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108TH CONGRESS
1ST SESSION

# H. R. 847

To amend the Federal Food, Drug, and Cosmetic Act with respect to the importation of prescription drugs from Canada.

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IN THE HOUSE OF REPRESENTATIVES

FEBRUARY 13, 2003

Mr. SANDERS (for himself, Mr. BURTON of Indiana, Ms. DELAURO, Mr. CROWLEY, Mrs. EMERSON, Mr. BERRY, Ms. KAPTUR, Mr. MCGOVERN, Mr. DEFAZIO, Mr. TIERNEY, Mr. DOGGETT, Mr. STARK, Ms. WOOLSEY, Ms. LEE, Mr. OLVER, Ms. SOLIS, Mr. EVANS, Mr. OWENS, Mr. SERRANO, Mr. ABERCROMBIE, Mr. NADLER, Ms. CORRINE BROWN of Florida, Mr. SABO, Mr. JACKSON of Illinois, Ms. VELÁZQUEZ, Mr. CAPUANO, Mr. HINCHEY, Mr. KUCINICH, Mr. MEEHAN, Mr. LEVIN, Mr. PALLONE, Mr. BROWN of Ohio, Ms. BALDWIN, and Mr. FILNER) introduced the following bill; which was referred to the Committee on Energy and Commerce

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# A BILL

To amend the Federal Food, Drug, and Cosmetic Act with respect to the importation of prescription drugs from Canada.

*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 ''Preserving Access to Safe, Affordable Canadian Medicines Act of 2003''.

**SEC. 2. FINDINGS.**

The Congress finds as follows:

(1) Prescription drug manufacturers charge substantially more for their products in the United States than in Canada.

(2) Many Americans cannot afford the higher U.S. prices and are forced to either go without their needed medications or sacrifice other necessities of life in order to afford them.

(3) Increasingly, Americans have turned to the Canadian market to purchase their needed medications at substantially lower prices and the Food and Drug Administration now estimates that two million parcels containing prescription drugs enter the U.S. for personal use each year.

(4) The Congressional Research Service has confirmed that Canada has a drug approval and distribution system comparable to that of the United States.

(5) Drug manufacturers are trying to cut off the supply of prescription drugs accessed by U.S. consumers on the Canadian market in blatant disregard of the health consequences for Americans.

**SEC. 3. NONDISCRIMINATION AGAINST IMPORTS OF PRESCRIPTION DRUGS.**

(a) IN GENERAL.—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 striking ''section 804,'' and inserting ''sections 804 and 805,''; and

(2) by adding at the end the following:

''PROHIBITION AGAINST DISCRIMINATION AGAINST IMPORTS

''SEC. 805. (a) REGULATIONS.—The Secretary, after consultation with the United States Trade Representative and the Commissioner of Customs, shall promulgate regulations prohibiting manufacturers of prescription medications from taking actions that discriminate against, or cause other persons to discriminate against, United States consumers regarding the purchase of prescription medications from Canadian pharmacies.

''(b) NONDISCRIMINATION.—No manufacturer of a prescription medication may take actions that discriminate against, or cause other persons to discriminate against, United States consumers regarding the purchase of a prescription medication from Canadian pharmacies.

''(c) DEFINITION.—For purposes of this section, the term 'discrimination' means a contract provision, a limitation on supply, or other measure which has the effect of

providing U.S. consumers access to prescription medications on terms or conditions that are less favorable than the terms or conditions provided to any foreign purchaser of such products, or otherwise has the effect of restricting or reducing access by United States consumers to a prescription medication from Canadian pharmacies.''.

(b) PROHIBITED ACT.—Section 301 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 331) is amended by adding at the end the following:

''(hh) Discrimination by a manufacturer in violation of section 805.''.

(c) CIVIL PENALTIES.—Section 303 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 333) is amended by adding at the end the following subsection:

''(h)(1) Any manufacturer of a prescription medication that knowingly violates section 805(b) shall be liable to the United States for a civil penalty in an amount not to exceed $1,000,000.

''(2) Paragraphs (3) through (5) of subsection (g) apply with respect to a civil penalty under paragraph (1) of this subsection to the same extent and in the same manner as such paragraphs (3) through (5) apply with respect to a civil penalty under paragraph (1) or (2) of subsection (g).''.

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