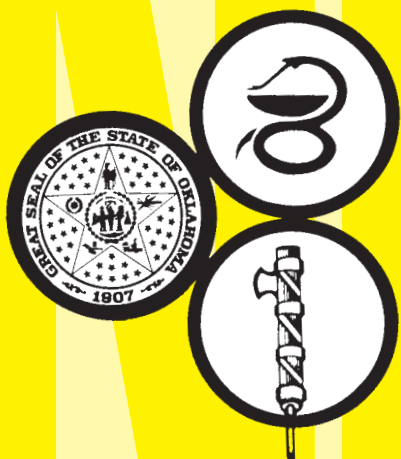


April 2006



Oklahoma State Board of Pharmacy

Published to promote voluntary compliance of pharmacy and drug law.

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Oklahoma City, OK 73105-3488

Board Meeting – January 18, 2006 Disciplinary Action

Tina Harbin, Tech #92 – Case 763: *Charges:* Possession of a controlled dangerous substance (CDS) without a valid prescription, theft of merchandise, and abusing alcohol or drugs. **Permit revoked.**

Zachary Scott Leadford, Tech #7720 – Case 764: *Charges:* Possession of a CDS without a valid prescription; theft of merchandise; abusing alcohol or drugs; and possessing with intent to manufacture, distribute, or dispense a CDS. **Permit revoked.**

Cindy MacKenzie, Tech #8230 – Case 765: *Charges:* Possession of a CDS without a valid prescription and theft of merchandise. **Permit revoked.**

Terry Justin Martin, Tech #2249 – Case 766: *Charges:* Violated Oklahoma Administrative Code 535:25-9-3 by directly (or indirectly, through actions of another), or by assisting or abetting in the violation of, or by conspiring to violate, any provision of the Oklahoma Pharmacy Act, Title 59, 353 et seq; the Prescription Drug Marketing Act; the Robinson-Patman Act; or federal, state, and local laws and rules. **Permit revoked.**

Lori Ann Sage, Tech #590 – Case 767: *Charges:* Giving fraudulent billing or reports to a third party payor of prescription drugs; theft of merchandise; failing to conduct business in conformity with all federal, state, and municipal laws; and failing to conduct herself at all times in a manner that will entitle her to the respect and confidence of the community in which she practices. **Permit revoked.**

Mary Marsha Robinson, Tech #8985 – Case 768: *Charges:* Possession of a CDS without a valid prescription and theft of merchandise. **Permit revoked.**

Jennie D. Triggs, Tech #665 – Case 772: *Charges:* Possession of a CDS without a valid prescription and theft of merchandise. **Permit revoked.**

David Hornsby, DPh, #7030 – Case 769: *Charges:* Received two or more warning notices within a twelve (12)-month period. **Respondent must watch a medication error prevention video, attend an approved one (1)-day law seminar in the year 2006, and pay a \$50 fine. A letter of reprimand shall be placed in his file for one year beginning January 18, 2006.**

The Oklahoma State Board of Pharmacy took action in four (4) impaired cases:

Case 773 – Tech #2578, technician permit was suspended indefinitely. Respondent shall submit to an evaluation by Oklahoma Pharmacists Helping Pharmacists (OPHP) and, if recommended, enter into and abide by a contract with OPHP. Respondent may appear after ninety (90) days and request the suspension be lifted upon presenting a letter of recommendation from a pharmacist who is prepared to employ her and showing full compliance with her Board order.

Case 758 – DPh, #11391, pharmacist license was suspended for ten (10) years. Respondent must enter into and abide by a contract with OPHP and attend a one-day Oklahoma Pharmacists Association Law Seminar in the year 2006. He may appear after July 1, 2006, to request probation provided that he has shown compliance with his OPHP contract and sobriety.

Case 738A – DPh, #9721, pharmacist license was revoked.

Case 737 – DPh, #11698, pharmacist license was revoked.

From the Inspectors

Pharmacists: Please keep your technicians and auxiliary supportive personnel (eg, clerks, typists, delivery persons, data entry persons, etc) updated. Make sure they are aware of the laws and rules regarding their duties. Also, the pharmacy must ensure that the public is able to distinguish technicians, auxiliary support personnel, and interns from any pharmacists. Identification/designation tags must be worn and they

Continued on page 4



FDA Cautions Consumers About Filling US Prescriptions Abroad

Food and Drug Administration (FDA) issued a warning to health care professionals and consumers that filling their prescriptions abroad may have adverse health consequences due to the confusion with drug brand names that could inadvertently lead consumers to take the wrong medication for their condition. In an investigation, FDA has found that many foreign medications, although marketed under the same or similar-sounding brand names as those in the United States, contain different active ingredients than in the US. Taking a different active ingredient could potentially harm the user.

FDA found 105 US brand names that have foreign counterparts that look or sound so similar that consumers who fill such prescriptions abroad may receive a drug with the wrong active ingredient. For example, in the United Kingdom, Amyben[®], a brand name for a drug product containing amiodarone, used to treat abnormal heart rhythms, could be mistaken for Ambien[®], a US brand name for a sedative. Using Amyben instead of Ambien could have a serious adverse outcome. For more information on this topic visit www.fda.gov/oc/opacom/reports/confusingnames.html.

Safety Can Not be Sacrificed For Speed



This column was prepared by the Institute for Safe Medication Practices (ISMP). ISMP is an independent nonprofit agency that works closely with United States Pharmacopeia (USP) and FDA in analyzing medication errors, near misses, and potentially hazardous conditions as

reported by pharmacists and other practitioners. ISMP then makes appropriate contacts with companies and regulators, gathers expert opinion about prevention measures, then publishes its recommendations. If you would like to report a problem confidentially to these organizations, go to the ISMP Web site (www.ismp.org) for links with USP, ISMP, and FDA. Or call 1-800/23-ERROR to report directly to the USP-ISMP Medication Errors Reporting Program. ISMP address: 1800 Byberry Rd, Huntingdon Valley, PA 19006. Phone: 215/947-7797. E-mail: ismpinfo@ismp.org.

Problem: Typically, pharmacies have developed well-established methods for monitoring the accuracy of the dispensing process. But today, pharmacy work is increasingly stressful and these checks and balances can easily be strained beyond capacity. With an increasing number of prescriptions and a shortage of qualified pharmacists, conditions are ripe for potentially unsafe working conditions – long hours without breaks; multitasking between answering phones, overseeing other pharmacy staff, dispensing prescriptions, and counseling patients; and ever-increasing time spent attending to insurance issues. Inevitably, these conditions can increase the chance for dispensing errors.

One pharmacy knows this all too well after a five-year-old boy died as a result of an order entry and medication compounding error that was not caught by the usual verification process. In this case, imipramine was dispensed in a concentration five times greater than prescribed. Imipramine is a tricyclic antidepressant used to treat adults, but it is also used to treat childhood enuresis.

An extemporaneous solution was to be prepared at this pharmacy that specialized in compounded prescriptions since a liquid formulation was not commercially available. A pharmacy technician incorrectly entered the concentration of the prescribed solution into the computer as **50 mg/mL** instead of **50 mg/5 mL**, along with the prescribed directions to give 2 tsp at bedtime. He then proceeded to prepare the solution using the incorrect concentration on the label rather than the concentration indicated on the prescription. When the compound was completed, the technician placed it in a holding area to await a pharmacist's verification. At this time, one of the two pharmacists on duty was at lunch and the high workload of the pharmacy made it difficult for the pharmacist to check the prescription right away. When the child's mother returned to pick up the prescription, the cash register clerk retrieved the prescription from the holding area without telling a pharmacist, and gave it to the mother, unaware that it had not yet been checked. At bedtime, the mother administered 2 tsp of the drug (500 mg instead of the intended 100 mg) to the child. When she went to wake him the next morning, the child was dead. An autopsy confirmed imipramine poisoning.

There are many factors that contributed to this error including inaccurate order entry and issues related to high workload. However, a critical breakdown in safety processes occurred when the cash register clerk took the prescription from the pharmacy holding area (to prevent the mother from waiting any longer for the prescription), thereby circumventing the usual pharmacist verification process.

While this error underscores a growing problem in health care, the problem was clearly evident to this pharmacy owner – even a year before the error occurred. When interviewed for an article that appeared in a national publication, he vented his frustrations about the scant attention paid in our society to pharmacist workload difficulties faced in today's health care environment. On the day of the interview, 49 prescriptions were in the process of being prepared and about a dozen patients were standing in line or wandering around the store waiting for prescriptions. Yet this was a slow day. The owner also said that, while managed care had reduced profits considerably over the past several years, prescription volume had increased 50% (at the time of the error, the pharmacy was dispensing about 10,000 prescriptions per month versus 7,000 per month during the prior year, without an increase in staff) and medication regimens and drug interactions were more complex. To overcome these barriers, the owner added private consultation areas for patient counseling; installed a \$175,000 robot that accurately dispenses the 200 most common drugs; and diversified sales to offset full-time pharmacists' salaries. But these efforts could not have prevented this tragic fatal error that circumvented the normal safety processes.

Safe Practice Recommendations: The environment and demands placed on health professionals significantly affect their ability to provide safe health care services. While technology such as robots can help, overstressed professionals cannot consistently perform at the maximum level of safety. Therefore, it is important that the public and health care leadership understand this problem so they can be more open to tradeoffs, such as working

Compliance News

Compliance News to a particular state or jurisdiction should not be assumed. The law of such state or jurisdiction.)



with one patient at a time and incurring longer turnaround times, which are necessary to enhance patient safety. With a shortage of qualified professionals, we need to demand more rapid adoption of computerized prescribing to reduce time spent with prescription transcription. We should identify the biggest distractions that occur in our workplaces and eliminate or reduce the source by batching common interruptions and reorganizing work areas. Staff members need to be properly trained to understand safety procedures that are in place and know the limits of their specific duties. Fail-safe processes to ensure an independent double check before dispensing medications and performing other critical processes are a must. The pharmacy where this error occurred now requires two pharmacists to check every prescription. Unfortunately, this level of vigilance is typical after a patient has been harmed from an error. In other pharmacies, especially where there is only one pharmacist on duty, technicians may be involved in the double-check process.

A few other strategies can be used to prevent similar errors:

- ◆ Have one person perform order entry and a different person prepare the prescription, if possible, to add an independent validation of the order entry process.
- ◆ Do not prepare prescriptions using only the computer-generated label, as order entry may have been incorrect.
- ◆ Ensure that the original prescription, computer-generated label, prepared product, and manufacturer's product(s) remain together throughout the preparation process.
- ◆ Verify dispensing accuracy by comparing the original prescription with the labeled patient product and the manufacturer's product(s) used.

NIH Develops Community Drug Alert Bulletin

The National Institute on Drug Abuse, as part of the National Institutes of Health (NIH), has developed a new Community Drug Alert Bulletin that addresses the latest scientific research on the non-medical use of prescription drugs of abuse and addiction.

This bulletin is geared toward parents, teachers, counselors, school nurses, and health professionals who are associated with those at risk from prescription drug abuse for non-medical purposes. It summarizes the growing problem in the US and the trend of non-medical use of prescription drugs. For more information on this bulletin visit www.nida.nih.gov/PrescripAlert/index.html.

Implementation of the Anabolic Steroid Control Act of 2004

According to the December 16, 2005 *Federal Register*, effective January 20, 2005, the Anabolic Steroid Control Act of 2004 amended the Controlled Substances Act (CSA) and replaced the existing definition of "anabolic steroid" with a new definition. This new definition changed the basis for all future administrative scheduling actions relating to the control of the anabolic steroids as Schedule III controlled substances (CS) by eliminating the requirement to prove muscle growth. Also, the Act lists 59 substances as being anabolic steroids; these substances and their salts, esters, and ethers are Schedule III CS. The Act also revised the language of the CSA requiring exclusion of certain over-the-counter products from regulation as CS.

According to the House Report, the purpose of the Act is "to prevent the abuse of steroids by professional athletes. It will also address the widespread use of steroids and steroid precursors by college, high school, and even middle school students."

The changes to the definition include the following:

- ◆ Correction of the listing of steroid names resulting from the passage of the Anabolic Steroid Control Act of 1990.
- ◆ Replacement of the list of 23 steroids with a list of 59 steroids, including both intrinsically active steroids as well as steroid metabolic precursors.
- ◆ Automatic scheduling of the salts, esters, and ethers of Schedule III anabolic steroids without the need to prove that these salts, esters, or ethers promote muscle growth.
- ◆ Removal of the automatic scheduling of isomers of steroids listed as Schedule III anabolic steroids.
- ◆ Addition of dehydroepiandrosterone to the list of excluded substances.

FDA Unveils New Package Insert Format

On January 18, 2006, FDA unveiled a major revision to the format of prescription drug information, commonly called the package insert, which will give health care professionals clear and concise prescribing information. This new format was developed in order to manage the risks of medication use and reduce medical errors; the new package insert will provide the most up-to-date information in an easy-to-read format. This new format will also make prescription information more accessible for use with electronic prescribing tools and other electronic information resources.

Revised for the first time in more than 25 years, the new format requires that the prescription information for new and recently approved products meet specific graphical requirements and includes the reorganization of critical information so physicians can find the information they need quickly. Some of the more important changes include:

- ◆ A new section called *Highlights* to provide immediate access to the most important prescribing information about benefits and risks.
- ◆ A table of contents for easy reference to detailed safety and efficacy information.
- ◆ The date of initial product approval, making it easier to determine how long a product has been on the market.
- ◆ A toll-free number and Internet reporting information for suspected adverse events to encourage more widespread reporting of suspected side effects.

This new format will be integrated into FDA's other e-Health initiatives and standards-settings through a variety of ongoing initiatives at FDA. For more information please visit www.fda.gov/cder/regulatory/physLabel/default.htm.

Continued from page 1

must identify themselves on any phone call initiated or received while performing pharmacy functions.

Technician training: Pharmacists need to check that they have proper documentation on all technicians. When technicians who have previously worked in another pharmacy are hired they still need to be trained in your pharmacy and the training must be documented. Inspectors will be checking for documentation of technician training during their routine inspections.

Alert: During inspections the compliance officers have observed several pharmacies selling Phenergan® with Codeine syrup as an exempt narcotic. **Phenergan with Codeine is not an exempt narcotic.** The codeine may fall within the limits, but promethazine is a prescription-only drug.

Annual CDS Inventory

Board rules require that “an inventory of all CDS must be taken between May 1 and July 1 of each year. A copy of this inventory will be included with the pharmacy renewal application.” As of May 1, 2006, Oklahoma pharmacies submitting a pharmacy renewal application must attach a copy of their annual CDS inventory taken between May 1, 2006, and July 1, 2006. Pharmacies must maintain their annual CDS inventory in the pharmacy and submit a copy to the Board at the time of their renewal. **Do not send your annual CDS inventory to the Board unless you are submitting a pharmacy renewal application.** CDS inventories taken due to a pharmacist-in-charge change must still be submitted to the Board at the time of the change. The Board will mail inventory forms to pharmacies the last week of April 2006. Forms are also available online at www.pharmacy.ok.gov under “Download Forms” and then “Pharmacies.”

Reminder

Board rules require that all registrants (pharmacists, technicians, and interns) notify the Board in writing within ten (10) days of a change of address or employment. Also, pharmacist licenses and technician permits are now renewed according to birth month. If you do not receive a renewal prior to expiration, it is your responsibility to contact the Board. It is crucial that we have your current, correct address on file at the Board.

Oklahoma Pharmacists Helping Pharmacists

If you or a pharmacist you care about is suffering from chemical dependency, there is a solution. OPHP is readily available for help. Pharmacists in Oklahoma, Texas, and Louisiana may call the OPHP Help Line at 1-800/260-7574 ext 5. All others may call OPHP at 405/528-3338. All calls are confidential.

Let Us Hear From You

The Board welcomes your comments and questions. You may mail them to the Oklahoma State Board of Pharmacy, 4545 Lincoln Blvd, Ste 112, Oklahoma City, OK 73105. Fax us at 405/521-3758 or e-mail us at:

Board e-mail: pharmacy@pharmacy.ok.gov

Board Web site: www.pharmacy.ok.gov

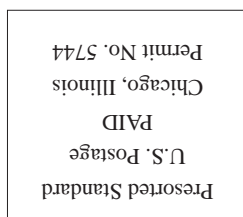
Page 4 – April 2006

The *Oklahoma State Board of Pharmacy News* is published by the Oklahoma State Board of Pharmacy and the National Association of Boards of Pharmacy Foundation, Inc, to promote voluntary compliance of pharmacy and drug law. The opinions and views expressed in this publication do not necessarily reflect the official views, opinions, or policies of the Foundation or the Board unless expressly so stated.

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