SENATE BILL REPORT SB 5960

As Reported By Senate Committee On: Health & Long-Term Care, February 6, 2002

Title: An act relating to the learned intermediary doctrine for prescription products.

Brief Description: Modifying prescription product liability.

Sponsors: Senators Parlette, Thibaudeau, Kohl-Welles and Honeyford.

Brief History:

Committee Activity: Health & Long-Term Care: 2/21/01, 2/27/01 [DP]; 1/16/02, 2/6/02

[DPS].

SENATE COMMITTEE ON HEALTH & LONG-TERM CARE

Majority Report: That Substitute Senate Bill No. 5960 be substituted therefor, and the substitute bill do pass.

Signed by Senators Thibaudeau, Chair; Franklin, Vice Chair; Costa, Deccio, Fraser, Parlette and Winsley.

Staff: Jonathan Seib (786-7427)

Background: In general, this state's product liability law holds a manufacturer liable for harm caused by its failure to adequately instruct and/or warn consumers regarding its products. In 1978, however, the state Supreme Court recognized an exception to this general approach for products available only by prescription. In the case of *Terhune v. A.H. Robins Co.*, the court held that "the duty of a manufacturer to warn of dangers involved in the use of a product is satisfied if he gives adequate warning to the physician who prescribes it." This is known as the "learned intermediary doctrine," and is consistent with holdings in a majority of states. It is premised on the notion that to a large extent, a patient relies on the independent judgment of his or her doctor in determining which prescriptions to take. Since the patient is not the primary decision-maker with regard to the product ultimately purchased, the manufacturer has no duty to instruct him or her as to its proper use and possible risks.

Some suggest that the emergence of direct-to-consumer advertising of prescription products has undermined the reasons given in support of the learned intermediary doctrine, and that its application is no longer appropriate where a product is so advertised. They contend that such advertising interjects itself between doctors and patients, prompting patients to seek prescriptions independent of the judgment of their doctors, and treating the patient as the primary decision-maker with regard to the product which is ultimately purchased.

This reasoning led the New Jersey Supreme Court, in August 1999, to abrogate the learned intermediary doctrine as applied to prescription drugs advertised directly to consumer. In becoming the first state court to do so, it held that "prescription drug manufacturers that

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market their products directly to consumers should be subject to claims by consumers if their advertising fails to provide adequate warning of the product's dangerous propensities."

Summary of Substitute Bill: The intent of the Legislature to create an exception to the learned intermediary doctrine for prescription products advertised directly to consumers is stated. Where a consumer has sought a prescription product in response to an advertisement, the manufacturer of that product, if it would otherwise be liable for harm caused by that product, is not relieved of that liability solely because the manufacturer warned the practitioner who prescribed the product of its proper use and attendant dangers.

Substitute Bill Compared to Original Bill: The substitute bill adds the language requiring that the consumer had sought the prescription product in response to an advertisement.

Appropriation: None.

Fiscal Note: Not requested.

Effective Date: Ninety days after adjournment of session in which bill is passed.

Testimony For: Prescription drug advertisements, particularly on TV, are incomplete and fail to provide consumers with important information regarding side effects. This leads to the incorrect conclusion that the drug advertised is safe and appropriate for anyone. This bill is designed to modernize the law to recognize a radically changed marketing environment. It will make drug manufacturers more responsible for claims made in ads, better protect consumers by assuring full disclosure, and will allow the proper allocation of responsibility for any harm done.

Testimony Against: There are sound reasons behind the learned intermediary doctrine. Patients rely on the judgment of their doctors. Any change in the existing standard creates the potential for unlimited liability. The drug labeling compelled by the bill would be too long for any reasonable consumer to read. The issue of manufacturer liability should be decided on a case-by-case basis.

Testified: PRO: Art Zoloth, Northwest Pharmacy Services; Larry Shannon, WSTLA; CON: Cliff Webster, Pharmaceutical Research & Manufacturers of America; Mellanie Hughes, AWB.

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