BILL ANALYSIS

C.S.H.B. 3174
By: Truitt
Public Health
Committee Report (Substituted)

BACKGROUND AND PURPOSE

The substitute would better ensure the safety, quality and integrity of the prescription drug distribution system in Texas. Counterfeit and adulterated drugs pose a growing threat to the health and safety of all Texans. Currently, there are no licensure requirements for wholesale drug distributors in Texas – only an application process with little or no oversight, enforcement and penalty mechanisms.

The substitute would strengthen the regulation and oversight of all drug wholesalers who do business in Texas, especially secondary wholesalers who operate outside the normal distribution channels. Most prescription drugs follow a simple path - from manufacturer to wholesaler to pharmacy to consumer. Ninety percent of prescription drugs are distributed by the three major wholesalers. However, some medicines are sold through smaller, regional wholesalers known as secondary wholesalers. There are an estimated 6,000 secondary wholesalers in the U.S. and an estimated 2,200 that operate in Texas. Secondary wholesalers buy and sell prescription drugs outside the normal distribution channel thus creating gaps in supply-chain integrity.

The substitute would provide greater transparency and tighter control over the movement of these drugs outside the normal channels. The World Customs Organization estimates counterfeiting of prescription drugs accounts for 5% to 7% of global merchandise trade and is a growing global problem. Seizures of counterfeit prescription drugs by U.S. Customs jumped by 46% in 2004 as counterfeiters boosted exports to Western markets. According to a 2004 FDA Report, the counterfeit pharmaceutical trade is largely operated by "well-organized criminal operations" producing look-alike products that contain only inactive ingredients, incorrect ingredients, improper or contaminated dosages. In the U.S., over 18 million counterfeit Lipitor tablets were seized in 2003 in the largest domestic counterfeit case to date. This growing crisis will only worsen and our state's drug supply will continue to come under an increasing counterfeit threat if Texas does not strengthen its licensure and oversight of the wholesale drug distribution system.

RULEMAKING AUTHORITY

It is the committee's opinion that rulemaking authority is expressly granted to the executive commissioner of the Health and Human Services Commission in Section 6, and Section 9 of this bill. Rulemaking authority is expressly transferred from the Texas Board of Health to the executive commissioner of the Health and Human Services Commission in Section 5 of this bill.

ANALYSIS

The substitute amends the Health and Safety Code to include definitions of chain pharmacy, warehouse, normal distribution chain, pedigree, place of business, prescription drug, repackage, repackager, wholesale distributor, wholesale distribution and its exemptions.

The substitute adds licensure requirements for a wholesale distributor, including a license for each place of business and a chain pharmacy license for a chain pharmacy warehouse. The substitute also adds requirements for an application for license and requires qualifications for licensure.

The substitute adds criminal history record information, including fingerprinting, and a bond requirement in the amount of $100,000. The substitute allows the executive commissioner of the Health and Human Services Commission by rule to set the fees in the amounts that are

reasonable and necessary to allow the department to recover the annual expenditures of state funds by the department in reviewing and acting on a license, amending and renewing a license, inspecting a licensed facility and implementing and enforcing this subchapter.

The substitute restricts "returned goods" that may be purchased by the wholesale distributor or manufacturer thus back into the distribution system. Also, this section creates an electronic pedigree study with an implementation date no earlier than December 31, 2007 and gives the executive commissioner of the Health and Human Services Commission rulemaking authority to implement an electronic pedigree program based on the results of the study.

The substitute gives the executive commissioner of Health and Human Services the authority to issue an order to cease distribution of prescription drugs for certain acts or knowledge, lists prohibited acts, and specifies criminal penalties for violations of this subchapter.

The substitute allows the Department of State Health Services to have access to criminal history record information of an applicant for a drug wholesale distributor license in this state.

The substitute allows the executive commissioner of the Health and Human Services Commission to adopt rules necessary to implement changes in the law made by the substitute not later than January 1, 2006. A wholesale drug distributor is not required to comply with this law before March 1, 2006.

The substitute states the change in law made by passage of this act applies only to an offense committed on or before March 1, 2006.

EFFECTIVE DATE

September 1, 2005, except that Section 431.2077, Health and Safety Code, as added by this Act, takes effect March 1, 2006.

COMPARISON OF ORIGINAL TO SUBSTITUTE

The substitute eliminates the definition of "Authentication" since corresponding sections where the definition was necessary were deleted from original language as filed.

The substitute adds that the definition of wholesale distribution include the distribution by a wholesale distributor, instead of a wholesaler.

The substitute gives the executive commissioner of Health and Human Services the rulemaking authority to implement the electronic pedigree program based on the recommendations of a study. The substitute also states that the electronic pedigree program require persons engaged in the wholesale distribution of prescription drugs to provide a pedigree on distribution of certain prescription drugs, and provides additional rulemaking authority for electronic pedigrees.

The substitute states that a manufacturer that engages in the wholesale distribution of drugs in this state before March 1, 2006, the manufacturer remains subject to law as it existed immediately before the effective date of this Act.

The substitute applies to offenses committed on or after March 1, 2006 instead of the effective date of the Act, and those offenses committed before March 1, 2006 are covered by the law in effect when the offense was committed, and the former law is continued in effect for that purpose.

The substitute converts the filed version into Legislative Council format.