II

107TH CONGRESS
1ST SESSION

S. 1132

To amend the Federal Food, Drug, and Cosmetic Act relating to the distribution chain of prescription drugs.

IN THE SENATE OF THE UNITED STATES

JUNE 28, 2001

Mr. CRAPO 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 relating to the distribution chain of prescription drugs.

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

SECTION 1. PRESCRIPTION DRUG DISTRIBUTION.

(a) DEFINITION OF AUTHORIZED DISTRIBUTOR.—

(1) IN GENERAL.—Section 503(e)(4) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 353(e)(4)) is amended by striking ''(4) For the purposes'' and all that follows through ''means distribution'' in subparagraph (B) and inserting the following:

''(4) DEFINITIONS.—In this subsection and subsection (d):

''(A) AUTHORIZED DISTRIBUTOR.—

''(i) IN GENERAL.—The term 'authorized distributor' means a distributor to which a manufacturer sells a prescription drug.

''(ii) EFFECTIVE TIME PERIOD.—A distributor that purchases a prescription drug from a manufacturer shall be treated as an authorized distributor with respect to that prescription drug for a period of 12 months following the date of the purchase.

''(B) WHOLESALE DISTRIBUTION.—The term 'wholesale distribution' means distribution.''.

(2) CONFORMING AMENDMENTS.—Section 503 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 353(e)(4)(A)) is amended in subsections (d) and (e)—

(A) by striking ''authorized distributor of record'' each place it appears and inserting ''authorized distributor''; and

(B) by striking ''authorized distributors of record'' each place it appears and inserting ''authorized distributors''.

(b) REQUIRED STATEMENT.—Section 503(e)(1)(A) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 353(e)(1)(A)) is amended by inserting ''a statement that the drug was first purchased from or through an authorized distributor or'' after ''who receives the drug''.

○