

108TH CONGRESS  
1ST SESSION

# H. R. 2497

To permit commercial importation of prescription drugs from Canada, and  
for other purposes.

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## IN THE HOUSE OF REPRESENTATIVES

JUNE 17, 2003

Mr. SANDERS (for himself, Mr. BROWN of Ohio, Mr. OLVER, Mrs. NAPOLITANO, Mr. SERRANO, Ms. LEE, Ms. CORRINE BROWN of Florida, Mr. MURTHA, Mr. HOLDEN, Mr. PALLONE, Mr. PAUL, Mr. LANTOS, Mr. FILNER, Mr. FROST, Ms. BALDWIN, Mr. FRANK of Massachusetts, Mr. CONYERS, Mr. HINCHEY, Mr. TIERNEY, Mr. ABERCROMBIE, Mr. WYNN, Ms. SLAUGHTER, Mr. NADLER, Ms. NORTON, Mr. COSTELLO, Mr. OWENS, Mr. CROWLEY, Mr. KLECZKA, Mr. KUCINICH, Mr. CASE, Mr. DEFAZIO, Ms. WOOLSEY, and Mr. DAVIS of Illinois) introduced the following bill; which was referred to the Committee on Energy and Commerce

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## A BILL

To permit commercial importation of prescription drugs from  
Canada, 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 “Prescription Drug Par-  
5 ity for Americans Act”.

1 **SEC. 2. IMPORTATION OF PRESCRIPTION DRUGS.**

2 (a) IN GENERAL.—Chapter VIII of the Federal  
3 Food, Drug, and Cosmetic Act (21 U.S.C. 381 et seq.)  
4 is amended by striking section 804 and inserting the fol-  
5 lowing:

6 **“SEC. 804. IMPORTATION OF PRESCRIPTION DRUGS.**

7 “(a) DEFINITIONS.—In this section:

8 “(1) IMPORTER.—The term ‘importer’ means a  
9 pharmacist or wholesaler.

10 “(2) PHARMACIST.—The term ‘pharmacist’  
11 means a person licensed by a State to practice phar-  
12 macy, including the dispensing and selling of pre-  
13 scription drugs.

14 “(3) PRESCRIPTION DRUG.—The term ‘pre-  
15 scription drug’ means a drug subject to section  
16 503(b), other than—

17 “(A) a controlled substance (as defined in  
18 section 102 of the Controlled Substances Act  
19 (21 U.S.C. 802));

20 “(B) a biological product (as defined in  
21 section 351 of the Public Health Service Act  
22 (42 U.S.C. 262));

23 “(C) an infused drug (including a peri-  
24 toneal dialysis solution);

25 “(D) an intravenously injected drug; or

26 “(E) a drug that is inhaled during surgery.

1           “(4) QUALIFYING LABORATORY.—The term  
2           ‘qualifying laboratory’ means a laboratory in the  
3           United States that has been approved by the Sec-  
4           retary for the purposes of this section.

5           “(5) WHOLESALER.—

6                   “(A) IN GENERAL.—The term ‘wholesaler’  
7                   means a person licensed as a wholesaler or dis-  
8                   tributor of prescription drugs in the United  
9                   States under section 503(e)(2)(A).

10                   “(B) EXCLUSION.—The term ‘wholesaler’  
11                   does not include a person authorized to import  
12                   drugs under section 801(d)(1).

13           “(b) REGULATIONS.—The Secretary, after consulta-  
14           tion with the United States Trade Representative and the  
15           Commissioner of Customs, shall promulgate regulations  
16           permitting pharmacists and wholesalers to import pre-  
17           scription drugs from Canada into the United States.

18           “(c) LIMITATION.—The regulations under subsection  
19           (b) shall—

20                   “(1) require that safeguards be in place to en-  
21                   sure that each prescription drug imported under the  
22                   regulations complies with section 505 (including  
23                   with respect to being safe and effective for the in-  
24                   tended use of the prescription drug), with sections

1 501 and 502, and with other applicable require-  
2 ments of this Act;

3 “(2) require that an importer of a prescription  
4 drug under the regulations comply with subsections  
5 (d)(1) and (e); and

6 “(3) contain any additional provisions deter-  
7 mined by the Secretary to be appropriate as a safe-  
8 guard to protect the public health or as a means to  
9 facilitate the importation of prescription drugs.

10 “(d) INFORMATION AND RECORDS.—

11 “(1) IN GENERAL.—The regulations under sub-  
12 section (b) shall require an importer of a prescrip-  
13 tion drug under subsection (b) to submit to the Sec-  
14 retary the following information and documentation:

15 “(A) The name and quantity of the active  
16 ingredient of the prescription drug.

17 “(B) A description of the dosage form of  
18 the prescription drug.

19 “(C) The date on which the prescription  
20 drug is shipped.

21 “(D) The quantity of the prescription drug  
22 that is shipped.

23 “(E) The point of origin and destination of  
24 the prescription drug.

1           “(F) The price paid by the importer for  
2 the prescription drug.

3           “(G) Documentation from the foreign sell-  
4 er specifying—

5                 “(i) the original source of the pre-  
6 scription drug; and

7                 “(ii) the quantity of each lot of the  
8 prescription drug originally received by the  
9 seller from that source.

10           “(H) The lot or control number assigned  
11 to the prescription drug by the manufacturer of  
12 the prescription drug.

13           “(I) The name, address, telephone number,  
14 and professional license number (if any) of the  
15 importer.

16           “(J)(i) In the case of a prescription drug  
17 that is shipped directly from the first foreign  
18 recipient of the prescription drug from the  
19 manufacturer:

20                 “(I) Documentation demonstrating  
21 that the prescription drug was received by  
22 the recipient from the manufacturer and  
23 subsequently shipped by the first foreign  
24 recipient to the importer.

1           “(II) Documentation of the quantity  
2           of each lot of the prescription drug re-  
3           ceived by the first foreign recipient dem-  
4           onstrating that the quantity being im-  
5           ported into the United States is not more  
6           than the quantity that was received by the  
7           first foreign recipient.

8           “(III)(aa) In the case of an initial im-  
9           ported shipment, documentation dem-  
10          onstrating that each batch of the prescrip-  
11          tion drug in the shipment was statistically  
12          sampled and tested for authenticity and  
13          degradation.

14          “(bb) In the case of any subsequent  
15          shipment, documentation demonstrating  
16          that a statistically valid sample of the ship-  
17          ment was tested for authenticity and deg-  
18          radation.

19          “(ii) In the case of a prescription drug  
20          that is not shipped directly from the first for-  
21          eign recipient of the prescription drug from the  
22          manufacturer, documentation demonstrating  
23          that each batch in each shipment offered for  
24          importation into the United States was statis-

1 tically sampled and tested for authenticity and  
2 degradation.

3 “(K) Certification from the importer or  
4 manufacturer of the prescription drug that the  
5 prescription drug—

6 “(i) is approved for marketing in the  
7 United States; and

8 “(ii) meets all labeling requirements  
9 under this Act.

10 “(L) Laboratory records, including com-  
11 plete data derived from all tests necessary to  
12 ensure that the prescription drug is in compli-  
13 ance with established specifications and stand-  
14 ards.

15 “(M) Documentation demonstrating that  
16 the testing required by subparagraphs (J) and  
17 (L) was conducted at a qualifying laboratory.

18 “(N) Any other information that the Sec-  
19 retary determines is necessary to ensure the  
20 protection of the public health.

21 “(2) MAINTENANCE BY THE SECRETARY.—The  
22 Secretary shall maintain information and docu-  
23 mentation submitted under paragraph (1) for such  
24 period of time as the Secretary determines to be nec-  
25 essary.

1       “(e) TESTING.—The regulations under subsection (b)  
2 shall require—

3           “(1) that testing described in subparagraphs  
4 (J) and (L) of subsection (d)(1) be conducted by the  
5 importer or by the manufacturer of the prescription  
6 drug at a qualified laboratory;

7           “(2) if the tests are conducted by the im-  
8 porter—

9           “(A) that information needed to—

10                  “(i) authenticate the prescription drug  
11 being tested; and

12                  “(ii) confirm that the labeling of the  
13 prescription drug complies with labeling re-  
14 quirements under this Act;

15 be supplied by the manufacturer of the pre-  
16 scription drug to the pharmacist or wholesaler;  
17 and

18           “(B) that the information supplied under  
19 subparagraph (A) be kept in strict confidence  
20 and used only for purposes of testing or other-  
21 wise complying with this Act; and

22           “(3) may include such additional provisions as  
23 the Secretary determines to be appropriate to pro-  
24 vide for the protection of trade secrets and commer-

1        cial or financial information that is privileged or  
2        confidential.

3        “(f) REGISTRATION OF FOREIGN SELLERS.—Any es-  
4        tablishment within Canada engaged in the distribution of  
5        a prescription drug that is imported or offered for impor-  
6        tation into the United States shall register with the Sec-  
7        retary the name and place of business of the establish-  
8        ment.

9        “(g) SUSPENSION OF IMPORTATION.—The Secretary  
10       shall require that importations of a specific prescription  
11       drug or importations by a specific importer under sub-  
12       section (b) be immediately suspended on discovery of a  
13       pattern of importation of the prescription drugs or by the  
14       importer that is counterfeit or in violation of any require-  
15       ment under this section, until an investigation is com-  
16       pleted and the Secretary determines that the public is ade-  
17       quately protected from counterfeit and violative prescrip-  
18       tion drugs being imported under subsection (b).

19       “(h) APPROVED LABELING.—The manufacturer of a  
20       prescription drug shall provide an importer written au-  
21       thorization for the importer to use, at no cost, the ap-  
22       proved labeling for the prescription drug.

23       “(i) PROHIBITION OF DISCRIMINATION.—

24                “(1) IN GENERAL.—It shall be unlawful for a  
25       manufacturer of a prescription drug to discriminate

1 against, or cause any other person to discriminate  
2 against, a pharmacist or wholesaler that purchases  
3 or offers to purchase a prescription drug from the  
4 manufacturer or from any person that distributes a  
5 prescription drug manufactured by the drug manu-  
6 facturer.

7 “(2) DISCRIMINATION.—For the purposes of  
8 paragraph (1), a manufacturer of a prescription  
9 drug shall be considered to discriminate against a  
10 pharmacist or wholesaler if the manufacturer enters  
11 into a contract for sale of a prescription drug, places  
12 a limit on supply, or employs any other measure,  
13 that has the effect of—

14 “(A) providing pharmacists or wholesalers  
15 access to prescription drugs on terms or condi-  
16 tions that are less favorable than the terms or  
17 conditions provided to a foreign purchaser  
18 (other than a charitable or humanitarian orga-  
19 nization) of the prescription drug; or

20 “(B) restricting the access of pharmacists  
21 or wholesalers to a prescription drug that is  
22 permitted to be imported into the United States  
23 under this section.

24 “(j) CHARITABLE CONTRIBUTIONS.—Notwith-  
25 standing any other provision of this section, section

1 801(d)(1) continues to apply to a prescription drug that  
2 is donated or otherwise supplied at no charge by the man-  
3 ufacturer of the drug to a charitable or humanitarian or-  
4 ganization (including the United Nations and affiliates)  
5 or to a government of a foreign country.

6 “(k) WAIVER AUTHORITY FOR IMPORTATION BY IN-  
7 DIVIDUALS.—

8 “(1) DECLARATIONS.—Congress declares that  
9 in the enforcement against individuals of the prohi-  
10 bition of importation of prescription drugs and de-  
11 vices, the Secretary should—

12 “(A) focus enforcement on cases in which  
13 the importation by an individual poses a signifi-  
14 cant threat to public health; and

15 “(B) exercise discretion to permit individ-  
16 uals to make such importations in cir-  
17 cumstances in which—

18 “(i) the importation is clearly for per-  
19 sonal use; and

20 “(ii) the prescription drug or device  
21 imported does not appear to present an  
22 unreasonable risk to the individual.

23 “(2) WAIVER AUTHORITY.—

24 “(A) IN GENERAL.—The Secretary may  
25 grant to individuals, by regulation or on a case-

1 by-case basis, a waiver of the prohibition of im-  
2 portation of a prescription drug or device or  
3 class of prescription drugs or devices, under  
4 such conditions as the Secretary determines to  
5 be appropriate.

6 “(B) GUIDANCE ON CASE-BY-CASE WAIV-  
7 ERS.—The Secretary shall publish, and update  
8 as necessary, guidance that accurately describes  
9 circumstances in which the Secretary will con-  
10 sistentlly grant waivers on a case-by-case basis  
11 under subparagraph (A), so that individuals  
12 may know with the greatest practicable degree  
13 of certainty whether a particular importation  
14 for personal use will be permitted.

15 “(3) DRUGS IMPORTED FROM CANADA.—In  
16 particular, the Secretary shall by regulation grant  
17 individuals a waiver to permit individuals to import  
18 into the United States a prescription drug that—

19 “(A) is imported from a licensed pharmacy  
20 for personal use by an individual, not for resale,  
21 in quantities that do not exceed a 90-day sup-  
22 ply;

23 “(B) is accompanied by a copy of a valid  
24 prescription;

1           “(C) is imported from Canada, from a sell-  
2           er registered with the Secretary;

3           “(D) is a prescription drug approved by  
4           the Secretary under chapter V;

5           “(E) is in the form of a final finished dos-  
6           age that was manufactured in an establishment  
7           registered under section 510; and

8           “(F) is imported under such other condi-  
9           tions as the Secretary determines to be nec-  
10          essary to ensure public safety.

11       “(I) STUDIES; REPORTS.—

12           “(1) BY THE INSTITUTE OF MEDICINE OF THE  
13          NATIONAL ACADEMY OF SCIENCES.—

14           “(A) STUDY.—

15           “(i) IN GENERAL.—The Secretary  
16          shall request that the Institute of Medicine  
17          of the National Academy of Sciences con-  
18          duct a study of—

19                   “(I) importations of prescription  
20                   drugs made under the regulations  
21                   under subsection (b); and

22                   “(II) information and docu-  
23                   mentation submitted under subsection  
24                   (d).

1           “(ii) REQUIREMENTS.—In conducting  
2 the study, the Institute of Medicine shall—

3           “(I) evaluate the compliance of  
4 importers with the regulations under  
5 subsection (b);

6           “(II) compare the number of  
7 shipments under the regulations  
8 under subsection (b) during the study  
9 period that are determined to be  
10 counterfeit, misbranded, or adulter-  
11 ated, and compare that number with  
12 the number of shipments made during  
13 the study period within the United  
14 States that are determined to be  
15 counterfeit, misbranded, or adulter-  
16 ated; and

17           “(III) consult with the Secretary,  
18 the United States Trade Representa-  
19 tive, and the Commissioner of Patents  
20 and Trademarks to evaluate the effect  
21 of importations under the regulations  
22 under subsection (b) on trade and  
23 patent rights under Federal law.

24           “(B) REPORT.—Not later than 2 years  
25 after the effective date of the regulations under

1 subsection (b), the Institute of Medicine shall  
2 submit to Congress a report describing the find-  
3 ings of the study under subparagraph (A).

4 “(2) BY THE COMPTROLLER GENERAL.—

5 “(A) STUDY.—The Comptroller General of  
6 the United States shall conduct a study to de-  
7 termine the effect of this section on the price of  
8 prescription drugs sold to consumers at retail.

9 “(B) REPORT.—Not later than 18 months  
10 after the effective date of the regulations under  
11 subsection (b), the Comptroller General of the  
12 United States shall submit to Congress a report  
13 describing the findings of the study under sub-  
14 paragraph (A).

15 “(m) CONSTRUCTION.—Nothing in this section limits  
16 the authority of the Secretary relating to the importation  
17 of prescription drugs, other than with respect to section  
18 801(d)(1) as provided in this section.

19 “(n) AUTHORIZATION OF APPROPRIATIONS.—There  
20 are authorized to be appropriated such sums as are nec-  
21 essary to carry out this section.”.

22 (b) CONFORMING AMENDMENTS.—The Federal  
23 Food, Drug, and Cosmetic Act is amended—

24 (1) in section 301(aa) (21 U.S.C. 331(aa)), by  
25 striking “covered product in violation of section

1 804” and inserting “prescription drug in violation of  
2 section 804”;

3 (2) in section 303(a)(6) (21 U.S.C. 333(a)(6),  
4 by striking “covered product pursuant to section  
5 804(a)” and inserting “prescription drug under sec-  
6 tion 804(b)”.

○