II

106TH CONGRESS
1ST SESSION

S. 1462

To amend the Federal Food, Drug, and Cosmetic Act to permit importation in personal baggage and through mail order of certain covered products for personal use from Canada, and for other purposes.

IN THE SENATE OF THE UNITED STATES

JULY 29, 1999

Mr. JEFFORDS introduced the following bill; which was read twice and referred to the Committee on Finance

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A BILL

To amend the Federal Food, Drug, and Cosmetic Act to permit importation in personal baggage and through mail order of certain covered products for personal use from Canada, and for other purposes.

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

SECTION 1. IMPORTATION OF COVERED PRODUCTS FOR PERSONAL USE.

Chapter VIII of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 381 et seq.) is amended—

(1) in section 801(d)(1), by inserting ''and section 804'' after ''paragraph (2)''; and

(2) by adding at the end the following:

"SEC. 804. IMPORTATION OF COVERED PRODUCTS FOR PERSONAL USE.

"(a) GENERAL AUTHORITY WITH RESPECT TO PERSONAL BAGGAGE.—

"(1) REGULATIONS.—

"(A) IN GENERAL.—Notwithstanding sections 301(d), 301(t), and 801(a), the Secretary shall promulgate regulations permitting individuals to import into the United States from Canada, in personal baggage, a covered product that meets—

"(i) the conditions described in subparagraph (B); and

"(ii) such additional criteria as the Secretary may specify in order to ensure the safety of patients in the United States.

"(B) CONDITIONS.—A covered product may be imported under such regulations if—

"(i) the intended use of the product is appropriately identified;

"(ii) the product is not considered to represent a significant health risk (as determined by the Secretary without any consideration given to the cost or availability

of such a product in the United States); and

''(iii) the individual seeking to import the product—

''(I) affirms in writing that the product is for the personal use of the individual;

''(II) seeks to import an amount of the product appropriate for personal use, such as a 3-month supply; and

''(III) provides the name and address of a health professional licensed to prescribe drugs in the United States that is responsible for treatment with the product or provides evidence that the product is for the continuation of a treatment begun in a foreign country.

''(IV) provides a detailed description of the covered product being imported, including the name, amount, and market value of the product;

"(V) provides the time when and the place where the covered product is purchased;

"(VI) provides the port of entry to which the covered product is destined;

"(VII) provides the name, address, and telephone number of the individual who is importing the covered product; and

"(VIII) provides any other information that the Secretary determines to be necessary, including such information as the Secretary determines to be appropriate to identify the facility in which the product was manufactured.

"(2) PROMULGATION.—In promulgating regulations under paragraph (1), the Secretary shall consult with the United States Trade Representative and the Commissioner of Customs.

"(b) GENERAL AUTHORITY WITH RESPECT TO MAIL ORDER.—

"(1) REGULATIONS.—Notwithstanding sections 301(d), 301(t), and 801(a), the Secretary shall pro-

mulgate regulations permitting individuals to import into the United States from Canada, by mail order, a covered product that meets such criteria as the Secretary specifies to ensure the safety of patients in the United States. The Secretary shall refer to the criteria described in subsection (a)(1), and, to the extent practicable, use such criteria as a guide in promulgating such regulations.

''(2) PROMULGATION.—In promulgating regulations under paragraph (1), the Secretary shall consult with the United States Trade Representative and the Commissioner of Customs.

''(3) RECORDS.—Any information documenting the importation of a covered product under the regulations described in paragraph (1) shall be gathered and maintained by the Secretary for such period as the Secretary determines to be appropriate.

''(c) STUDY AND REPORT.—

''(1) STUDY.—The Secretary shall conduct a study on the imports permitted under this section, taking into consideration the information received under subsections (a)(4) and (b)(3). In conducting the study, the Secretary shall evaluate the safety and purity of the products imported, and other pat-

ent and trade issues that may have an effect on the safety or availability of such products.

''(2) REPORT.—Not later than 5 years after the date of enactment of this section, the Secretary shall prepare and submit to Congress a report containing the study described in paragraph (1).

''(d) CONSTRUCTION.—Nothing in this section shall be construed to limit the statutory, regulatory, or enforcement authority of the Secretary relating to importation of covered products, other than the importation described in subsections (a) and (b).

''(e) LIMITATION.—Information collected pursuant to this section shall be subject to the provisions of section 522a of title 5, United States Code (commonly known as the 'Privacy Act of 1974').

''(f) DEFINITIONS.—In this section:

''(1) COVERED PRODUCT.—The term 'covered product' means a prescription drug under section 503(b)(1).

''(2) MARKET VALUE.—The term 'market value' means the price actually paid for the covered product in Canada or, in the case of a gift, the price at which the covered product is being sold in Canada.''.

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