SUBJECT: Regulation of wholesale distributors of prescription drugs

COMMITTEE: Public Health — favorable, without amendment

VOTE: 8 ayes — Delisi, Laubenberg, Jackson, Cohen, Coleman, Gonzales, Olivo, Truitt

0 nays

1 absent — S. King

SENATE VOTE: On final passage, April 17 — 30-0

WITNESSES: (*On original version of House companion bill, HB 2316 by Truitt:*)
For — Daniel Bellingham, Healthcare Distribution Management Association; (*Registered, but did not testify:* Yvonne Barton, Abbott Laboratories; Frank Calhoun, Johnson & Johnson; Randall Erben, Genentech; Robert Jones, Pfizer; Gaspar Laca, GlaxoSmithKline; Michele O'Brien, CHRISTUS Santa Rosa Healthcare; Amber Pearce, Texas Healthcare and Bioscience Institute) (*On committee substitute:* Matthew Van Hook, PhRMA)

Against — Doug Karins, Controlled Healthcare LLC

On — *Registered, but did not testify:* Karen Tannert, Department of State Health Services

BACKGROUND: The federal Prescription Drug Marketing Act of 1987 (PDMA) requires, among other provisions, that certain wholesale distributors of prescription drugs pass a pedigree with a drug identifying each prior sale, purchase, or trade of the drug. The manufacturer and certain wholesalers that have an ongoing relationship with the manufacturer — authorized distributors of record (ADRs) — are exempt from having to pass a pedigree. Wholesalers that are not ADRs are called secondary wholesalers.

A Guidance Letter issued by the federal Food and Drug Administration (FDA) in 1988 interpreted the PDMA to require that the pedigree provided by secondary wholesalers track back to the manufacturer or the last ADR

that handled the drugs. The FDA issued new regulations interpreting the PDMA as requiring secondary wholesalers to provide pedigree information all the way back to the manufacturer. These regulations were to become effective on December 4, 2000.

After multiple delays, regulations to implement the PDMA of 1987 went into effect December 1, 2006. On December 8, 2006, a federal district court in the Eastern District of New York issued a temporary injunctive order as part of proceedings related to *RxUSA Wholesale, Inc., et al. v. U.S. Department of Health and Human Services, Food and Drug Administration*, 06-CV-5086(JS)(AKT). The order prohibits the FDA from implementing the regulation that a secondary wholesaler must provide pedigrees tracking back to the manufacturer. Until a final ruling is made on this issue, secondary wholesalers can provide pedigrees tracking to either the manufacturer or the last ADR that sold, purchased, or traded the prescription drugs.

In 2005, the 79th Legislature enacted HB 164 by Berman, et al. which regulates the wholesale distribution of prescription drugs. The bill revises licensing standards for wholesale distributors who are regulated by the Department of State Health Services (DSHS). HB 164 also requires that drug pedigrees tracking back to the manufacturer be issued for drugs that are sold or transferred outside the normal distribution chain. The normal distribution chain is the history of custody for a drug as it is transferred from the manufacturer to an ADR or various other parties that either use or further distribute the drug.

DIGEST:

SB 943 would revise the licensing and regulation of wholesale distributors of prescription drugs. The bill would define additional parties involved in the wholesale drug distribution process, including third-party logistics providers, co-licensed product partners, manufacturers, and manufacturer's exclusive distributors. The bill would change the definition of a normal distribution channel to include additional chains of custody between a manufacturer or certain manufacturers' agents to the patient or other entity authorized to dispense or prescribe a drug for a patient.

Licensing revisions for wholesale distributors. The bill would exempt from the definition of wholesale distribution:

- transactions between co-licensed holders of co-licensed products;
- the sale of reasonable quantities of a prescription drug to a licensed practitioner;
- the offer to sell, purchase, or trade a drug under prescription;
- any consolidation of a pharmacy business with another pharmacy;
- the sale or transfer between ADRs of prescription drugs that had remained in the normal distribution channel;
- the delivery of prescription drugs by common carrier if the carrier did not store or take legal ownership of the drugs;
- any transfer of drugs from a pharmacy to the original manufacturer or a returns processor because of expiration, damage, or recall; and
- third-party logistics providers operating on behalf of manufacturers

The required information for a wholesale distributor license application would be revised. A license applicant would have to submit a photo taken no earlier than 180 days before the application date. A wholesale distributor license could not be issued unless DSHS conducted a physical inspection of the place of business and determined that the designated representatives of the business met qualification requirements for licensing. DSHS would send licensed wholesale distributors a copy of their license application information prior to their license expiration, and the licensee would have to correct under oath to DSHS any changes to the information by the 30th day after the form was received from DSHS. DSHS would hold all license application information confidential.

Required information for the criminal history check on a designated representative of a wholesale distributor licensee would include information on any criminal proceeding the subject was involved in and the disposition of the proceeding as well as a description of any misdemeanor offense for which the person was found guilty. The designated representative of a wholesale distributor licensee could not serve as the representative for more than one licensed applicant at any time unless he represented co-located wholesale distributors from an affiliated organization. The designated representative of a licensed wholesale distributor would have to complete continuing training regarding state and federal laws regarding prescription drug distribution.

Any account for the purchase of prescription drugs would be established in the name of the license holder or the license holder's entity. A manufacturer or wholesale distributor could not accept payment or allow

the use of personal credit for the purchase of prescription drugs from any person other than the owner of record.

A single surety bond could cover all the places of business operated by a wholesale distributor in Texas. A pharmacy warehouse that was not a wholesale distributor would be exempt from the requirement to obtain a surety bond to operate as a wholesale distributor.

Pedigree requirements. A pedigree would have to be provided for each prescription drug that at any time had left a normal distribution channel and was sold, traded, or transferred to any other person. A pharmacy or pharmacy warehouse only would have to provide a pedigree if engaging in wholesale distribution of the prescription drug.

A pedigree would have to include information concerning each sale in the product's chain of distribution from the manufacturer or manufacturer's third-party logistics provider, co-licensed product partner, or exclusive distributor to final sale. The pedigree would have to contain contact information for each wholesale distributor of the drug. The pedigree would have to be available for inspection by DSHS or a peace officer not later than the fifth business day after the date the pedigree was requested.

The return of expired, damaged, recalled, or otherwise nonsalable prescription drugs by the wholesale distributor to the manufacturer or third-party returns processor would be exempt from pedigree requirements. Pharmacies that otherwise were not required to obtain a wholesale distributor license would not be required to obtain such a license for processing returned drugs. Wholesale distributors and pharmacies would ensure that counterfeit drugs did not enter into the distribution channel while processing returned drugs.

The bill would remove the requirement that electronic pedigrees be implemented by December 31, 2007, and would allow for a flexible implementation date for electronic pedigrees no earlier than July 1, 2010.

Offenses, penalties, and enforcement. The bill would add prohibitions against certain acts or aiding and abetting in certain acts pertaining to the distribution or failure to distribute prescription drugs. The prohibitions would include:

- certain acts of fraud;
- conducting activities pertaining to drug distribution without the appropriate license;
- failing to obtain appropriate pedigrees;
- selling, transferring delivering, or receiving adulterated, misbranded, or counterfeit drugs; and
- altering, labeling, or otherwise misbranding a prescription drug.

If a person knowingly committed a violation in the distribution of prescription drugs, the penalty would increase from a felony punishable by not more than 15 years imprisonment to an offense punishable by between 15 and 99 years imprisonment. Other offenses would increase from no jail time to a felony punishable by imprisonment for up to 15 years. The bill would maintain existing maximum fines, and the penalty for violations could include only jail time, only a fine, or both jail time and a fine.

The commissioner of DSHS could suspend or revoke a license if the license holder no longer met the qualification for obtaining a wholesale distributor license. DSHS no longer could issue a cease and desist order against a manufacturer if a wholesale distributor distributed a counterfeit drug that could cause adverse health consequences.

Effective date. The bill would take effect September 1, 2007, and would apply only to offenses committed on or after this date. The executive commissioner of the Health and Human Services Commission would have to adopt rules to implement the provisions of the bill by December 1, 2007.

SUPPORTERS SAY:

SB 943 would strengthen state law governing wholesale drug distributors to ensure the safety, quality, and integrity of prescription drugs distributed in Texas. This bill would tighten general wholesaler license requirements to ensure bad actors could not enter the system and that licensees could be properly punished for violations. The strict criminal penalties would pose a greater disincentive for violators to cause harm, yet would leave discretion to impose only a fine if an offense was less severe.

The bill would align Texas law with changes in the interpretation of the PDMA. These changes would enable better state monitoring and enforcement of counterfeit drug prohibitions by further defining requirements for a pedigree for drugs that leave the normal distribution channel.

Counterfeiting of prescription drugs is an increasingly prevalent crime that can cause personal injury or even death to people consuming them. Drugs that are transferred outside normal distribution channels, such as those sold to secondary wholesalers, can be returned to the manufacturer or ADR. While most industry participants are legitimate, some people sell prescription drugs on the black market and then return counterfeit drugs to the manufacturer. The pedigree requirements of this bill would prevent the majority of counterfeiting that is taking place.

The provisions of SB 943 would be even more stringent than federal regulations in that they would hold ADRs accountable for pedigrees if the drugs went outside the normal distribution channels. Other than this exception, ADRs would be exempted from pedigree requirements, because these distributors have a special, ongoing relationship with manufactures that secondary wholesalers do no possess. Scandals such as counterfeiting can severely impact a manufacturer's reputation, so manufacturers are very judicious in selecting ADRs that will properly handle the distribution of the manufacturer's drugs.

Given that the problem of counterfeit drugs cannot be ignored, SB 943 would present the best possible balance of the safety and welfare of Texans with the business needs of distributors. The bill would not drive secondary wholesalers out of business. It would make no sense for ADRs to refuse to provide secondary wholesalers with pedigrees, because this would interfere with the operations of the secondary market which provides significant business to ADRs. Harming the secondary market would only harm the ADRs in turn. However, it would not be inappropriate for ADRs to charge a reasonable fee for providing pedigree information to secondary wholesalers, because providing pedigree information would entail additional effort and expense for the ADR.

Because the secondary market would not be harmed by the provisions of this bill, claims that drug costs could rise are unfounded, and the niche market of physicians that secondary wholesalers serve would be safe. The injunction in the *RxUSA Wholesale* case does not represent a final ruling but rather allows a delay for further review in which these reasonable arguments will be considered.

Finally, the author intends to accept several amendments that would address concerns such as allowing DSHS cease and desist authority

against manufacturers and defining more legitimate chains in the normal distribution channel.

OPPONENTS SAY:

SB 943 would endanger secondary wholesalers by implementing similar questionable provisions to those that have led to the seven-year delay and ultimate injunction in implementing new regulatory interpretations of the PDMA. The injunction in the *RxUSA Wholesale* case was granted on the grounds that there was reasonable evidence to suggest that the new FDA regulations would violate the right to equal protection under the laws afforded by the Fourteenth Amendment. The injunction also acknowledged the potential that the regulations could cause irreparable harm to secondary wholesalers. Texas should await the outcome of the federal case on PDMA regulations before implementing potentially unconstitutional statutes in this state.

SB 943, like the PDMA, could put secondary wholesalers out of business because these distributors would be at the mercy of ADRs to comply with the law. As acknowledged in the injunction, ADRs could choose not to provide pedigree information and halt a secondary wholesaler's ability to distribute drugs. ADRs also could impose prohibitive costs on the secondary market to provide pedigree information. Secondary wholesalers are typically small businesses, and ADRs have charged some of these small businesses thousands of dollars each month to provide pedigree information.

Damaging the business of secondary wholesalers would have a ripple effect on the niche market that they serve. Physicians and other practitioners that use prescription drugs in their offices cannot obtain drugs from larger wholesale distributors, because most large wholesalers will not distribute drugs if the purchase does not surpass a certain monetary value. A physician might require only $300 worth of a drug in a month while a large wholesaler could require its customers to purchase at least $30,000 of that drug in a single order. Secondary wholesalers allow physicians to buy drugs in smaller quantities with a more protracted period to pay.

Designation as an ADR should not confer special exemptions from requirements to provide pedigrees. This special treatment is the grounds for claims of unequal protection under the law. An ADR designation is often only indicative of the ADR being large enough to buy drugs in greater quantities that would qualify the distributor for ADR status based

on sales volume. Secondary wholesalers should not be penalized simply because they have fewer resources. ADRs and secondary wholesalers are regulated under the same licensing statute and hence should adhere to the same standards.

OTHER OPPONENTS SAY:

While pedigrees would provide a valuable benefit to Texas consumers, they should not have to be tracked back to the manufacturer. If ADRs are a safer distributor that should be afforded the special privilege of exemption from certain pedigree requirements, then ADRs should be an equally sound source from which to originate a pedigree. Therefore, secondary wholesalers should be able to report pedigrees from either an ADR or the manufacturer, as has been the status quo for over a decade at the federal level.

NOTES:

Rep. Truitt intends to accept five floor amendments. The first would:

- clarify that pedigrees would be provided for prescription drugs intended for human consumption;
- require that pedigrees be available upon request by DSHS or a peace officer within two days rather than five;
- restore the right for DSHS to issue a cease and desist order against a manufacturer;
- require that the executive commissioner of the HHSC adopt rules to implement the provisions of this bill by May 1, 2008 rather than December 1, 2007; and
- remove the requirement that a pedigree include information on the manufacturer's third-party logistics provider, co-licensed product partner, or exclusive distributor.

The second amendment would:

- create a chain under the definition of a normal distribution channel from a manufacturer to an authorized distributor of record to a licensed practitioner for office use;
- remove from the definition of wholesale distribution the ability to sell or transfer between ADRs prescription drugs that had remained in the normal distribution channel; and
- allow sale or transfer among ADRs for emergency medical reasons such as a drug shortage.

The third amendment would remove training requirements for designated representatives and duplicated confidentiality requirements for license applications. It also would remove regulation of the way drugs are paid for from the Health and Safety Code.

The fourth amendment would move the prohibited acts in this bill to an existing prohibited acts section in a different area of the Health and Safety Code. It would clarify that the prohibited behaviors associated with wholesale drug distribution would not apply to prescription drugs used by a manufacturer for testing the authenticity of the drug.

The fifth amendment would:

- allow DSHS to determine that an inspection was unnecessary based on specified grounds;
- require that DSHS review 21 C.F.R. Part 205 to determine if the agency could issue a wholesale distribution license; and
- give DSHS the discretion to determine if a person could serve as a designated representative for co-located wholesale distributors.

The fiscal note indicates there would be no significant impact to state general revenue. Any costs would be addressed by raising licensing fees.

The companion bill, HB 2316 by Truitt, was left pending in the House Public Health Committee.