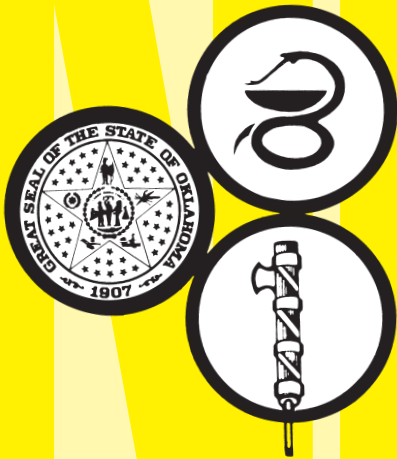


July 2006



Oklahoma State Board of Pharmacy

4545 N Lincoln Blvd, Suite 112
Oklahoma City, OK 73105-3488

Published to promote voluntary compliance of pharmacy and drug law.

Jim Spoon Re-appointed to Board

Governor Brad Henry has appointed Jim Spoon of Sand Springs, OK, to a second term ending June 30, 2011. Best wishes to Jim as he continues to serve the public for the next five years.

Board Meeting – March 8, 2006

Disciplinary Action

Bonnie Garrett, Tech #4089 – Case 775: Charges: Abuse of alcohol or drugs and theft of merchandise. **Permit Revoked.**

Julie Ann Glaze, Tech #2077 – Case 776: Charges: Possession of a controlled dangerous substance (CDS) without a valid prescription and theft of merchandise. **Permit Revoked.**

Shawna Ridenour, Tech #5685 – Case 777: Charges: Abuse of alcohol or drugs and theft of merchandise. **Permit Revoked.**

Deril J. Lees, DPh #9635 and The Apothecary Shoppe – Tulsa, #2-4226 – Case 779: Charges: Conduct and habits inconsistent with the rules of professional conduct, failing to conduct business as a pharmacist in conformity with all federal, state, and municipal laws and failing to have a pharmacy manager who was responsible for all aspects of the operation related to the practice of pharmacy. **Respondent and all staff pharmacists working for him must watch an error correction video. Respondent must attend an approved one (1)-day law seminar in the year 2006 and pay a \$3,000 fine (\$2,000 from respondent pharmacist and \$1,000 from respondent pharmacy). A letter of reprimand shall be placed in his file for one year beginning March 8, 2006.**

Diane Elizabeth Feightner, DPh #12673 – Case 781: Charges: Receiving two (2) or more warning notices within a twelve (12)-month period. **Respondent must watch an error correction video and attend an approved one (1)-day law seminar in the year 2006.**

George Eddie McCollum, DPh #11402 – Case 782: Charges: Receiving two (2) or more warning notices within a twelve (12)-month period. **Respondent must watch an error correction video and attend an approved one (1)-day law seminar in the year 2006.**

The Board took action in three (3) impaired cases:

Case 771 – DPh #11243, the suspension of respondent's pharmacist license was reinstated. Respondent is suspended until November 19, 2012. Respondent must abide by her contract with Oklahoma Pharmacists Helping Pharmacists (OPHP) until the completion of its ten (10)-year term. Respondent may apply to have the suspension stayed and her license placed on probation after one (1) year of documented sobriety and compliance with her OPHP contract.

Case 770 – DPh #10013, respondent was given sixty (60) days to become compliant with his OPHP contract. Failure to abide by these terms could result in suspension or revocation of his license.

Case 780 – DPh #9741, respondent's pharmacist license was suspended for ten (10) years until March 8, 2016. The suspension was stayed and placed on probation March 8, 2006. Respondent must enter into and abide by a contract with OPHP. Respondent was also fined a total of \$700 and must attend a law seminar in 2006.

Board Meeting – April 26, 2006

Disciplinary Action

Kim Holder, Tech #2146 – Case 783: Charges: Possession of a CDS without a valid prescription, obtaining or attempting to obtain a CDS by fraud and theft of merchandise. **Permit Revoked.**

Denise A. Sherman, Tech #7562 – Case 784: Charges: Possession of a CDS without a valid prescription and fraudulent billing or reports to a third party payer of prescription drugs. **Permit Revoked.**

Victor Wanjiku, Tech #9214 – Case 785: Charges: Theft of merchandise and 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, the Prescription Drug Marketing Act, the Robinson-Patman Act, or federal, state and local laws and rules. **Permit Revoked.**

Nerissa Dionne Wynn, Tech #6091 – Case 786: Charges: Theft of merchandise. **Permit Revoked.**

Ronnie Biles, DPh #7915, Sherrills Pharmacy #25-3481, and Sherrill's Resp and Diabetic Medications #25-4303 – Case 778: Charges: Directly, indirectly, through actions of another, assisting in or abetting the violation of, or conspiring to violate, any provision or term of the Oklahoma Pharmacy Act, the Prescription Drug Marketing Act, the Robinson-Patman Act, or federal, state and local laws; knowingly billing or charging for quantities greater than delivered, or for a brand when a generic or a compounded product is dispensed; submitting fraudulent billing or reports to a third party payer of prescription drugs; misfilling a prescription; allowing non-pharmacists to enter and operate the pharmacy in the absence of the pharmacist; failing to include on the prescription label the following: "An appropriate designation that this is a compounded prescription"; and failing to maintain a ratio of no more than two (2) pharmacy technicians per supervising pharmacist on duty. **Respondent Biles' license is placed on probation for three (3) years until April 26, 2009. Respondent Biles will also sell all of his pharmacies and/or close them within ninety (90) days, will petition the Oklahoma State Board of Pharmacy prior to owning a pharmacy in the future, will attend a one (1)-day law seminar in 2006 and pay a fine of \$4,300.**



Generic Substitution Issues

This is a reminder to pharmacists regarding the legal generic substitution of certain drug products. Recent practices by pharmaceutical manufacturers involving the reformulation of drugs into alternative dosage forms (eg, tablets to capsules) seem to have caused some confusion.

Generic substitution is the act of dispensing a different brand or unbranded drug product than the one prescribed. Generic substitution is only allowable when the substituted product is therapeutically equivalent to the prescribed innovator product. Generic drug manufacturers must provide evidence to Food and Drug Administration (FDA) of therapeutic equivalence, which means that both products are pharmaceutically equivalent (eg, have the same active ingredients in the same dosage form and strength, and use the same route of administration) and bioequivalent (eg, have more or less the same rate and extent of absorption). Therapeutically equivalent drugs are expected to produce the same clinical benefits when administered for the conditions approved in the product labeling.

FDA assigns two-letter therapeutic equivalence codes to generic products when the products meet both the aforementioned requirements, are approved as safe and effective, are adequately labeled, and are manufactured in compliance with current Good Manufacturing Practice regulations. The primary reference guide for pharmacists on therapeutic equivalence is FDA's Approved Drug Products with Therapeutic Equivalence Evaluations, otherwise known as the "Orange Book." Drug products determined to be therapeutically equivalent to innovator drugs are assigned an "A" for the initial letter of their therapeutic equivalence code. The second letter provides additional information regarding the product: products rated AA, AN, AO, AP, or AT are those with no known or suspected bioequivalence problems (rating depends on dosage form). An AB rated product indicates that actual or potential bioequivalence problems have been resolved with adequate in vivo and/or in vitro evidence. In contrast, drugs assigned a "B" for the initial letter are not considered therapeutically equivalent because bioequivalence problems have not been resolved to the satisfaction of FDA.

A recent example of improper substitution has been brought to the attention of several boards of pharmacy by Acorda Therapeutics, the maker of Zanaflex[®] tablets, who recently released Zanaflex Capsules[™] (tizanidine hydrochloride). Although the active ingredient in Zanaflex Capsules is the same as the active ingredient in Zanaflex tablets and generic tizanidine tablets, their formulations are different. For this reason, FDA has deemed there to be no therapeutic equivalent to Zanaflex Capsules and has not assigned a therapeutic equivalence code.

A similar situation existed in 1995 when the manufacturer of Sandimmune[®] (cyclosporine) capsules and oral solution, Sandoz, (now Novartis), came out with NEORAL[®] (cyclosporine) capsules and oral solution for microemulsion. Due to differences in bioavailability, Sandimmune and Neoral, and their accompanying generic versions, were not, and still are not, rated as substitutable.

It must be emphasized that generic substitution mandates are found in individual state laws and regulations. In states where generic substitution is allowed only for "Orange Book" A-rated

products, pharmacists may not substitute a generic product for a non-A-rated product. Some states may have developed their own generic substitution lists or formularies. Pharmacists are encouraged to review the laws and regulations in their states to determine the appropriate legal methods by which to perform generic substitution.

Preventing Errors Linked to Name Confusion



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.

The Institute for Safe Medication Practices (ISMP) regularly hears about confusion between products with similar names. One such pair is OMACOR (omega-3-acid ethyl esters) and AMICAR (aminocaproic acid) an antifibrinolytic. Omacor is indicated as an adjunct to diet to reduce very high triglyceride levels (500 mg/dL or more) in adult patients. The drug is also being studied as adjuvant therapy for the prevention of further heart attacks in patients who have survived at least one. A pharmacist reported an error in which a telephone order for Omacor 1 gram BID was interpreted and dispensed as Amicar 1 gram BID. Counseling was not provided, but fortunately the patient read the drug information sheet for Amicar before taking any medication and called the pharmacy stating that he was expecting a medication to reduce his triglyceride levels.

While this case illustrates why manufacturers should review and test new trademarks for error potential before the product reaches the market, there are some things that practitioners can do to help prevent errors with products that have look-alike or sound-alike names.

- ◆ Look for the possibility of name confusion before a product is used. Use the concepts of failure mode and effects analysis (FMEA) to assess the potential for error with new medications that will be prescribed or added to your inventory. If the potential for confusion with other products is identified, take the steps listed below to help avoid errors.
- ◆ Prescriptions should clearly specify the drug name, dosage form, strength, complete directions, as well as its indication. Most products with look- or sound-alike names are used for different purposes. If the indication is not available, pharmacists and nurses should verify the purpose of the medication with the patient, caregiver, or physician before it is dispensed or administered.
- ◆ Reduce the potential for confusion with name pairs known to be problematic by including both the brand and generic name on prescriptions, computer order entry screens, prescription labels, and MARs.



- ◆ When accepting verbal or telephone orders, require staff to write down the order and then perform a read back (or even spell back) of the medication name, strength, dose, and frequency of administration for verification.
- ◆ Change the appearance of look-alike product names on computer screens, pharmacy product labels, and MARs by emphasizing, through bold face, color, and/or tall man letters, the parts of the names that are different (eg, hydrOXYzine, hydrALAzine).
- ◆ Pharmacists should work under good lighting and use magnifying lenses and copyholders (keep prescriptions at eye level during transcription) to improve the likelihood of proper interpretation of look-alike product names.
- ◆ Install computerized reminders for the most commonly confused name pairs at your site so that an alert is generated when entering prescriptions for either drug. If possible, make the reminder auditory as well as visual.
- ◆ Store commonly confused products in different locations. Avoid storing both products in a "fast-mover area." Use a shelf sticker to help find relocated products.
- ◆ Affix "name alert" stickers to areas where look- or sound-alike products are stored (available from pharmacy label manufacturers) or to the actual product containers.
- ◆ Employ at least two independent checks in the dispensing process (one person interprets and enters the prescription into the computer and another compares the printed label with the original prescription as well as the manufacturer's product).
- ◆ Open the prescription bottle or package in front of the patient to confirm the expected appearance of the medication and review the indication. Caution patients about error potential when taking a product that has a look- or sound-alike counterpart. Encourage patients to ask questions if the appearance of their medication changes. Take time to fully investigate any patient concerns.
- ◆ Encourage reporting of errors and potentially hazardous conditions with look- and sound-alike names to the ISMP-USP Medication Errors Reporting Program and use the information to establish priorities, as listed above, for error reduction. Maintain an awareness of problematic product names and error prevention recommendations provided by ISMP (www.ismp.org), FDA (www.fda.gov), and USP (www.usp.org).

If you are interested in learning what look-alike and sound-alike name pairs have been published in the ISMP Medication Safety Alert!®, a free list is available at www.ismp.org/Tools/confuseddrugnames.pdf.

Combat Methamphetamine Epidemic Act Phasing In

This year, new requirements of the federal Combat Methamphetamine Epidemic Act passed by Congress for the sale of all single and multi-ingredient pseudoephedrine and ephedrine-containing products will become effective. The new law places non-prescription ephedrine, pseudoephedrine, and phenylpropanolamine in a new Controlled Substances Act category of "scheduled listed chemical products." Drug products containing ephedrine, pseudoephedrine, and phenylpropanolamine are subject to sales restrictions, storage requirements, and record keeping requirements.

A 3.6-grams-per-day base product sales limit, 9-grams-per-30-days base product purchase limit, a blister package requirement, and mail-order restrictions went into effect on April 8, 2006,

for all sellers of these products. All other provisions of the law require compliance by September 30, 2006. If a state has more stringent requirements, the stronger requirements remain in place. A summary of this Act's requirements can be found on the United States Drug Enforcement Administration's (DEA) Web site at www.dea diversion.usdoj.gov/meth/cma2005.htm.

Explanation of DEA Regulations on Partial Refilling of Prescriptions

Pharmacists often question the DEA rule regarding the partial refilling of Schedule III, IV, and V prescriptions as stated in Section 1306.23 of the Code of Federal Regulations. Confusion lies in whether or not a partial fill or refill is considered one fill or refill, or if the prescription can be dispensed any number of times until the total quantity prescribed is met or six months has passed. According to DEA's interpretation, as long as the total quantity dispensed meets the total quantity prescribed with the refills and they are dispensed within the six-month period the number of times it is refilled is irrelevant. The DEA rule is printed below:

Section 1306.23 Partial Filling of Prescriptions.

The partial filling of a prescription for a controlled substance listed in Schedule III, IV, or V is permissible provided that:

- (a) Each partial filling is recorded in the same manner as a refilling,
- (b) The total quantity dispensed in all partial fillings does not exceed the total quantity prescribed, and
- (c) No dispensing occurs after 6 months after the date on which the prescription was issued.

[21 CFR 1306.23]

Electronic Version of DEA Form 106 Now Available

DEA has announced that a secure, electronic version of the DEA Form 106 (Report of Theft or Loss of Controlled Substances) is now available to DEA registrants. The electronic form may now be completed online through a secure connection and submitted via the Internet to DEA Headquarters. Copies of the letter from DEA and the 2005 Final Rule were published in the *Federal Register*. The new interactive form is located at the Diversion Control Program's Web site and may be accessed at www.DEAdiversion.usdoj.gov.

Patients Rely on Pharmacists' Recommendations

Patients consider their pharmacists a trusted source for medication recommendations, as evidenced by the result of a poll recently conducted by the American Pharmacists Association (APhA). APhA polled 3,000 community pharmacists and found that pharmacists were asked about over-the-counter (OTC) products an average of 32 times each week. Of those pharmacists surveyed, 55% said they spend three to five minutes with each patient who asks about an OTC. And patients are listening, for during this consultation time, according to the survey, 81% of patients purchased OTC products recommended by the pharmacist.

The results of the poll was published in APhA's *Pharmacy Today*. Other topics researched in the poll include recommendation habits of pharmacists in leading OTC therapeutic areas including treatments for allergies, adult cold symptoms, adult headache remedies, heartburn, pain relief, and tooth whitening products among others.

Board Meeting – May 23-24, 2006

Disciplinary Action

John Braly, Tech #6505 – Case 787: Charges: Abuse of alcohol or drugs and theft of merchandise. **Permit Revoked.**

Gary Nichols, DPh #12862, Moore Clinic Pharmacy, Inc, Lakehurst Pharmacy, LLC, Williams Pharmacy #7-4543, Allen Community Pharmacy #23-4707, Central Pharmacy #17-4718, Newt's Discount Pharmacy #32-3288 – Case 774: Charges: Respondents faced a total of nineteen (19) counts including forging and/or increasing the quantity of drugs in prescriptions; knowingly billing or charging for quantities greater than delivered, or for a brand when a generic or a compounded product is dispensed; and submitting fraudulent billing or reports to a third-party payor. Records revealed that respondent pharmacies had billed Medicaid during the year 2004 for \$399,436.87 more than was purchased on forty-one (41) drugs. Respondents failed to keep proper records and there were several CDS violations including patient address; practitioner name, address, and DEA number; date of prescription; incomplete DEA 222 Forms and the transfer of C-II's from one pharmacy to another without using a DEA 222 Form. Nichols had tried to return drugs to a wholesaler valued at over \$100,000. He could not verify where he had purchased these drugs and had no invoices. He claimed to have purchased these drugs for \$25,000 cash in the parking lot of his pharmacy. He did not know the man, his name, or the make or color of his car. **Respondent Nichols' pharmacist license was revoked. He cannot appear before the Board to request to apply for a pharmacist license for five (5) years. He was given ninety (90) days to divest himself of ownership of his pharmacies. If he does not, he is to close the pharmacies. Nichols is required to pay \$11,000 personally. Williams Pharmacy is to pay \$4,000, Allen Community Pharmacy \$2,000, Central Pharmacy \$2,000, Newt's Discount Pharmacy \$2,000, Lakehurst Pharmacy \$2,000, and Clinic Pharmacy \$12,000.** Note: The Board has been notified that Respondent Nichols will appeal to District Court.

Fifty-year Gold Certificates Issued

The following individuals have been issued gold certificates in recognition for the distinction of having been a licensed pharmacist in Oklahoma for 50 years. The Oklahoma State Board of Pharmacy recognizes these pharmacists and gratefully acknowledges their years of contribution to the pharmacy profession. These individuals may take great pride in being part of such an honorable profession for so long.

1956-2006: John Y. Barton; Verdie M. Conley; James L. Dixon; John W. Elliot; James D. Funnell, MD; Charles M. Hall; James N. Hall, Jr; Lloyd B. Helms; Donald C. Keaton; Michael E. Lokensgard; John P. Martin; Ed H. McDonald, Jr; Jack R. Myrick; William E. Osborn;

Betty Jean Perdue; John W. Pettit; Harold J. Raff; Jane H. Richards; D. M. Sokolosky; Donald L. Spainhower; Kenneth R. Turner; Don A. Turner; Mary Kay Worrell.

From The Inspectors

- ♦ **Pharmacists:** Please remember that when changing the pharmacy manager, a controlled drug inventory must be taken and sent to the Board within ten (10) days. Also, please include the effective date of the change along with the name and license number of the outgoing and incoming pharmacy manager.
- ♦ **Pseudoephedrine (PSE):** A new Federal law implemented on April 8, 2006, requires that a consumer can purchase no more than 3.6 grams of PSE in a given day. Also, ephedrine products such as Primatene[®] Tablets, Bronkaid[®] Tablets, etc, are restricted in the same manner as PSE products under this law. Phase 2 of the federal law to be implemented on September 30, 2006, requires all PSE products regardless of form (including liquids, liquid-filled gel capsules, and pediatric liquids) to be kept behind the pharmacy counter or in a locked display case and logs to be kept on the purchase of these products. The limit of 9 grams per customer per 30 days has not changed.

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 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 pharmacy@pharmacy.ok.gov. Visit our Web site at www.pharmacy.ok.gov.

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