

# SENATE BILL REPORT

## SB 6591

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As of January 24, 2006

**Title:** An act relating to the distribution of dangerous drugs.

**Brief Description:** Expanding provisions relating to wholesale distribution of dangerous drugs.

**Sponsors:** Senators Keiser and Deccio.

**Brief History:**

**Committee Activity:** Health & Long-Term Care: 1/23/06.

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### SENATE COMMITTEE ON HEALTH & LONG-TERM CARE

**Staff:** Edith Rice (786-7444)

**Background:** The Food and Drug Administration has seen growing evidence of efforts by increasingly well-organized counterfeiters backed by increasingly sophisticated technologies and criminal operations to profit from drug counterfeiting at the expense of patients. A report produced by the U.S. Department of Health and Human Services, Food and Drug Administration, in February, 2004, outlines methods to protect against counterfeit drugs. These methods include utilizing new technologies for tracking and authenticating drugs, increasing criminal penalties, adopting secure business practices, and educating consumers. Although not yet widespread because of the existing regulatory oversight at the federal and state level, as well as steps taken by drug manufacturers, distributors, and pharmacies, counterfeiting poses a serious public health and safety threat. Currently, wholesale drug distributors operating in Washington must pay a license fee and file a declaration of ownership and location with the Board of Pharmacy.

**Summary of Bill:** Wholesale distributors cannot be located in a residence. Wholesale distributors must be licensed by the Board of Pharmacy prior to engaging in distribution, regardless of where they are located. Specific information required for initial and renewal licensing is described, including contact information, type of business, proof of ability to pay any fines or penalties, and inspection. The Board of Pharmacy will adopt rules to establish a pedigree or means to electronically track drug distribution between wholesalers, chain pharmacy warehouses, and repackagers, when the product leaves the normal distribution channel. Definitions are provided for "chain drug warehouse," "designated representative," "normal distribution channel," "pedigree," and "third party logistics provider." The board has the authority to deny, limit, or revoke a wholesaler's license for violating these rules. Criminal sanctions are outlined for offenses involving counterfeiting drugs, failure to maintain an accurate account of distribution, false labeling, and possession of illegal drugs. Sanctions include forfeiture of property involved in commission of the offense.

**Appropriation:** None.

**Fiscal Note:** Requested on January 18, 2006

**Committee/Commission/Task Force Created:** No.

**Effective Date:** The bill contains an emergency clause and takes effect immediately.

**Testimony For:** The U.S. system of drug distribution is among the safest in the world; however, counterfeiting of drugs has grown exponentially. This bill provides a framework for preventing misbranding, maintaining the integrity of drug products. Penalties should be increased.

**Testimony Against:** We support the concept behind this bill. We have technical concerns, and suggestions regarding definitions in this bill.

**Who Testified:** PRO: Dr. Art Zoloth, Northwest Pharmacy Service; Eleni Anagnostiadis, National Association of Boards of Pharmacy; Steven Saxe, Washington State Board of Pharmacy; Jackie Der, UW Pharmacies; Don Williams, Pharmacist.

CON: Tim Pawlak, McKesson; Rod Shafer WSPA; Dan Bellingham, Healthcare Distribution Management Association.