

107TH CONGRESS
1ST SESSION

S. 1229

To amend the Federal Food, Drug, and Cosmetic Act to permit individuals to import prescription drugs in limited circumstances.

IN THE SENATE OF THE UNITED STATES

JULY 24, 2001

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

A BILL

To amend the Federal Food, Drug, and Cosmetic Act to permit individuals to import prescription drugs in limited circumstances.

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 “Personal Prescription
5 Drug Import Fairness Act”.

1 **SEC. 2. IMPORTATION OF PRESCRIPTION DRUGS BY INDI-**
2 **VIDUALS.**

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

6 **“SEC. 805. IMPORTATION OF PRESCRIPTION DRUGS BY IN-**
7 **DIVIDUALS.**

8 “(a) DEFINITIONS.—In this section:

9 “(1) IMPORT FORM.—The term ‘import form’
10 means a form prescribed by the Secretary, in con-
11 sultation with the Secretary of the Treasury, that
12 discloses—

13 “(A) the name, address, and telephone
14 number of an individual who imports a pre-
15 scription drug;

16 “(B) the name, address, and telephone
17 number of the pharmacy or other entity that
18 dispensed the prescription drug to the indi-
19 vidual or ships the prescription drug to the in-
20 dividual in the United States;

21 “(C)(i) the name, address, and telephone
22 number of the health care practitioner licensed
23 to prescribe drugs in the United States who is
24 responsible for the individual’s treatment with
25 the prescription drug; or

1 “(ii) evidence that the prescription drug is
2 for the continuation of treatment begun outside
3 the United States;

4 “(D) the location of the establishment that
5 manufactured the prescription drug, to the ex-
6 tent known; and

7 “(E) such other information as the Sec-
8 retary may require.

9 “(2) PRESCRIPTION DRUG.—The term ‘pre-
10 scription drug’ means a drug subject to section
11 503(b), other than a controlled substance (as de-
12 fined in section 102 of the Controlled Substances
13 Act (21 U.S.C. 802)) or a biological product (as de-
14 fined in section 351(i) of the Public Health Service
15 Act (42 U.S.C. 262(i))).

16 “(b) REGULATIONS.—The Secretary, after consulta-
17 tion with the United States Trade Representative and the
18 Commissioner of Customs, shall promulgate regulations
19 permitting individuals to import into the United States in
20 personal baggage or by mail (or by other approved delivery
21 service) a prescription drug that—

22 “(1) is imported for personal use by an indi-
23 vidual, not for resale, at intervals of not less than
24 approximately 90 days in quantities that do not ex-
25 ceed a 90-day supply;

1 “(2) is imported from a country, union, or eco-
2 nomic area referred to in section 802(b)(1)(A) and
3 is a legally dispensed drug in that country, union, or
4 economic area;

5 “(3) is a prescription drug approved by the Sec-
6 retary under chapter V;

7 “(4) is in the form of a final finished dosage
8 that was manufactured in an establishment reg-
9 istered under section 510;

10 “(5) is accompanied by an import form; and

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

14 “(c) RECORDS.—The Secretary shall collect, and
15 maintain for a period of time that the Secretary deter-
16 mines to be necessary, records of imports of prescription
17 drugs under this section.

18 “(d) LIST OF DRUGS MANUFACTURED OUTSIDE THE
19 UNITED STATES.—

20 “(1) IN GENERAL.—The Secretary shall main-
21 tain and make readily available to the public a list
22 of drugs approved under chapter V that—

23 “(A) are manufactured in establishments
24 outside the United States that are registered
25 under section 510; or

1 “(B) are manufactured in establishments
2 inside the United States that are registered
3 under section 510 and are exported to a coun-
4 try, union, or economic area referred to in sec-
5 tion 802(b)(1)(A).

6 “(2) AUTHORIZATION OF APPROPRIATIONS.—
7 There is authorized to be appropriated to carry out
8 this subsection \$1,000,000.”.

9 (b) CONFORMING AMENDMENT.—Section 801(d)(1)
10 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C.
11 821(d)(1)) is amended by striking “section 804” and in-
12 serting “sections 804 and 805”.

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