

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

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.

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

1 **SECTION 1. SHORT TITLE.**

2 This Act may be cited as the “Affordable Medicine
3 Safety and Access Act”.

4 **TITLE I—INTERNET AND MAIL-**
5 **ORDER PHARMACIES**

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

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

11 **“SEC. 503B. VOLUNTARY CERTIFICATIONS REGARDING**
12 **INTERNET AND MAIL-ORDER PHARMACIES.**

13 “(a) IN GENERAL.—The Secretary, directly or
14 through contract with one or more public or nonprofit pri-
15 vate entities, shall establish a program under which Inter-
16 net and mail-order pharmacies, on a voluntary basis, are
17 certified by the Secretary as meeting the requirements of
18 this section for certification.

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

23 “(c) CONDITIONS FOR CERTIFICATION.—As a condi-
24 tion of certifying an Internet or mail-order pharmacy
25 under subsection (a), the Secretary shall require the fol-
26 lowing with respect to such pharmacy:

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

6 “(A) the practice of pharmacy, including
7 licensing laws; and

8 “(B) the manufacturing and distribution of
9 controlled substances, including with respect to
10 mailing or shipping such substances to con-
11 sumers.

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

17 “(3) The prominent display of contact informa-
18 tion for the pharmacy, including a telephone num-
19 ber, an electronic mail address, a mailing address,
20 and (if different from the mailing address) the ad-
21 dress for the physical location of the principal place
22 of business of the pharmacy.

23 “(4) The prominent display of complete and ac-
24 curate information concerning the ownership and

1 management of the pharmacy, including addresses
2 and contact information.

3 “(5) A certification from the person who owns
4 or manages the pharmacy that a certification under
5 subsection (a) for the pharmacy has not previously
6 been terminated by the Secretary, and that no other
7 Internet or mail-order pharmacy owned or managed
8 by such person has received a certification under
9 subsection (a) that has been terminated by the Sec-
10 retary.

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

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

21 “(8) Controls to ensure that, prior to dis-
22 pensing a drug to a consumer, a prospective review
23 of the use of the drug by the consumer is completed,
24 based on accurate information about the consumer

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

3 “(9) Effective, accessible systems for commu-
4 nication with consumers, including systems for con-
5 sumer reporting of adverse drug reactions and er-
6 rors, systems by which consumers can effectively
7 track and report problems with unfulfilled orders,
8 systems for the investigation and redress of con-
9 sumer complaints, and systems facilitating effective
10 communication between the pharmacy and con-
11 sumers concerning drug recalls.

12 “(10) Controls to ensure the protection of pa-
13 tient privacy and confidentiality, including but not
14 limited to the prevention of unauthorized internal
15 and external use of personally-identifiable patient in-
16 formation.

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

22 “(12) Such additional criteria as the Secretary
23 determines, after notice and opportunity for com-
24 ment, to be appropriate for the sound operation of
25 certified pharmacies or the protection of consumers.

1 “(d) ANNUAL APPLICATION; DURATION OF CERTIFI-
2 CATION.—

3 “(1) IN GENERAL.—The Secretary may certify
4 an Internet or mail-order pharmacy under sub-
5 section (a) only if the pharmacy submits to the Sec-
6 retary an application for such certification that dem-
7 onstrates compliance with the conditions under sub-
8 section (c) and is in such form, and is made in such
9 manner, as the Secretary may require. The Sec-
10 retary shall establish an application form for pur-
11 poses of the preceding sentence, including an elec-
12 tronic application form.

13 “(2) DURATION OF CERTIFICATION; RE-
14 NEWAL.—

15 “(A) IN GENERAL.—A certification under
16 subsection (a) is effective for the one-year pe-
17 riod beginning on the date on which the appli-
18 cation under paragraph (1) for such certifi-
19 cation is approved by the Secretary. The Sec-
20 retary may renew the certification, pursuant to
21 the submission of an additional application
22 under paragraph (1), and the number of renew-
23 als of the certification is not limited. The Sec-
24 retary may establish an abbreviated process for
25 such renewal applications.

1 “(B) RENEWAL EVALUATION.—Before re-
2 newing a certification under subsection (a), the
3 Secretary shall conduct an evaluation to deter-
4 mine whether the pharmacy involved is in com-
5 pliance with the conditions under subsection
6 (c). The evaluation, at the Secretary’s discre-
7 tion and as applicable, may include testing of
8 the Internet site of the pharmacy or other sys-
9 tems through which the pharmacy commu-
10 nicates with consumers, and may include phys-
11 ical inspection of the records and premises of
12 the pharmacy pursuant to subsection (c)(6).

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

18 “(f) INFORMATION CAMPAIGN.—The Secretary shall
19 carry out activities to inform the public of the program
20 under subsection (a), including information on the signifi-
21 cance of the seal under subsection (b) when displayed by
22 an Internet or mail-order pharmacy, and including infor-
23 mation on the benefits of doing business with a pharmacy
24 certified under subsection (a) as compared to a pharmacy
25 that is not so certified.

1 “(g) TERMINATION OF CERTIFICATION.—The Sec-
2 retary, upon the own initiative of the Secretary or a peti-
3 tion by an interested person, may terminate a certification
4 under subsection (a), after notice to the Internet or mail-
5 order pharmacy involved and an opportunity for a hearing.

6 “(h) CONTRACT FOR OPERATION OF PROGRAM.—

7 “(1) DETERMINATION REGARDING USE OF CON-
8 TRACT AUTHORITY.—The Secretary may award a
9 contract under subsection (a) for the operation of
10 the program under such subsection only if the Sec-
11 retary determines that the administration by the
12 contractor of such program would be as protective or
13 more protective of the public than direct administra-
14 tion of the program by the Secretary.

15 “(2) CERTAIN REQUIREMENTS.—With respect
16 to a contract under subsection (a):

17 “(A) The duration of the contract may not
18 exceed two years.

19 “(B) The Secretary may renew the con-
20 tract, subject to compliance with subparagraph
21 (A).

22 “(C) The Secretary shall annually review
23 performance under the contract.

1 “(D) The contract shall specify that the
2 Secretary may terminate the contract for unsat-
3 isfactory performance under the contract.

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

5 “(1) The term ‘Internet pharmacy’ means a
6 pharmacy that, by shipping, mailing, or transporting
7 a prescription drug, dispenses such drug pursuant to
8 a sale of the drug by the pharmacy in circumstances
9 in which the purchaser of the drug submitted the
10 purchase order for the drug, or conducted any other
11 part of the sales transaction for the drug, through
12 an Internet site.

13 “(2) The term ‘mail-order pharmacy’ means a
14 pharmacy that, by shipping, mailing, or transporting
15 a prescription drug, dispenses such drug pursuant to
16 a sale of the drug by the pharmacy in circumstances
17 in which the purchaser of the drug submitted the
18 purchase order for the drug, or conducted any other
19 part of the sales transaction for the drug, through
20 the mail or through any telecommunications means
21 other than an Internet site.

22 “(3)(A) Subject to subparagraph (B), the term
23 ‘pharmacy’ means an organization licensed by a
24 State to practice pharmacy, including the dispensing
25 and selling of prescription drugs.

1 “(B) The Secretary shall consider an organiza-
2 tion as meeting the definition established in sub-
3 paragraph (A) if the Secretary determines that the
4 organization would qualify for licensure in at least
5 one of the States but for a policy of such State that
6 denies licensure as a pharmacy on the basis that the
7 organization dispenses prescription drugs from loca-
8 tions in Canada or dispenses prescription drugs ob-
9 tained by such organization from an entity in Can-
10 ada.

11 “(4) The term ‘prescription drug’ means a drug
12 subject to section 503(b).”.

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

17 “(hh) The display by an Internet or mail-order phar-
18 macy of the seal under section 503B without a certifi-
19 cation in effect under such section for the pharmacy, or
20 the making by such a pharmacy of a false claim that such
21 a certification is in effect for the pharmacy.”.

1 **TITLE II—PERSONAL IMPORTA-**
2 **TION OF PRESCRIPTION**
3 **DRUGS FROM CANADA**

4 **Subtitle A—Waiver Requirement**

5 **SEC. 201. WAIVER REQUIREMENT FOR PERSONAL IMPOR-**
6 **TATION OF PRESCRIPTION DRUGS FROM**
7 **CANADA.**

8 Chapter VIII of the Federal Food, Drug, and Cos-
9 metic Act (21 U.S.C. 381 et seq.) is amended by adding
10 at the end the following section:

11 “WAIVER REQUIREMENT FOR PERSONAL IMPORTATION
12 OF PRESCRIPTION DRUGS FROM CANADA

13 “SEC. 805. With respect to the importation by indi-
14 viduals of prescription drugs from Canada, the Secretary
15 shall in accordance with this section establish by regula-
16 tion a waiver of prohibitions under this Act that apply to
17 the importation of drugs. Such a waiver shall permit an
18 individual to import into the United States any prescrip-
19 tion drug that—

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

22 “(2) is approved by the Secretary under section
23 505, is manufactured in an establishment registered
24 with the Secretary under section 510, and is not a

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

3 “(3) is imported from a Canadian pharmacy
4 that has submitted to the Secretary a registration
5 that identifies the pharmacy and provides docu-
6 mentation that the pharmacy is licensed in Canada;

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

10 “(5) at the time of importation, is accompanied
11 by a copy of a valid prescription for the drug for the
12 individual, issued in the United States by a practi-
13 tioner in accordance with section 503(b), or is ac-
14 companied by documentation that verifies the
15 issuance of such a prescription for the individual;

16 “(6) is in the form of a final finished dosage;
17 and

18 “(7) is imported under such other conditions as
19 the Secretary determines to be necessary to ensure
20 public safety.”.

21 **Subtitle B—Studies**

22 **SEC. 211. STUDY REGARDING IN-PERSON PERSONAL IM- 23 PORTATION FROM CANADA.**

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

1 retary”), acting through the Commissioner of Food and
2 Drugs, shall conduct a study for the purpose of developing
3 recommendations regarding any legislative or administra-
4 tive changes that may be necessary to provide reasonable
5 assurance concerning the safety and effectiveness of pre-
6 scription drugs that are purchased in-person at a licensed
7 pharmacy in Canada and imported from Canada into the
8 United States for personal use by individuals who are not
9 in the business of importing such drugs (referred to in
10 this section with respect to such drugs as “in-person per-
11 sonal importation”). Not later than 18 months after the
12 date of the enactment of this Act, the Secretary shall sub-
13 mit to the Congress a report describing the findings of
14 such study.

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

18 (1) With respect to prescription drugs that are
19 commonly purchased from Canadian pharmacies for
20 in-person personal importation, the purchase of a
21 representative sample of such drugs at randomly-se-
22 lected Canadian pharmacies that are representative
23 of Canadian pharmacies from which prescription
24 drugs are purchased for personal importation.

1 through the Commissioner of Food and Drugs, shall con-
2 duct a study through which the Secretary—

3 (1) makes purchases of such drugs from Inter-
4 net pharmacies and mail-order pharmacies that
5 make sales to consumers in the United States and
6 claim such drugs are obtained from Canadian phar-
7 macies or wholesalers, which purchases are a rep-
8 resentative sample of such drugs purchased from
9 such pharmacies; and

10 (2) determines whether the drugs purchased
11 under paragraph (1) are approved for commercial
12 distribution in Canada and are obtained from Cana-
13 dian pharmacies or wholesalers.

14 The Secretary shall seek the cooperation of the Govern-
15 ment of Canada in making the determination under para-
16 graph (2). Not later than 18 months after the date of the
17 enactment of this Act, the Secretary shall submit to the
18 Congress a report describing the findings of such study.

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