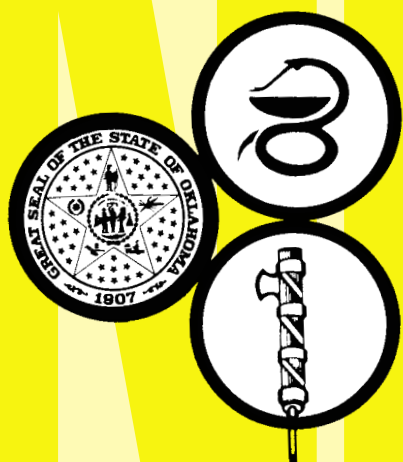


April 2005



Oklahoma State Board of Pharmacy

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Board Meeting – January 19, 2005

Disciplinary Action

Ryan Sellers, Tech #4339 – Case 732: Charges: Abuse of alcohol or drugs and/or use of an illegal CDS [controlled dangerous substance]. Permit revoked.

Wes Kifer, DPh #9140 – Case 733: Charges: Received two or more warning notices within a twelve (12)-month period. Respondent was given a letter of reprimand for a period of one (1) year until January 19, 2006, and shall attend a one (1)-day law seminar during the calendar year 2005.

Alfred Jackson, DPh #9967 – Case 734: Charges: Received two or more warning notices within a twelve (12)-month period. Respondent was given a letter of reprimand for a period of one (1) year until January 19, 2006, and shall attend a one (1)-day law seminar during the calendar year 2005.

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

Case 739 – DPh #7465, was suspended for five (5) years until January 19, 2010. Respondent may petition the Board to stay the suspension and place him on probation upon showing continuous compliance with an Oklahoma Pharmacists Helping Pharmacists (OPHP) contract for a period of one (1) year.

Case 591-A – DPh #10306, had the probation of his license revoked and was placed on suspension for thirty (30) days. At the end of 30 days, the probation was reinstated. Respondent was also fined a total of \$1,500.

Case 643-B – DPh #11307, was removed from suspension and placed on probation until November 19, 2012. He must work the first 160 hours of probation under the supervision of another pharmacist.

Case 594 – DPh #11972, was removed from suspension upon meeting the reinstatement requirements and placed on probation until May 31, 2011. He must work the first 160 hours of probation under the supervision of another pharmacist.

Board Meeting – February 16, 2005

Disciplinary Action

Lonnie Morrow, Tech #7558 – Case 736: Charges: Filing a report or record which the registrant knows to be false; possession of a CDS without a valid prescription. Permit revoked.

Jason L. Dugan, Tech #5411 – Case 735: Charges: Possession of a CDS with intent to distribute; possession of a CDS without a valid prescription; theft of merchandise. Permit revoked.

Sherry Lynn Ross, DPh #9815, and Sherry's Discount Drug, Inc #1-2558 – Case 742: Charges: Failing to report the required Oklahoma Schedule Two Abuse Reduction information to the Oklahoma State Bureau of Narcotics and Dangerous Drugs Control (OBN); misfilling a prescription; failing to conduct an inventory at renewal of all CDSs between May 1 and July 1; failing to maintain a proper record keeping system; filling Schedule II prescriptions that were invalid; failing to enter the date of filling on a prescription; distributing a Schedule II prescription to a practitioner without using a Drug Enforcement Administration (DEA) Form 222; failing to keep records and maintain inventories in conformance with the record keeping and inventory requirements of federal law and with rules issued by the OBN commissioner; failing to conduct business in conformity with all federal, state, and municipal laws. Respondents' licenses are suspended for four (4) years beginning August 10, 2005, until August 10, 2009. The suspensions shall be stayed and the respondents placed on probation. Respondent pharmacist shall attend live continuing education (CE) programs to fulfill her Board CE requirements in 2006, 2007, 2008, and 2009. Respondent pharmacist was fined \$2,300 and respondent pharmacy was fined \$2,600.

The Board also took action in two (2) impaired cases:

Case 740 – DPh #9952, was suspended for ten (10) years until January 19, 2015. Respondent may petition the Board to stay the suspension and place him on probation upon showing continuous compliance with an OPHP contract for a period of one (1) year. He must also attend a one (1)-day law seminar in the calendar year 2005.

Case 483 – DPh #10584, had the remainder of the suspension/probation of his license removed. His license was returned to good standing providing he continues his OPHP contract until February 16, 2008.



Accutane, Palladone RMPs Designed to Protect Patient Safety

Risk Management Programs (RMPs) are developed by drug manufacturers to meet the requirements of FDA's drug approval process, in conjunction with FDA, to minimize risks associated with specific drug products. To date, several specific drug products have formal risk management programs beyond labeling alone, to further ensure patient safety. Two relevant examples are Accutane® (Roche Pharmaceuticals) and Palladone Capsules (Purdue Pharma LP).

Accutane

On November 23, 2004, FDA announced changes to the RMP for isotretinoin (Accutane) that will be implemented in mid-2005 in order to reduce the risk of birth defects associated with fetal exposure to the medication. All of the manufacturers of isotretinoin have entered into an agreement with Covance, a drug development services company that currently coordinates the registry for Celgene's thalidomide. Covance's task is to develop and operate a universal enhanced RMP by mid 2005; this program will require patients, dispensing pharmacists, and prescribers to register in a single, centralized clearinghouse. The program will also mandate that a pregnancy test be performed at certified laboratories instead of home or in-office testing. According to the Accutane RMP, System to Manage Accutane Related Teratogenicity, when the registry denies an authorization to fill the prescription, the prescribing physician must explain the reason for denial to the patient; FDA specifically states that the physician is responsible for informing a woman if a pregnancy test result comes back positive.

Palladone

Due to Palladone's (hydromorphone hydrochloride) high potential for abuse and respiratory depression, the drug's manufacturer, Purdue Pharma LP, in conjunction with FDA, developed an RMP for this new extended-release analgesic. Introduced to the market in January 2005, Palladone is approved for the management of persistent, moderate to severe pain in patients requiring continuous, around-the-clock analgesia with a high potency opioid for an extended period of time (weeks to months) or longer. Palladone is to be used in patients who are already receiving opioid therapy, who have demonstrated opioid tolerance, and who require a minimum total daily dose of opiate medication equivalent to 12 mg of oral hydromorphone.

The analgesic's RMP was devised with four goals:

1. Facilitation of proper use (patient selection, dosing)
2. Avoidance of pediatric exposure
3. Minimization of abuse, and
4. Reduction of diversion

Palladone's RMP includes provisions for understandable and appropriate labeling, and proper education of health care professionals, patients, and caregivers. In addition, the manufacturer has offered training sessions to its sales representatives. The RMP provides for the observation and surveillance of abuse and, if abuse, misuse, and/or diversion occur, this program includes an array of interventions. A Medication Guide will be distributed to patients prescribed Palladone.

During the initial 18 months of Palladone's release to the market, the manufacturer will only promote Palladone to a limited number of medical practitioners experienced in prescribing opioid analgesics and will closely monitor and gather data on Palladone's use and any incidences of abuse or diversion, and report this information to FDA on a regular basis.



Metronidazole and Metformin: Names Too Close for Comfort

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.

A family practice physician in a community health center prescribed metformin 500 mg b.i.d. to a newly diagnosed diabetic man from India who did not speak English. When the patient returned to his office a few months later, he brought his medications with him, as requested. His physician quickly noticed that metformin was missing. Instead, the patient had a prescription bottle labeled as metronidazole with directions to take 500 mg twice a day. The prescription had been refilled several times. Luckily, the patient's diabetes remained stable, and he seemed to suffer no adverse effects from two months of unnecessary antimicrobial therapy. The physician notified the pharmacy of the error and asked the pharmacist to check the original prescription, which had been written clearly and correctly for metformin. Upon further investigation, the pharmacist found that the computer entry screen for selecting these medications included "METF" (for metformin) and "METR" (for metronidazole). Apparently, one of the pharmacy staff members had entered "MET" and selected the wrong medication that appeared on the screen.

In another community pharmacy, the same mix-up happened twice, one day apart. In one case, metformin was initially dispensed correctly, even though the prescription had been entered incorrectly as metronidazole – again, when the wrong mnemonic was chosen. The pharmacist who filled the prescription clearly understood that the physician had prescribed metformin, so he filled the prescription accordingly. However, he failed to notice the order entry error, as he did not compare the prescription vial label to the drug container label. Unfortunately, the initial order entry error led to subsequent erroneous refills of metronidazole, as stated on the label. In the other case, bulk containers of the medication were available from the same manufacturer, both with similar highly stylized labels. Thus, confirmation bias contributed to staff's selection of the wrong drug. After reading "MET" and "500" on the label, the staff member believed he had the correct drug.

In a hospital pharmacy, metronidazole 500 mg and metformin ER 500 mg were accidentally mixed together in the metronidazole storage bin. This resulted in dispensing metformin instead of metronidazole. Fortunately, a nurse recognized the error before giving the patient the wrong medication. Both were generic products, although the brands Flagyl® (metronidazole) and Glucophage®



(metformin) are also available. Unit-dose packages of these drugs contain bar codes, and the printed information is very small, which adds to their similar appearance.

Metronidazole-metformin mix-ups could be serious, considering the different indications and the potential for drug interactions. To avoid selecting the wrong drug from the screen, consider programming the computer to display the specific brand names along with the generic names whenever the “MET” stem is used as a mnemonic. To reduce similarity of the containers, purchase these medications from different manufacturers. Another option in hospital settings is to stock only the 250 mg tablets of metronidazole, since metformin is not available in that strength. This option allows a small risk for nurses who may administer just 250 mg when 500 mg is prescribed, but the potential for harm from giving the wrong drug is greater.

It is also a good idea to separate the storage of these products. During the dispensing process, drug names listed on written prescriptions and hospital orders should be matched to computer labels and manufacturers’ products. Since metformin is used to treat a chronic condition, and metronidazole is more likely to be used for an acute condition, outpatient refills for metronidazole are less common and, therefore, bear a second look. Asking physicians to include the drug’s indication on the prescription can also help prevent errors.

We have asked FDA to add these drugs to the list of nonproprietary names that would benefit from using “Tall Man” letters. Meanwhile, underline or highlight the unique letter characters in these drug names to make their differences stand out.

‘Dietary Supplements’ Contain Undeclared Prescription Drug Ingredient

In early November 2004, Food and Drug Administration (FDA) cautioned the public about the products Actra-Rx and Yilishen, which have been promoted via the Internet. These products, purported as “dietary supplements” to treat erectile dysfunction and enhance sexual performance, were actually found to contain the active prescription drug ingredient, sildenafil, the active drug ingredient in Viagra®, which is approved in the United States for the treatment of erectile dysfunction.

The *Journal of the American Medical Association (JAMA)* published a research letter that explained the results of a chemical analysis that found that Actra-Rx contained prescription strength quantities of sildenafil. FDA conducted its own analysis, the results of which corroborated the analysis published in *JAMA*.

Sildenafil is known to interact with a number of prescription medications. For example, sildenafil may potentiate the hypotensive effects of medications containing nitrates, which are commonly used to treat congestive heart failure and coronary artery disease.

FDA instructed those who are taking Actra-Rx and/or Yilishen to stop and consult their health care provider and warned that the use of these products could be dangerous to patients’ health.

For more information, please visit the following Web site: www.fda.gov/bbs/topics/ANSWERS/2004/ANS01322.html.

NABP Releases Criteria for National Specified List of Susceptible Products, Adds One Drug to List

In late 2004, the National Association of Boards of Pharmacy® (NABP®) Executive Committee finalized the criteria that detail standards and guidance for NABP’s “National Specified List of Susceptible Products” (List) based upon recommendations made by NABP’s National Drug Advisory Coalition (NDAC). Also, in accordance with NDAC’s recommendation, the Executive Committee decided to include Viagra® (sildenafil) on NABP’s List. NABP’s List, which the Association first released in early 2004, was created to help states reduce redundancy and represented a starting point for states that had an imminent need for such direction. In addition, by adopting NABP’s List, states collectively would be able to recognize one national list instead of potentially 50 different lists.

The NDAC is a standing committee that was appointed by NABP’s Executive Committee in accordance with the updated Model Rules for the Licensure of Wholesale Distributors, which is a part of the *Model State Pharmacy Act and Model Rules of the National Association of Boards of Pharmacy*. The Model Rules were released by the NABP Task Force on Counterfeit Drugs and Wholesale Distributors, with the aid of representatives from the pharmacy profession, government, and the wholesale distributor industry, to protect the public from the ill effects of counterfeit drugs and devices. In addition to stricter licensing requirements such as criminal background checks and due diligence procedures prior to wholesale distribution transactions, the Model Rules mandate specific pedigree requirements for products that are particularly prone to adulteration, counterfeiting, or diversion. These products, as defined in the updated Model Rules, are designated as the “National Specified List of Susceptible Products.”

The updated “National Specified List of Susceptible Products” is available on NABP’s Web site at www.nabp.net. NABP’s List criteria that detail standards and guidance (eg, under what circumstances a product will be considered for addition to NABP’s List) are also available on the Association Web’s site and detailed in the February 2005 *NABP Newsletter*.

FDA Announces New CDERLearn Educational Tutorial

The US Food and Drug Administration’s (FDA) Center for Drug Evaluation and Research (CDER) recently announced that its new online educational tutorial “The FDA Process for Approving Generic Drugs” is now available at <http://www.connectlive.com/events/genericdrugs/>.

This seminar provides viewers with an overview of FDA’s role in the generic drug process. The tutorial also discusses various aspects of the Abbreviated New Drug Application (ANDA) process, including how FDA’s approval assures that generic drugs are safe, effective, and high quality drug products.

This program meets the criteria for up to one Accreditation Council for Pharmacy Education contact hour (or 0.1 CEU).

From the Inspectors

Medical Residents and Interns: Medical residents and interns may use the teaching hospital's DEA number when writing CDS prescriptions while working at the teaching hospital. These prescriptions may be filled at outside pharmacies. They must use an internal code number in addition to the DEA number that identifies them. **An intern's prescription must be countersigned by a physician. A resident's prescription does not have to be countersigned.** So that pharmacies can differentiate between a resident and an intern, the University of Oklahoma Health Science Center has asked interns and residents to write either "intern" or "resident" after their name **or** to place an "I" or "R" after the internal code number (ie, AB1234567-012R would be a resident prescription and would not have to be countersigned).

Over-the-Counter (OTC) Pseudoephedrine (PSE) Sales: During inspections, inspectors are observing that not all of the required information is being recorded on OTC PSE sales. We are typically seeing that either the state the patient identification is issued in, the total number of grams or milligrams of PSE, the date of transaction, or the patient signature is not being recorded on these sales. Please review your process on these sales with all pharmacists and pharmacy technicians. Precautions should be taken to ensure that no person purchases more than nine grams in 30 days from each pharmacy.

Compounded Prescription Only and Prescription Generated Products: All compounded products must be prepared at the pharmacy from which they are dispensed or sold. You cannot transfer or sell them to another pharmacy or prescriber for dispensing or resale. This would be considered manufacturing.

Selling Drugs to Physicians or Pharmacies: Retail pharmacies that sell medications to physicians and/or pharmacies must first obtain a drug supplier permit from the Board. Prescribers **may not** write a prescription "For Office Use." Prepare an invoice containing the name and address of purchaser, quantity sold, drug description, price, and date of transaction. Schedule II drugs must be transferred using a DEA Form 222. These records must be readily available for inspection. Drug supplier sales are limited to less than 5% of the total annual sales of the pharmacy.

Rules on USP 797

The Board has been informed that United States Pharmacopeia (USP) will be releasing some exceptions to the requirements of Chapter 797. The Board will not promulgate rules regarding Chapter 797 until after January 2006. If you would like to participate on the committee working on these rules, please notify the Board in writing. **Thanks!**

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.

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 at 4545 Lincoln Blvd, Suite 112, Oklahoma City, OK 73105; fax us at 405/521-3758; or e-mail us at: pharmacy@osbp.state.ok.us.

Board Web site: www.pharmacy.state.ok.us

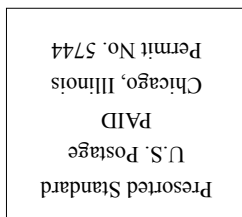
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