

108TH CONGRESS
1ST SESSION

H. R. 2769

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

IN THE HOUSE OF REPRESENTATIVES

JULY 17, 2003

Mrs. EMERSON introduced the following bill; which was referred to the
Committee on Energy and Commerce

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 “Save Our Seniors Act
5 of 2003”.

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.)
9 is amended by striking section 804 and inserting the fol-
10 lowing:

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

2 “(a) DEFINITIONS.—In this section:

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

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

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

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

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

18 “(C) an infused drug (including a peri-
19 toneal dialysis solution);

20 “(D) an intravenously injected drug;

21 “(E) a drug that is inhaled during surgery;

22 or

23 “(F) a drug that is a parenteral drug, the
24 importation of which pursuant to subsection (b)
25 is determined by the Secretary to pose a threat

1 to the public health, in which case section
2 801(d)(1) shall continue to apply.

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

7 “(5) WHOLESALER.—

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

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

15 “(b) REGULATIONS.—

16 “(1) IMPORTATION FROM CANADA.—The Sec-
17 retary shall promulgate regulations permitting phar-
18 macists and wholesalers to import prescription drugs
19 from Canada into the United States.

20 “(2) IMPORTATION FROM EUROPEAN UNION.—
21 Not sooner than 3 years after the date of the enact-
22 ment of the Save Our Seniors Act of 2003, if the
23 Secretary finds that drugs imported from Canada
24 into the United States under this section have
25 proved safe and effective, the Secretary may expand

1 the application of regulations promulgated under
2 this section to permit pharmacists and wholesalers
3 to import prescription drugs from any member of
4 the European Union into the United States.

5 “(c) LIMITATION.—The regulations under subsection
6 (b)—

7 “(1) shall require that safeguards be in place to
8 ensure that each prescription drug imported under
9 the regulations complies with section 505 (including
10 with respect to being safe and effective for the in-
11 tended use of the prescription drug), with sections
12 501 and 502, and with other applicable require-
13 ments of this Act;

14 “(2) shall require that an importer of a pre-
15 scription drug under the regulations comply with
16 subsections (d)(1) and (e);

17 “(3) may require the incorporation of—

18 “(A) overt optically variable counterfeit re-
19 sistant packaging technologies that—

20 “(i) are visible to the naked eye;

21 “(ii) are similar to the technologies
22 used by the Bureau of Engraving and
23 Printing to secure United States currency;

1 “(iii) are manufactured and distrib-
2 uted in a highly secure, tightly controlled
3 environment; and

4 “(iv) incorporate any additional visible
5 and non-visible security features deter-
6 mined to be appropriate by the Secretary;
7 or

8 “(B) technologies that are determined by
9 the Secretary to have a function of security
10 equivalent to such optically variable counterfeit
11 resistant packaging technologies; and

12 “(4) may contain any additional provisions de-
13 termined by the Secretary to be appropriate as a
14 safeguard to protect the public health or as a means
15 to facilitate the importation of prescription drugs.

16 “(d) INFORMATION AND RECORDS.—

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

21 “(A) The name and quantity of the active
22 ingredient of the prescription drug.

23 “(B) A description of the dosage form of
24 the prescription drug.

1 “(C) The date on which the prescription
2 drug is shipped.

3 “(D) The quantity of the prescription drug
4 that is shipped.

5 “(E) The point of origin and destination of
6 the prescription drug.

7 “(F) The price paid by the importer for
8 the prescription drug.

9 “(G) Documentation from the foreign sell-
10 er specifying—

11 “(i) the manufacturer or the original
12 source of the prescription drug; and

13 “(ii) the quantity of each lot of the
14 prescription drug originally received by the
15 seller from that source.

16 “(H) The lot or control number assigned
17 to the prescription drug by the manufacturer of
18 the prescription drug.

19 “(I) The name, address, telephone number,
20 and professional license number (if any) of the
21 importer.

22 “(J)(i) In the case of a prescription drug
23 that is shipped directly from the first foreign
24 recipient of the prescription drug from the
25 manufacturer, documentation demonstrating

1 that the prescription drug was received by the
2 recipient from the manufacturer and subse-
3 quently shipped by the recipient to the im-
4 porter.

5 “(ii) In the case of any subsequent ship-
6 ment, documentation identifying each prior
7 sale, purchase, or trade of the prescription drug
8 (including the date of the transaction and the
9 names and addresses of all parties to the trans-
10 action).

11 “(iii) Documentation of the quantity of
12 each lot of the prescription drug received by the
13 first foreign recipient demonstrating that the
14 quantity being imported into the United States
15 is not more than the quantity that was received
16 by the first foreign recipient.

17 “(iv)(I) In the case of an initial imported
18 shipment from the recipient involved, docu-
19 mentation demonstrating that each batch of the
20 prescription drug in the shipment was statis-
21 tically sampled and tested for authenticity and
22 degradation.

23 “(II) In the case of any subsequent ship-
24 ment, documentation demonstrating that a sta-

1 tistically valid sample of the shipment was test-
2 ed for authenticity and degradation.

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

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

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

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

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

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

20 “(2) MAINTENANCE BY THE SECRETARY.—The
21 Secretary shall maintain information and docu-
22 mentation submitted under paragraph (1) for such
23 period of time as the Secretary determines to be nec-
24 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 (or within any member of the
5 European Union with respect to which the Secretary pro-
6 mulgates regulations under subsection (b)(2)) engaged in
7 the distribution of a prescription drug that is imported
8 or offered for importation into the United States shall reg-
9 ister with the Secretary the name and place of business
10 of the establishment.

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

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

25 “(i) OPEN MARKET ACCESS.—

1 “(1) IN GENERAL.—It shall be unlawful for a
2 manufacturer of a prescription drug to discriminate
3 against, or cause any other person to discriminate
4 against, a pharmacist or wholesaler that purchases
5 or offers to purchase a prescription drug from the
6 manufacturer or from any person that distributes a
7 prescription drug manufactured by the drug manu-
8 facturer.

9 “(2) APPLICATION.—For the purposes of para-
10 graph (1), a manufacturer of a prescription drug
11 shall be considered to discriminate against a phar-
12 macist or wholesaler if the manufacturer enters into
13 a contract for sale of a prescription drug, places a
14 limit on supply, or employs any other measure, that
15 has the effect of—

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

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

1 “(j) CHARITABLE CONTRIBUTIONS.—Notwith-
2 standing any other provision of this section, section
3 801(d)(1) continues to apply to a prescription drug that
4 is donated or otherwise supplied at no charge by the man-
5 ufacturer of the drug to a charitable or humanitarian or-
6 ganization (including the United Nations and affiliates)
7 or to a government of a foreign country.

8 “(k) WAIVER AUTHORITY FOR IMPORTATION BY IN-
9 DIVIDUALS.—

10 “(1) DECLARATIONS.—The Congress declares
11 that in the enforcement against individuals of the
12 prohibition of importation of prescription drugs and
13 devices, the Secretary should—

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

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

20 “(i) the importation is clearly for per-
21 sonal use; and

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

25 “(2) WAIVER AUTHORITY.—

1 “(A) IN GENERAL.—The Secretary may
2 grant to individuals, by regulation or on a case-
3 by-case basis, a waiver of the prohibition of im-
4 portation of a prescription drug or device or
5 class of prescription drugs or devices, under
6 such conditions as the Secretary determines to
7 be appropriate.

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

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

21 “(A) is imported from a licensed pharmacy
22 for personal use by an individual, with a valid
23 prescription, not for resale, in quantities that
24 do not exceed a 90-day supply;

1 “(B) is imported from Canada, or from
2 any member of the European Union with re-
3 spect to which the Secretary promulgates regu-
4 lations under subsection (b)(2), from a seller
5 registered with the Secretary;

6 “(C) is a prescription drug approved by
7 the Secretary under chapter V;

8 “(D) is in the form of a final finished dos-
9 age that was manufactured in an establishment
10 registered under section 510; and

11 “(E) is imported under such other condi-
12 tions as the Secretary determines to be nec-
13 essary to ensure public safety.

14 “(I) STUDIES; REPORTS.—

15 “(1) BY THE INSTITUTE OF MEDICINE OF THE
16 NATIONAL ACADEMY OF SCIENCES.—

17 “(A) STUDY.—

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

22 “(I) importations of prescription
23 drugs made under the regulations
24 under subsection (b); and

1 “(II) information and docu-
2 mentation submitted under subsection
3 (d).

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

6 “(I) evaluate the compliance of
7 importers with the regulations under
8 subsection (b);

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

20 “(III) consult with the Secretary
21 to evaluate the effect of importations
22 under the regulations under sub-
23 section (b) on trade and patent rights
24 under Federal law.

1 “(B) REPORT.—Not later than 2 years
2 after the effective date of the regulations under
3 subsection (b), the Institute of Medicine shall
4 submit to the Congress a report describing the
5 findings of the study under subparagraph (A).

6 “(2) BY THE COMPTROLLER GENERAL.—

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

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

17 “(m) CONSTRUCTION.—Nothing in this section limits
18 the authority of the Secretary relating to the importation
19 of prescription drugs, other than with respect to section
20 801(d)(1) as provided in this section.

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

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

1 (1) in section 301(aa) (21 U.S.C. 331(aa)), by
2 striking “covered product in violation of section
3 804” and inserting “prescription drug in violation of
4 section 804”; and

5 (2) in section 303(a)(6) (21 U.S.C. 333(a)(6)),
6 by striking “covered product pursuant to section
7 804(a)” and inserting “prescription drug under sec-
8 tion 804(b)”.

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