Secretary to protect the public health.

''(d) DEFINITION.—For purposes of this section, the term 'prescription drug' means a drug that is subject to section 503(b).''.

(b) ASSESSMENT REGARDING ADDITIONAL AGENCY INSPECTORS AT PORTS OF ENTRY.—The Secretary of Health and Human Services shall conduct an assessment to determine the additional number of inspectors that should be added for the Food and Drug Administration at ports of entry into the United States in order to provide adequate assurance that drugs imported into the United States meet the standards of the Federal Food, Drug, and Cosmetic Act. Not later than 180 days after the date of the enactment of this Act, the Secretary shall submit to

the Congress a report describing the findings of the assessment.

SEC. 3. CONTROLLED SUBSTANCES; IMPORTATION WITHOUT VALID PRESCRIPTIONS.

Section 1006(a)(2) of the Controlled Substances Import and Export Act (21 U.S.C. 956(a)(2)) is amended by striking ''that exceeds 50 dosage units'' and all that follows and inserting the following: ''that exceeds 10 dosage units of the controlled substance, except that if the individual is importing more than one such controlled substance into the United States, the combined total number of dosage units of such substances imported by the individual may not exceed 10 dosage units.''.

SEC. 4. INTERNET SALES OF PRESCRIPTION DRUGS.

(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. INTERNET SALES OF PRESCRIPTION DRUGS.

''(a) REQUIREMENTS REGARDING INFORMATION ON INTERNET SITE.—

''(1) IN GENERAL.—A person may not dispense a prescription drug pursuant to a sale of the drug by such person if—

''(A) 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; and

''(B) such site, or any other Internet site used by such person for purposes of sales of a prescription drug, fails to meet each of the requirements specified in paragraph (2) (other than a site or pages on a site that are not intended to be accessed by purchasers or prospective purchasers).

''(2) REQUIREMENTS.—With respect to an Internet site, the requirements referred to in subparagraph (B) of paragraph (1) for a person to whom such paragraph applies are as follows:

''(A) Each page of the site shall include either the following information or a link to a page that provides the following information:

''(i) The name of such person; the address of the principal place of business of the person with respect to sales of prescription drugs through the Internet; and the telephone number for such place of business.

''(ii) Each State in which the person is authorized by law to dispense prescription drugs.

''(iii) The name of each individual who serves as a pharmacist for purposes of the site, and each State in which the individual is authorized by law to dispense prescription drugs.

''(iv) If the person provides for medical consultations through the site for purposes of providing prescriptions, the name of each individual who provides such consultations; each State in which the individual is licensed or otherwise authorized by law to provide such consultations; and the type or types of health professions for which the individual holds such licenses or other authorizations.

''(B) A link to which paragraph (1) applies shall be clearly visible on the page involved, shall not be of a size smaller than other links on the page (if any), and shall include in the caption for the link the words 'licensing and contact information'.

''(b) INTERNET SALES WITHOUT APPROPRIATE MEDICAL RELATIONSHIPS.—

''(1) IN GENERAL.—A person may not dispense a prescription drug, or arrange the dispensing of such a drug, pursuant to a sale of the drug if—

''(A) for purposes of such sale, the purchaser communicated with the person through the Internet;

''(B) the patient for whom the drug was purchased did not, when such communications began, have a prescription for the drug;

''(C) pursuant to such communications, the person provided for the involvement of a practitioner and the practitioner issued a prescription for the drug that was purchased;

''(D) the person knew, or had reason to know, that the practitioner did not, when issuing the prescription, have a qualifying medical relationship with the patient; and

''(E)(i) the person received payment for the drug from the purchaser; or

''(ii) in the case of arranging the dispensing of the drug, the person received payment for doing so from the person who dispensed the drug.

For purposes of subparagraph (E), payment is received if money or other valuable consideration is received.

''(2) QUALIFYING MEDICAL RELATIONSHIP.—

''(A) IN GENERAL.—With respect to issuing a prescription for a drug for a patient, a practitioner has a qualifying medical relationship with the patient for purposes of this section if at least one in-person medical evaluation of the patient has been conducted by the practitioner. This subparagraph and subparagraph (B) may not be construed as having any applicability beyond this section.

''(B) IN-PERSON MEDICAL EVALUATION.—A medical evaluation by a practitioner is an in-person medical evaluation for purposes of this section if the practitioner is in the physical presence of the patient as part of conducting the evaluation, without regard to whether portions of the evaluation are conducted by other health professionals.

''(c) ACTIONS BY STATES.—

''(1) IN GENERAL.—Whenever an attorney general of any State has reason to believe that the interests of the residents of that State have been or

are being threatened or adversely affected because any person has engaged or is engaging in a pattern or practice that violates section 301(l), the State may bring a civil action on behalf of its residents in an appropriate district court of the United States to enjoin such practice, to enforce compliance with such section (including a nationwide injunction), to obtain damages, restitution, or other compensation on behalf of residents of such State, to obtain reasonable attorneys fees and costs if the State prevails in the civil action, or to obtain such further and other relief as the court may deem appropriate.

''(2) NOTICE.—The State shall serve prior written notice of any civil action under paragraph (1) or (5)(B) upon the Secretary and provide the Secretary with a copy of its complaint, except that if it is not feasible for the State to provide such prior notice, the State shall serve such notice immediately upon instituting such action. Upon receiving a notice respecting a civil action, the Secretary shall have the right—

''(A) to intervene in such action;

''(B) upon so intervening, to be heard on all matters arising therein; and

''(C) to file petitions for appeal.

''(3) CONSTRUCTION.—For purposes of bringing any civil action under paragraph (1), nothing in this chapter shall prevent an attorney general of a State from exercising the powers conferred on the attorney general by the laws of such State to conduct investigations or to administer oaths or affirmations or to compel the attendance of witnesses or the production of documentary and other evidence.

''(4) VENUE; SERVICE OF PROCESS.—Any civil action brought under paragraph (1) in a district court of the United States may be brought in the district in which the defendant is found, is an inhabitant, or transacts business or wherever venue is proper under section 1391 of title 28, United States Code. Process in such an action may be served in any district in which the defendant is an inhabitant or in which the defendant may be found.

''(5) ACTIONS BY OTHER STATE OFFICIALS.—

''(A) Nothing contained in this section shall prohibit an authorized State official from proceeding in State court on the basis of an alleged violation of any civil or criminal statute of such State.

''(B) In addition to actions brought by an attorney general of a State under paragraph

(1), such an action may be brought by officers of such State who are authorized by the State to bring actions in such State on behalf of its residents.

"(d) DEFINITIONS.—

"(1) INTERNET-RELATED DEFINITIONS.—For purposes of this section:

"(A) The term 'Internet' means collectively the myriad of computer and telecommunications facilities, including equipment and operating software, which comprise the interconnected world-wide network of networks that employ the transmission control protocol/internet protocol, or any predecessor or successor protocols to such protocol, to communicate information of all kinds by wire or radio.

"(B) The term 'link', with respect to the Internet, means one or more letters, words, numbers, symbols, or graphic items that appear on a page of an Internet site for the purpose of serving, when activated, as a method for executing an electronic command—

"(i) to move from viewing one portion of a page on such site to another portion of the page;

"(ii) to move from viewing one page on such site to another page on such site; or

"(iii) to move from viewing a page on one Internet site to a page on another Internet site.

"(C) The term 'page', with respect to the Internet, means a document or other file accessed at an Internet site.

"(D)(i) The terms 'site' and 'address', with respect to the Internet, mean a specific location on the Internet that is determined by Internet Protocol numbers. Such term includes the domain name, if any.

"(ii) The term 'domain name' means a method of representing an Internet address without direct reference to the Internet Protocol numbers for the address, including methods that use designations such as '.com', '.edu', '.gov', '.net', or '.org'.

"(iii) The term 'Internet Protocol numbers' includes any successor protocol for determining a specific location on the Internet.

"(2) OTHER DEFINITIONS.—For purposes of this section:

''(A) The term 'practitioner', with respect to the issuance of a prescription for a drug for a patient, means—

''(i) an individual authorized by law to administer the drug; or

''(ii) an individual who is not so authorized but represents himself or herself as an individual who is so authorized.

''(B) The term 'prescription drug' means a drug that is subject to section 503(b).

''(C) The term 'qualifying medical relationship', with respect to a practitioner and a patient, has the meaning indicated for such term in subsection (b).''.

(b) INCLUSION AS PROHIBITED ACT.—Section 301 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 331) is amended by inserting after paragraph (k) the following:

''(l) The dispensing of a prescription drug in violation of section 503B, or arranging for the dispensing of such a drug in violation of such section.''.

(c) INTERNET SALES OF PRESCRIPTION DRUGS; CONSIDERATION BY SECRETARY OF PRACTICES AND PROCEDURES FOR CERTIFICATION OF LEGITIMATE BUSINESSES.—In carrying out section 503B of the Federal

Food, Drug, and Cosmetic Act (as added by subsection (a) of this section), the Secretary of Health and Human Services shall take into consideration the practices and procedures of public or private entities that certify that businesses selling prescription drugs through Internet sites are legitimate businesses, including practices and procedures regarding disclosure formats and verification programs.

(d) EFFECTIVE DATE.—The amendments made by subsections (a) and (b) take effect upon the expiration of the 60-day period beginning on the date of the enactment of this Act, without regard to whether a final rule to implement such amendments has been promulgated by the Secretary of Health and Human Services under section 701(a) of the Federal Food, Drug, and Cosmetic Act. The preceding sentence may not be construed as affecting the authority of such Secretary to promulgate such a final rule.

○