SUBJECT: Regulating distributors and others under the Food, Drug and Cosmetic Act

COMMITTEE: Public Health — committee substitute recommended

VOTE: 6 ayes — Berlanga, Hirschi, Delisi, Janek, Maxey, Rodriguez

0 nays

3 absent — Coleman, Glaze, McDonald

WITNESSES: For — William Lynn Switzer, Medical Device Manufacturers Association; Eric P. Ankerud, Bausch and Lomb; George Bettinger; Karol Rice, Kimberly-Clarke; Thomas Tremble, Health Industry Manufacturers Association

Against — None

On — Dennis Baker and Cynthia Culmo, Texas Department of Health

DIGEST: CSHB 2550 would exempt out-of-state medical device distributors and manufacturers from licensing requirements and create a manufacturer and distributor advisory committee to advise the board of the Department of Health. CSHB 2550 would amend the definition of a food wholesaler to specifically exempt from department licensure an establishment engaged solely in the distribution of alcoholic or nonalcoholic beverages in sealed containers.

CSHB 2550 would make technical amendments to the Texas Food, Drug and Cosmetic Act by revising the definition of wholesale distributors to remove references to manufacturers, adding a definition of manufacturers, and make conforming amendments to license requirements incorporating the new definitions.

CSHB 2550 would define a distributor to mean a person who furthers the marketing of a finished domestic or imported device from the original place of manufacture to the person who makes final delivery or sale to the consumer. The term would include an importer or an own-label distributor

but not a person who repackages a finished device or who otherwise changes the container or labelling of the device.

A manufacturer would be defined as a person who manufactures, fabricates, assembles or processes a finished device, including a person who repackages or relabels a device.

The board of health would be required to establish an advisory committee to advise in the development of licensing standards and procedures for distributors and manufacturers. The advisory committee would be composed of one distributor representative, two manufacturer representatives and two public members. The unpaid advisory committee would serve staggered-three year terms and would be reimbursed for travel expenses. Advisory members would be required to be appointed by January 1, 1996.

This bill would take effect September 1, 1995.

SUPPORTERS SAY:

CSHB 2550 would assist enforcement and compliance with Texas Food, Drug and Cosmetic Act provisions by giving manufacturers and distributors a voice in their regulation through the establishment of an advisory committee. Licensure is an effective way to systematically identify and monitor businesses that directly affect citizen health and safety and creates an ongoing incentive for those businesses to comply with state requirements.

Last session the Legislature required food manufacturers, food wholesalers and medical device distributors (and manufacturers under the definition of "distribution") to be licensed under the act. Licensure and inspection requirements became effective October 1, 1994. Medical device manufacturers and distributors are concerned that they will be caught between conflicting state and federal requirements and will be subjected to duplicative surveys and reviews.

CSHB 2550 would reduce potentially conflicting and confusing requirements on out-of-state manufacturers and distributors by removing them from Texas requirements. Public safety will be protected because all medical device distributors and manufacturers must comply with federal

requirements. Interstate commerce is also more effectively enforced through federal agencies.

The bill would clarify the law so it would easier to understood. Distributors of alcoholic and nonalcoholic beverages are sufficiently regulated by the Texas Alcoholic Beverage Commission — including them under department of health regulation would be a waste of state resources and money.

OPPONENTS SAY:

There is little reason for medical device manufacturers and distributors to worry about conflicting and confusing state and federal regulation. The Texas Food, Drug and Cosmetic Act parallels federal law and regulations. The Texas Department of Health and the federal Food and Drug Administration work closely together to schedule nonduplicative inspections and to maximize agency personnel and regulatory oversight. Manufacturers and distributors have opportunities for comment and review of department activities through Texas rulemaking and legislative proceedings.

Out-of-state manufacturers and distributors should still be subject to state licensure. Without licensure requirements, the state has little recourse to legally prohibit or penalize out-of-state businesses for the sale or distribution of faulty or harmful medical devices.

NOTES:

The filed version of HB 2550 would have repealed licensure requirements for all medical device distributors and manufacturers.