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

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A BILL

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

Be it enacted by the Senate and House of Representatives of the United States of America in Congress assembled,

SECTION 1. SHORT TITLE.

This Act may be cited as the ''Personal Prescription Drug Import Fairness Act''.

SEC. 2. IMPORTATION OF PRESCRIPTION DRUGS BY INDIVIDUALS.

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

"SEC. 805. IMPORTATION OF PRESCRIPTION DRUGS BY INDIVIDUALS.

''(a) DEFINITIONS.—In this section:

''(1) IMPORT FORM.—The term 'import form' means a form prescribed by the Secretary, in consultation with the Secretary of the Treasury, that discloses—

''(A) the name, address, and telephone number of an individual who imports a prescription drug;

''(B) the name, address, and telephone number of the pharmacy or other entity that dispensed the prescription drug to the individual or ships the prescription drug to the individual in the United States;

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

''(ii) evidence that the prescription drug is for the continuation of treatment begun outside the United States;

''(D) the location of the establishment that manufactured the prescription drug, to the extent known; and

''(E) such other information as the Secretary may require.

''(2) PRESCRIPTION DRUG.—The term 'prescription drug' means a drug subject to section 503(b), other than a controlled substance (as defined in section 102 of the Controlled Substances Act (21 U.S.C. 802)) or a biological product (as defined in section 351(i) of the Public Health Service Act (42 U.S.C. 262(i))).

''(b) REGULATIONS.—The Secretary, after consultation with the United States Trade Representative and the Commissioner of Customs, shall promulgate regulations permitting individuals to import into the United States in personal baggage or by mail (or by other approved delivery service) a prescription drug that—

''(1) is imported for personal use by an individual, not for resale, at intervals of not less than approximately 90 days in quantities that do not exceed a 90-day supply;

''(2) is imported from a country, union, or economic area referred to in section 802(b)(1)(A) and is a legally dispensed drug in that country, union, or economic area;

''(3) is a prescription drug approved by the Secretary under chapter V;

''(4) is in the form of a final finished dosage that was manufactured in an establishment registered under section 510;

''(5) is accompanied by an import form; and

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

''(c) RECORDS.—The Secretary shall collect, and maintain for a period of time that the Secretary determines to be necessary, records of imports of prescription drugs under this section.

''(d) LIST OF DRUGS MANUFACTURED OUTSIDE THE UNITED STATES.—

''(1) IN GENERAL.—The Secretary shall maintain and make readily available to the public a list of drugs approved under chapter V that—

''(A) are manufactured in establishments outside the United States that are registered under section 510; or

"(B) are manufactured in establishments inside the United States that are registered under section 510 and are exported to a country, union, or economic area referred to in section 802(b)(1)(A).

"(2) AUTHORIZATION OF APPROPRIATIONS.—There is authorized to be appropriated to carry out this subsection $1,000,000.".

(b) CONFORMING AMENDMENT.—Section 801(d)(1) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 821(d)(1)) is amended by striking "section 804" and inserting "sections 804 and 805".

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