

107TH CONGRESS
2D SESSION

S. 2244

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

IN THE SENATE OF THE UNITED STATES

APRIL 24, 2002

Mr. DORGAN (for himself, Mr. JEFFORDS, Ms. COLLINS, Ms. STABENOW, Ms. SNOWE, Mr. WELLSTONE, Mr. LEVIN, and Mr. DAYTON) introduced the following bill; which was read twice and referred to the Committee on Health, Education, Labor, and Pensions

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
5 Price Parity for Americans Act”.

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

7 (a) IN GENERAL.—Chapter VIII of the Federal
8 Food, Drug, and Cosmetic Act (21 U.S.C. 381 et seq.)

1 is amended by striking section 804 and inserting the fol-
 2 lowing:

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

4 “(a) DEFINITIONS.—In this section:

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

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

11 “(3) PRESCRIPTION DRUG.—The term ‘pre-
 12 scription drug’ means a drug subject to section
 13 503(b), other than—

14 “(A) a controlled substance (as defined in
 15 section 102 of the Controlled Substances Act
 16 (21 U.S.C. 802));

17 “(B) a biological product (as defined in
 18 section 351 of the Public Health Service Act
 19 (42 U.S.C. 262));

20 “(C) an infused drug (including a peri-
 21 toneal dialysis solution);

22 “(D) an intravenously injected drug; or

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

24 “(4) QUALIFYING LABORATORY.—The term
 25 ‘qualifying laboratory’ means a laboratory in the

1 United States that has been approved by the Sec-
2 retary for the purposes of this section.

3 “(5) WHOLESALER.—

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

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

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

16 “(c) LIMITATION.—The regulations under subsection
17 (b) shall—

18 “(1) require that safeguards be in place to en-
19 sure that each prescription drug imported under the
20 regulations complies with section 505 (including
21 with respect to being safe and effective for the in-
22 tended use of the prescription drug), with sections
23 501 and 502, and with other applicable require-
24 ments of this Act;

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

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

8 “(d) INFORMATION AND RECORDS.—

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

13 “(A) The name and quantity of the active
14 ingredient of the prescription drug.

15 “(B) A description of the dosage form of
16 the prescription drug.

17 “(C) The date on which the prescription
18 drug is shipped.

19 “(D) The quantity of the prescription drug
20 that is shipped.

21 “(E) The point of origin and destination of
22 the prescription drug.

23 “(F) The price paid by the importer for
24 the prescription drug.

1 “(G) Documentation from the foreign sell-
2 er specifying—

3 “(i) the original source of the pre-
4 scription drug; and

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

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

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

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

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

23 “(II) Documentation of the quantity
24 of each lot of the prescription drug re-
25 ceived by the first foreign recipient dem-

1 onstrating that the quantity being im-
2 ported into the United States is not more
3 than the quantity that was received by the
4 first foreign recipient.

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

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

16 “(ii) In the case of a prescription drug
17 that is not shipped directly from the first for-
18 eign recipient of the prescription drug from the
19 manufacturer, documentation demonstrating
20 that each batch in each shipment offered for
21 importation into the United States was statis-
22 tically sampled and tested for authenticity and
23 degradation.

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

4 “(i) is approved for marketing in the
5 United States; and

6 “(ii) meets all labeling requirements
7 under this Act.

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

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

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

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

24 “(e) TESTING.—The regulations under subsection (b)
25 shall require—

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

5 “(2) if the tests are conducted by the
6 importer—

7 “(A) that information needed to—

8 “(i) authenticate the prescription drug
9 being tested; and

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

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

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

20 “(3) may include such additional provisions as
21 the Secretary determines to be appropriate to pro-
22 vide for the protection of trade secrets and commer-
23 cial or financial information that is privileged or
24 confidential.

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

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

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

21 “(i) PROHIBITION OF DISCRIMINATION.—

22 “(1) IN GENERAL.—It shall be unlawful for a
23 manufacturer of a prescription drug to discriminate
24 against, or cause any other person to discriminate
25 against, a pharmacist or wholesaler that purchases

1 or offers to purchase a prescription drug from the
2 manufacturer or from any person that distributes a
3 prescription drug manufactured by the drug manu-
4 facturer.

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

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

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

22 “(j) CHARITABLE CONTRIBUTIONS.—Notwith-
23 standing any other provision of this section, section
24 801(d)(1) continues to apply to a prescription drug that
25 is donated or otherwise supplied at no charge by the man-

1 manufacturer of the drug to a charitable or humanitarian or-
2 ganization (including the United Nations and affiliates)
3 or to a government of a foreign country.

4 “(k) WAIVER AUTHORITY FOR IMPORTATION BY IN-
5 DIVIDUALS.—

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

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

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

16 “(i) the importation is clearly for per-
17 sonal use; and

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

21 “(2) WAIVER AUTHORITY.—

22 “(A) IN GENERAL.—The Secretary may
23 grant to individuals, by regulation or on a case-
24 by-case basis, a waiver of the prohibition of im-
25 portation of a prescription drug or device or

1 class of prescription drugs or devices, under
2 such conditions as the Secretary determines to
3 be appropriate.

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

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

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

21 “(B) is accompanied by a copy of a valid
22 prescription;

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

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

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

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

9 “(I) STUDIES; REPORTS.—

10 “(1) BY THE INSTITUTE OF MEDICINE OF THE
11 NATIONAL ACADEMY OF SCIENCES.—

12 “(A) STUDY.—

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

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

20 “(II) information and docu-
21 mentation submitted under subsection
22 (d).

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

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

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

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

22 “(B) REPORT.—Not later than 2 years
23 after the effective date of the regulations under
24 subsection (b), the Institute of Medicine shall

1 submit to Congress a report describing the find-
2 ings of the study under subparagraph (A).

3 “(2) BY THE COMPTROLLER GENERAL.—

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

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

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

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

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

23 (1) in section 301(aa) (21 U.S.C. 331(aa)), by
24 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)”.

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