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107TH CONGRESS
1ST SESSION

H. R. 698

To amend the Federal Food, Drug, and Cosmetic Act with respect to the importation of certain prescription drugs by pharmacists and wholesalers.

IN THE HOUSE OF REPRESENTATIVES

FEBRUARY 14, 2001

Mr. SANDERS (for himself, Mr. DEUTSCH, Mr. SHOWS, Mr. BROWN of Ohio, Mr. BONIOR, Ms. KAPTUR, Ms. DELAURO, Mr. CONYERS, Mr. NADLER, Mrs. MINK of Hawaii, Mr. OBERSTAR, Mr. CROWLEY, Mr. ABERCROMBIE, Mr. DEFAZIO, Mr. HILLIARD, Mr. FILNER, Mr. OLVER, Mr. LAFALCE, and Mr. HINCHEY) 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 certain prescription drugs by pharmacists and wholesalers.

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 ''Prescription Reimportation, Improvement, Correction, and Enhancement Act''.

SEC. 2. AMENDMENTS TO PROGRAM FOR IMPORTATION OF CERTAIN PRESCRIPTION DRUGS BY PHARMACISTS AND WHOLESALERS.

Section 804 of the Federal Food, Drug, and Cosmetic Act (as added by section 745(c)(2) of Public Law 106–387) is amended—

(1) by striking subsections (e) and (f) and inserting the following subsections:

''(e) TESTING; APPROVED LABELING.—

''(1) TESTING.—Regulations under subsection (a)—

''(A) shall require that testing referred to in paragraphs (6) through (8) of subsection (d) be conducted by the importer of the covered product pursuant to subsection (a), or the manufacturer of the product;

''(B) shall require that, if such tests are conducted by the importer, information needed to authenticate the product being tested be supplied by the manufacturer of such product to the importer; and

''(C) shall provide for the protection of any information supplied by the manufacturer under subparagraph (B) that is a trade secret or commercial or financial information that is privileged or confidential.

''(2) APPROVED LABELING.—For purposes of importing a covered product pursuant to subsection (a), the importer involved may use the labeling approved for the product under section 505, notwithstanding any other provision of law.

''(f) DISCRETION OF SECRETARY REGARDING TESTING.—The Secretary may waive or modify testing requirements described in subsection (d) if, with respect to specific countries or specific distribution chains, the Secretary has entered into agreements or otherwise approved arrangements that the Secretary determines ensure that the covered products involved are not adulterated or in violation of section 505.'';

(2) by striking subsections (h) and (i) and inserting the following subsections:

''(h) PROHIBITED AGREEMENTS; NONDISCRIMINATION.—

''(1) PROHIBITED AGREEMENTS.—No manufacturer of a covered product may enter into a contract or agreement that includes a provision to prevent the sale or distribution of covered products imported pursuant to subsection (a).

''(2) NONDISCRIMINATION.—No manufacturer of a covered product may take actions that discriminate against, or cause other persons to discriminate

against, United States pharmacists, wholesalers, or consumers regarding the sale or distribution of covered products.

''(i) STUDY AND REPORT.—

''(1) STUDY.—The Comptroller General of the United States shall conduct a study on the imports permitted under this section, taking into consideration the information received under subsection (a). In conducting such study, the Comptroller General shall—

''(A) evaluate importers' compliance with regulations, determine the number of shipments, if any, permitted under this section that have been determined to be counterfeit, misbranded, or adulterated; and

''(B) consult with the United States Trade Representative and United States Patent and Trademark Office to evaluate the effect of importations permitted under this section on trade and patent rights under Federal law.

''(2) REPORT.—Not later than 5 years after the effective date of final regulations issued pursuant to this section, the Comptroller General of the United States shall prepare and submit to Congress a re-

port containing the study described in paragraph (1).'';

(3) in subsection (k)(2)—

(A) by redesignating subparagraphs (A) through (E) as subparagraphs (B) through (F), respectively; and

(B) by inserting before subparagraph (B) (as so redesignated) the following subparagraph:

''(A) The term 'discrimination' includes a contract provision, a limitation on supply, or other measure which has the effect of providing United States pharmacists, wholesalers, or consumers access to covered products on terms or conditions that are less favorable than the terms or conditions provided to any foreign purchaser of such products.'';

(4) by striking subsection (m); and

(5) by inserting after subsection (l) the following subsection:

''(m) FUNDING.—For the purpose of carrying out this section, there are authorized to be appropriated such sums as may be necessary for fiscal year 2002 and each subsequent fiscal year.''.

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