

107TH CONGRESS
2^D 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.

1 *Be it enacted by the Senate and House of Representa-*
2 *tives of the United States of America in Congress assembled,*

3 **SECTION 1. SHORT TITLE.**

4 This Act may be cited as the “Affordable Drugs Ac-
5 cess Act”.

1 **SEC. 2. WAIVER REQUIREMENT FOR PERSONAL IMPORTA-**
2 **TION OF PRESCRIPTION DRUGS FROM CAN-**
3 **ADA.**

4 (a) IN GENERAL.—Chapter VIII of the Federal
5 Food, Drug, and Cosmetic Act (21 U.S.C. 381 et seq.)
6 is amended by adding at the end the following section:

7 “WAIVER REQUIREMENT FOR PERSONAL IMPORTATION
8 OF PRESCRIPTION DRUGS FROM CANADA

9 “SEC. 805. (a) IN GENERAL.—With respect to the
10 importation by individuals of prescription drugs from Can-
11 ada, the Secretary shall in accordance with this section
12 establish by regulation a waiver of prohibitions under this
13 Act that apply to the importation of drugs. Such a waiver
14 shall permit an individual to import into the United States
15 any prescription drug that—

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

18 “(2) is approved by the Secretary under section
19 505, is manufactured in an establishment registered
20 with the Secretary under section 510, and is not a
21 controlled substance in schedule I, II, or III under
22 section 202(c) of the Controlled Substances Act;

23 “(3) is imported from a Canadian pharmacy
24 that has submitted to the Secretary a registration
25 that identifies the pharmacy and provides docu-
26 mentation that the pharmacy is licensed in Canada;

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

4 “(5) at the time of importation, is accompanied
5 by a copy of a valid prescription for the drug for the
6 individual, issued in the United States by a practi-
7 tioner in accordance with section 503(b), or is ac-
8 companied by documentation that verifies the
9 issuance of such a prescription for the individual;

10 “(6) is in the form of a final finished dosage;
11 and

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

15 “(b) STUDY; LIMITATION ON WAIVER REQUIRE-
16 MENT.—

17 “(1) STUDY.—During the one-year period be-
18 ginning on the effective date of this section, the Sec-
19 retary shall conduct a study of prescription drugs
20 imported from Canada under subsection (a), and of
21 prescription drugs that are imported into the United
22 States from other countries for personal use, in
23 order to determine the authenticity and quality of
24 such drugs.

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

5 “(A) The Secretary may, in order to pro-
6 tect the public health, establish one or more
7 conditions for the importation from Canada of
8 prescription drugs for personal use that are dif-
9 ferent than the conditions described in such
10 subsection, in which case any conflicting condi-
11 tion described in such subsection ceases to
12 apply.

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

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

1 establishes conditions in order to protect the public health,
2 the Secretary may, in the case of such countries in addi-
3 tion to Canada as the Secretary determines to be appro-
4 priate, establish by regulation a waiver of prohibitions
5 under this Act that apply to the importation of drugs,
6 under which waiver individuals are permitted to import
7 into the United States prescription drugs that meet the
8 conditions that apply under subsection (a) (or under sub-
9 section (b)(2)(A), as the case may be). Such regulations
10 may establish country-specific conditions, as determined
11 appropriate by the Secretary to protect the public health.

12 “(d) DEFINITION.—For purposes of this section, the
13 term ‘prescription drug’ means a drug that is subject to
14 section 503(b).”.

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

1 the Congress a report describing the findings of the as-
2 sessment.

3 **SEC. 3. CONTROLLED SUBSTANCES; IMPORTATION WITH-**
4 **OUT VALID PRESCRIPTIONS.**

5 Section 1006(a)(2) of the Controlled Substances Im-
6 port and Export Act (21 U.S.C. 956(a)(2)) is amended
7 by striking “that exceeds 50 dosage units” and all that
8 follows and inserting the following: “that exceeds 10 dos-
9 age units of the controlled substance, except that if the
10 individual is importing more than one such controlled sub-
11 stance into the United States, the combined total number
12 of dosage units of such substances imported by the indi-
13 vidual may not exceed 10 dosage units.”.

14 **SEC. 4. INTERNET SALES OF PRESCRIPTION DRUGS.**

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

18 **“SEC. 503B. INTERNET SALES OF PRESCRIPTION DRUGS.**

19 “(a) REQUIREMENTS REGARDING INFORMATION ON
20 INTERNET SITE.—

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

24 “(A) the purchaser of the drug submitted
25 the purchase order for the drug, or conducted

1 any other part of the sales transaction for the
2 drug, through an Internet site; and

3 “(B) such site, or any other Internet site
4 used by such person for purposes of sales of a
5 prescription drug, fails to meet each of the re-
6 quirements specified in paragraph (2) (other
7 than a site or pages on a site that are not in-
8 tended to be accessed by purchasers or prospec-
9 tive purchasers).

10 “(2) REQUIREMENTS.—With respect to an
11 Internet site, the requirements referred to in sub-
12 paragraph (B) of paragraph (1) for a person to
13 whom such paragraph applies are as follows:

14 “(A) Each page of the site shall include ei-
15 ther the following information or a link to a
16 page that provides the following information:

17 “(i) The name of such person; the ad-
18 dress of the principal place of business of
19 the person with respect to sales of pre-
20 scription drugs through the Internet; and
21 the telephone number for such place of
22 business.

23 “(ii) Each State in which the person
24 is authorized by law to dispense prescrip-
25 tion drugs.

1 “(iii) The name of each individual
2 who serves as a pharmacist for purposes of
3 the site, and each State in which the indi-
4 vidual is authorized by law to dispense pre-
5 scription drugs.

6 “(iv) If the person provides for med-
7 ical consultations through the site for pur-
8 poses of providing prescriptions, the name
9 of each individual who provides such con-
10 sultations; each State in which the indi-
11 vidual is licensed or otherwise authorized
12 by law to provide such consultations; and
13 the type or types of health professions for
14 which the individual holds such licenses or
15 other authorizations.

16 “(B) A link to which paragraph (1) applies
17 shall be clearly visible on the page involved,
18 shall not be of a size smaller than other links
19 on the page (if any), and shall include in the
20 caption for the link the words ‘licensing and
21 contact information’.

22 “(b) INTERNET SALES WITHOUT APPROPRIATE
23 MEDICAL RELATIONSHIPS.—

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

4 “(A) for purposes of such sale, the pur-
5 chaser communicated with the person through
6 the Internet;

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

10 “(C) pursuant to such communications, the
11 person provided for the involvement of a practi-
12 tioner and the practitioner issued a prescription
13 for the drug that was purchased;

14 “(D) the person knew, or had reason to
15 know, that the practitioner did not, when
16 issuing the prescription, have a qualifying med-
17 ical relationship with the patient; and

18 “(E)(i) the person received payment for
19 the drug from the purchaser; or

20 “(ii) in the case of arranging the dis-
21 pensing of the drug, the person received pay-
22 ment for doing so from the person who dis-
23 pensed the drug.

1 For purposes of subparagraph (E), payment is re-
2 ceived if money or other valuable consideration is re-
3 ceived.

4 “(2) QUALIFYING MEDICAL RELATIONSHIP.—

5 “(A) IN GENERAL.—With respect to
6 issuing a prescription for a drug for a patient,
7 a practitioner has a qualifying medical relation-
8 ship with the patient for purposes of this sec-
9 tion if at least one in-person medical evaluation
10 of the patient has been conducted by the practi-
11 tioner. This subparagraph and subparagraph
12 (B) may not be construed as having any appli-
13 cability beyond this section.

14 “(B) IN-PERSON MEDICAL EVALUATION.—

15 A medical evaluation by a practitioner is an in-
16 person medical evaluation for purposes of this
17 section if the practitioner is in the physical
18 presence of the patient as part of conducting
19 the evaluation, without regard to whether por-
20 tions of the evaluation are conducted by other
21 health professionals.

22 “(c) ACTIONS BY STATES.—

23 “(1) IN GENERAL.—Whenever an attorney gen-
24 eral of any State has reason to believe that the in-
25 terests of the residents of that State have been or

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

13 “(2) NOTICE.—The State shall serve prior writ-
14 ten notice of any civil action under paragraph (1) or
15 (5)(B) upon the Secretary and provide the Secretary
16 with a copy of its complaint, except that if it is not
17 feasible for the State to provide such prior notice,
18 the State shall serve such notice immediately upon
19 instituting such action. Upon receiving a notice re-
20 specting a civil action, the Secretary shall have the
21 right—

22 “(A) to intervene in such action;

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

25 “(C) to file petitions for appeal.

1 “(3) CONSTRUCTION.—For purposes of bring-
2 ing any civil action under paragraph (1), nothing in
3 this chapter shall prevent an attorney general of a
4 State from exercising the powers conferred on the
5 attorney general by the laws of such State to con-
6 duct investigations or to administer oaths or affir-
7 mations or to compel the attendance of witnesses or
8 the production of documentary and other evidence.

9 “(4) VENUE; SERVICE OF PROCESS.—Any civil
10 action brought under paragraph (1) in a district
11 court of the United States may be brought in the
12 district in which the defendant is found, is an inhab-
13 itant, or transacts business or wherever venue is
14 proper under section 1391 of title 28, United States
15 Code. Process in such an action may be served in
16 any district in which the defendant is an inhabitant
17 or in which the defendant may be found.

18 “(5) ACTIONS BY OTHER STATE OFFICIALS.—

19 “(A) Nothing contained in this section
20 shall prohibit an authorized State official from
21 proceeding in State court on the basis of an al-
22 leged violation of any civil or criminal statute of
23 such State.

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

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

5 “(d) DEFINITIONS.—

6 “(1) INTERNET-RELATED DEFINITIONS.—For
7 purposes of this section:

8 “(A) The term ‘Internet’ means collectively
9 the myriad of computer and telecommunications
10 facilities, including equipment and operating
11 software, which comprise the interconnected
12 world-wide network of networks that employ the
13 transmission control protocol/internet protocol,
14 or any predecessor or successor protocols to
15 such protocol, to communicate information of
16 all kinds by wire or radio.

17 “(B) The term ‘link’, with respect to the
18 Internet, means one or more letters, words,
19 numbers, symbols, or graphic items that appear
20 on a page of an Internet site for the purpose
21 of serving, when activated, as a method for exe-
22 cuting an electronic command—

23 “(i) to move from viewing one portion
24 of a page on such site to another portion
25 of the page;

1 “(ii) to move from viewing one page
2 on such site to another page on such site;
3 or

4 “(iii) to move from viewing a page on
5 one Internet site to a page on another
6 Internet site.

7 “(C) The term ‘page’, with respect to the
8 Internet, means a document or other file
9 accessed at an Internet site.

10 “(D)(i) The terms ‘site’ and ‘address’, with
11 respect to the Internet, mean a specific location
12 on the Internet that is determined by Internet
13 Protocol numbers. Such term includes the do-
14 main name, if any.

15 “(ii) The term ‘domain name’ means a
16 method of representing an Internet address
17 without direct reference to the Internet Protocol
18 numbers for the address, including methods
19 that use designations such as ‘.com’, ‘.edu’,
20 ‘.gov’, ‘.net’, or ‘.org’.

21 “(iii) The term ‘Internet Protocol num-
22 bers’ includes any successor protocol for deter-
23 mining a specific location on the Internet.

24 “(2) OTHER DEFINITIONS.—For purposes of
25 this section:

1 “(A) The term ‘practitioner’, with respect
2 to the issuance of a prescription for a drug for
3 a patient, means—

4 “(i) an individual authorized by law to
5 administer the drug; or

6 “(ii) an individual who is not so au-
7 thorized but represents himself or herself
8 as an individual who is so authorized.

9 “(B) The term ‘prescription drug’ means a
10 drug that is subject to section 503(b).

11 “(C) The term ‘qualifying medical relation-
12 ship’, with respect to a practitioner and a pa-
13 tient, has the meaning indicated for such term
14 in subsection (b).”.

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

19 “(l) The dispensing of a prescription drug in violation
20 of section 503B, or arranging for the dispensing of such
21 a drug in violation of such section.”.

22 (c) INTERNET SALES OF PRESCRIPTION DRUGS;
23 CONSIDERATION BY SECRETARY OF PRACTICES AND PRO-
24 CEDURES FOR CERTIFICATION OF LEGITIMATE BUSI-
25 NESSES.—In carrying out section 503B of the Federal

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

9 (d) EFFECTIVE DATE.—The amendments made by
10 subsections (a) and (b) take effect upon the expiration of
11 the 60-day period beginning on the date of the enactment
12 of this Act, without regard to whether a final rule to im-
13 plement such amendments has been promulgated by the
14 Secretary of Health and Human Services under section
15 701(a) of the Federal Food, Drug, and Cosmetic Act. The
16 preceding sentence may not be construed as affecting the
17 authority of such Secretary to promulgate such a final
18 rule.

○