BILL ANALYSIS

Senate Research Center
76R6521 MI-F

S.B. 645
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Technology & Business Growth
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DIGEST

Currently, under Texas law, manufacturers and distributors of prescription and nonprescription drugs are liable for punitive damages in product liability actions, despite compliance with all federal standards for product formulation, packaging, and labeling. This bill would establish a defense for punitive damages in which a drug manufacturer or distributor has complied with the pre-marketing federal standards established by the Food and Drug Administration.

PURPOSE

As proposed, S.B. 645 establishes a defense for punitive damages in which a drug manufacturer or distributor has complied with the pre-marketing federal standards established by the Food and Drug Administration.

RULEMAKING AUTHORITY

This bill does not grant any additional rulemaking authority to a state officer, institution, or agency.

SECTION BY SECTION ANALYSIS

SECTION 1. Amends Chapter 41, Civil Practice and Remedies Code, by adding Section 41.014, as follows:

> Sec. 41.014. COMPLIANCE WITH GOVERNMENT STANDARDS FOR DRUG SAFETY. Defines "drug," "products liability action,""manufacturer," and "seller." Prohibits exemplary damages from being awarded in a products liability action against a manufacturer or seller of a drug that caused the claimants' harm in certain situations. Provides that Subsection (b) does not apply to a manufacturer of a drug if the claimant proves by clear and convincing evidence that the manufacturer intentionally or wrongfully withheld from or misrepresented to the federal Food and Drug Administration (FDA) certain required information that is material and relevant to the harm suffered by the claimant or made an illegal payment to an official or employee of the federal FDA for the purpose of securing or maintaining approval of the drug.

SECTION 2. Effective date: September 1, 1999.
Makes application of this Act prospective.

SECTION 3. Emergency clause.