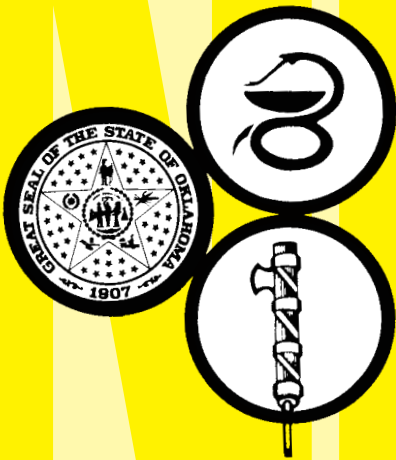


January 2006



Oklahoma State Board of Pharmacy

Published to promote voluntary compliance of pharmacy and drug law.

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Oklahoma City, OK 73105-3488

HAPPY NEW YEAR

- from the Members and Staff of the Oklahoma State Board of Pharmacy

BOARD MEETING – October 26, 2005

Disciplinary Action

Susan Carter, Tech #6506 – Case 749: Charges: Possession of a controlled dangerous substance (CDS) without a valid prescription and theft of merchandise. Permit revoked.

Aaron M. Long, Tech #8461 – Case 755: Charges: Theft. Permit revoked.

Beryl DeVaughan, DPh #5894 – Case 760: Charges: Failing to take appropriate steps to solve a problem identified in a prospective drug review, failing to attempt to address the possible addiction or dependency of a patient to a drug dispensed by the pharmacist, forging or increasing the quantity of a drug in a prescription, providing more than one (1) refill of a CDS at any one time, filling a prescription for a Schedule III or IV drug more than six (6) months after the prescription was issued, failing to properly maintain prescription files. **Respondent's license was placed on probation for four (4) years until October 26, 2009. Respondent shall attend a one (1)-day law seminar in 2005 and 2006. Total fine of \$2,100.**

Lindy Allen Rowland, DPh #10368 – Case 761: Charges: Two (2) or more warning notices in a twelve (12)-month period. **Respondent must view an error correction video and attend a one (1)-day law seminar before December 31, 2006.**

The Board took action in four (4) impaired cases:

Case 754 – Tech #550, was suspended for five (5) years with all of the suspension stayed and placed on probation. Respondent must 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 and request the suspension be removed upon showing two

(2) years continuous compliance with his OPHP contract and positive OPHP recommendation.

Case 603B – DPh #11834, pharmacist license was revoked.

Case 757 – DPh #11265, pharmacist license was revoked.

Case 721 – DPh #7657, appealed to request probation. Respondent must submit to OPHP for a "Fit For Duty" evaluation. If passed, she may practice in a non-dispensing capacity. Respondent must continue with her OPHP contract and provide OPHP with evidence of bipolar disease treatment.

Board Meeting – November 30, 2005

Disciplinary Action

Pamela Lawrence, Tech #994 – Case 759: Charges: Possession of a CDS without a valid prescription and theft of merchandise. Permit revoked.

Jeremy N. Sexton, Tech #6755 – Case 762: Charges: Possession of a CDS without a valid prescription, theft of merchandise and prescription drug abuse. Permit revoked.

The Board took action in one (1) impaired case:

Case 756 – DPh #9982, pharmacist license was suspended indefinitely.

From the Inspectors

◆ Change in Oklahoma Bureau of Narcotics Law and Rules:

- **Marinol®** was changed from Schedule II to Schedule III in Oklahoma as of November 1, 2005.
- Schedule II prescriptions are valid for thirty (30) days. This is an increase from five (5) days. **Note:** The length of time on "partial fills" remains the same – 72 hours (see 475:30-1-7).
- After contacting the prescriber, pharmacists may make the following additions to Schedule II prescriptions: the patient's age, address, the practitioner's Drug Enforcement Administration (DEA) number, and the generic drug name, if used. Also, if the quantity or strength of drug is not indicated, the pharmacist may fill it in after contacting the prescriber. **Note:** Date of prescription **cannot** be added.
- In addition to nursing homes, a Schedule II facsimile prescription may serve as the original prescription for patients in a federally certified hospice program.

Continued on page 4



DEA Releases Final Rule on Approved Narcotic Controlled Substances for Maintenance of Detoxification Treatment

According to the June 23, 2005 *Federal Register*, Drug Enforcement Administration (DEA) has amended its regulations (§1301 and §1306) to allow qualified practitioners not registered as a narcotic treatment program to dispense and prescribe to narcotic-dependent persons Schedule III, IV, and V narcotic controlled drugs approved by Food and Drug Administration (FDA) specifically for use in maintenance or detoxification treatment. This final rule is in response to amendments to the Controlled Substances Act by the Drug Addiction Treatment Act of 2000 (DATA) that are designed to increase and improve the treatment of narcotic addiction. In addition, the final rule is intended to accomplish the goals of DATA while preventing the diversion of Schedule III, IV, and V narcotic drugs approved for maintenance/detoxification treatment. This rule went into effect July 25, 2005.

Additionally, the amended regulations require the practitioner to include on the prescription the identification number or written notice that the practitioner is acting under the good faith exception of §1301.28(e). In order to be valid, a prescription must be written for a legitimate medical purpose by a practitioner acting in the usual course of his or her professional practice. The prescription must also be dated as of, and signed on, the day issued and must contain the full name and address of the patient, the drug name, strength, dosage form, quantity prescribed, directions for use as well as the name, address, and registration number of the practitioner. Practitioners are not normally required to keep records of prescriptions issued, but DEA regulations require records to be kept by practitioners prescribing controlled substances listed in any schedule for maintenance or detoxification treatment of an individual.

Any practitioner who dispenses or prescribes Schedule III, IV, or V narcotic drugs in violation of any of the conditions as specified in §1301.28(b), may have their practitioner's DEA registration revoked in accordance with §1301.36.

Due to the potential for diversion, and in an effort to verify compliance with these regulations, DEA intends to conduct at least two regulatory investigations per field office per year of practitioners dispensing and prescribing to narcotic-dependent persons Schedule III, IV, and V narcotic controlled drugs approved by FDA specifically for use in maintenance or detoxification treatment.

How FDA Reviews Drug Names

By Carol Holquist, RPh, FDA, Office of Drug Safety

FDA has received approximately 18,000 reports of actual or potential medication errors since 1992 and continues to improve the process by which these errors are assessed. Over the past nine years, FDA has increased the safe use of drug products by minimizing user errors attributed to nomenclature, labeling, and/or packaging of drug products. The group in charge of these activities is the Office of Postmarketing Drug Risk Assessment (OPDRA) under FDA's Center for Drug Evaluation and Research. Ten clinical pharmacists and physicians make up OPDRA's medication error staff.

The Name Review Process

Since October 1999, OPDRA has reviewed approximately 400 drug products. Proprietary names undergo a multifactorial review designed to improve consistency and minimize risk due to sound-alike and look-alike names. The process includes:

- ◆ *Expert panel review.* An expert panel meets weekly to exchange opinions on the safety of a new proprietary name. The panel comprises OPDRA medication error prevention staff and representatives from the Division of Drug Marketing and Advertising Communications, who rely on their clinical, regulatory, and professional experiences to decide on the acceptability of a proprietary name.
- ◆ *Handwriting and verbal analysis.* These are conducted within FDA to determine the degree of confusion in visual appearance or pronunciation between the proposed proprietary name and names of other United States drugs. FDA health professionals (nurses, pharmacists, and physicians) are requested to interpret both written inpatient and outpatient prescriptions and verbal orders in an attempt to simulate the Rx ordering process.
- ◆ *Computer-assisted analysis.* Currently, OPDRA utilizes existing FDA databases to identify potential sound-alike and/or look-alike proprietary names. In the future, OPDRA plans to use validated computer software that will improve the ability to detect similarities in spelling and sound among proprietary names.
- ◆ *Labeling and packaging analysis.* OPDRA provides a safety assessment of the container labels, carton and package insert labeling, and proposed packaging of each product to identify areas of potential improvement.
- ◆ *Overall risk evaluation.* This final phase of the name review process weighs the results of each phase of the review as well as additional risk factors such as overlapping strengths, dosage forms, dosing recommendations, indications for use, storage, labeling, and packaging, and important lessons learned from the agency's post-marketing experience.

How Can You Help?

Pharmacists and other health professionals can assist FDA in minimizing medication errors by reporting any actual or potential medication errors to MedWatch, FDA's medical product reporting and safety information program launched in June 1993. All identification of reporter, institution, and patient are kept confidential and are protected from disclosure by the Freedom of Information Act.

Medication errors can easily be reported to MedWatch via telephone (1-800/FDA-1088), Web site (www.fda.gov/medwatch), and fax (1-800/FDA-0178). In addition, a standardized MedWatch adverse event reporting form (FDA Form 3500) is available to aid in submitting voluntary reports of medication errors. You should provide a complete description of the error; level of staff (eg, pharmacist, nurse, physician) involved; medication involved; patient outcome; setting of the incident (eg, inpatient, outpatient); relevant patient information (eg, age and gender); date of event; manufacturer of the drug; dosage form and strength; and size of container. Finally, you will need to check both "Product Problem and/or Adverse Event" and "other" on the form.



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

We also encourage you to include your suggestions for preventing errors. With your contributions to increased reporting and the new processes implemented by OPDRA, the agency can provide effective intervention strategies that will minimize the risks associated with medication errors.

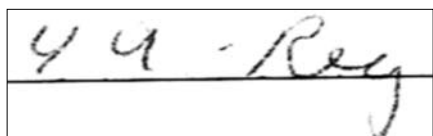
What's wrong with "U"?



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, and 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 use of abbreviations is always problematic when communicating medical information. All too often, medical abbreviations hinder our understanding or are misread. Insulin errors are common and can cause significant patient harm. The cause of many insulin errors is related to the use of abbreviations when communicating prescription information. The abbreviation "U" to indicate "units" has contributed to many errors when it was misread as a zero (0) or a number 4.

Over the years, numerous reports have been received through the USP-ISMP Medication Errors Reporting Program that describe the occurrence of 10-fold or greater overdoses of insulin because the



abbreviation "U" has been misinterpreted. It is not uncommon for a "U" to be misread as a zero (0). For example, prescriptions for "6U regular insulin" have been misinterpreted and administered as 60 units of regular insulin. In another report, a prescriber wrote an order for "4U Reg" (see photo); however, someone misinterpreted the "U" as a "4." The person who injected the insulin did not recognize that this was an excessive dose and proceeded to administer 44 units to the patient. The patient required glucose to reverse his acute hypoglycemia.

In order to prevent errors such as these, health care practitioners should **always** write out the word "units." Educate staff about the dangers involved with using this abbreviation. Practitioners must recognize the need for good communication skills and realize that the perceived time saved when using the abbreviation "U" for units may actually result in serious patient harm. Occasionally, while intending to do the "right thing," errors still can occur. This was the case when a physician wrote a sliding scale insulin order for a hospitalized patient with a blood sugar of 396 mg/dL. When writing the insulin order, the physician included the word "units." According to the order, this patient should have received 4 units of regular insulin subcutaneously. Unfortunately, because the letter "U" in units was separated from

the rest of the word, "-nits," the nurse read the order as 40 units and administered the dose to the patient. His blood sugar dropped to 54 mg/dL and he required dextrose to correct the hypoglycemia. The error was realized when the nursing notes were reviewed and it was documented that 40 units was administered.

Pharmacy and nursing staff must carefully review insulin prescriptions, knowing that errors involving this abbreviation are common and can result in 10-fold or greater overdoses. Clarify any questionable insulin dosages and inform the prescriber of misinterpretations that could occur due to use of the abbreviation "U" for units. In addition, whenever possible, require an independent double check of insulin prescriptions before they are dispensed or administered.

Safeguards for Severe Acne Medication Announced

Because isotretinoin (Accutane[®]) carries significant risks of birth defects for women who are pregnant or might become pregnant, FDA has unveiled safeguards for its distribution. (See related article, March 2005 NABP Newsletter, page 61.) The manufacturers of isotretinoin are launching a program called iPLEDGE[™] in which doctors and patients register with the program and agree to accept certain responsibilities as a condition of prescribing or using the drug. Wholesalers and pharmacies must also comply with the program to be able to distribute and dispense the drug.

In the wake of a February 2004 joint meeting between FDA's Drug Safety and Risk Management Advisory Committee and Ophthalmic Drugs Advisory Committee, major improvements were recommended for the restricted distribution program for isotretinoin, which has proven effective in treating severe recalcitrant nodular acne. Under the recommendations, patients who could become pregnant are to have negative pregnancy testing and birth control counseling before receiving the drug. In addition, patients must complete an informed consent form and obtain counseling about the risks and requirements for safe use of the drug. Starting December 31, 2005, all patients and prescribers must register and comply with requirements for office visits, counseling, birth control, and other program components. After October 31, 2005, wholesalers and pharmacies were required to register with iPLEDGE in order to obtain isotretinoin from a manufacturer.

Program information and registration is available at www.ipledgeprogram.com or 866/495-0654.

For the purpose of increasing available information about isotretinoin and its associated risks, FDA also issued a Public Health Advisory and revised the Patient and Health Care Provider Information Sheets that detail the new patient and practitioner restrictions and responsibilities under the program. A reporting and collection system for serious adverse events associated with the use of the drug has also been established. Pregnancy exposures to isotretinoin must be reported immediately to FDA at the MedWatch phone number (1-800/332-1088), the iPLEDGE pregnancy registry (866/495-0654), or on the iPLEDGE Web site.

Besides approving the iPLEDGE program, FDA approved changes to the existing warnings, patient information, and informed consent form to help patients and prescribers better identify and manage the risks of psychiatric symptoms and depression before and after taking the medication.

Continued from page 1

- ◆ **DEA Form 222:** We are finding that a number of pharmacies do not finish their DEA Form 222 by filling in the quantity and date received.
- ◆ **Expired Stock:** We suggest that pharmacies check their stock for expiration dates. We are seeing out-of-date drugs on the shelves.
- ◆ **Reminder:** Pharmacist licenses and technician permits are now renewed during your birth month. If you do not receive a renewal prior to expiration, it is your responsibility to contact the Board. **Note:** Pharmacies begin monthly renewals in January 2006. Please be sure to keep an eye on the expiration date of your pharmacy license. All renewals are mailed sixty (60) days prior to the date of expiration.
- ◆ **CE:** Continuing education (CE) for pharmacists is still required to be obtained in the **previous calendar year**. For example, the 2006-2007 renewal requires fifteen (15) hours of **2005 CE**.
- ◆ **Technician training current?** Pharmacies must maintain proof of technician training and have it available for inspection. Please take time to check your files that verify your technicians' training. These files will be checked by the inspectors. Also, for those pharmacies that use relief pharmacists, let them know where you keep these files along with CDS invoices and DEA Form 222.
- ◆ **Are your licenses current?** Be sure to monitor expiration dates of all Board licenses and permits posted in your pharmacy, **especially for pharmacy technicians and pharmacists**. It is the responsibility of each registrant to keep the Board informed of any new address, new employment, etc. The inspectors are particularly finding technicians working with expired permits during routine inspections.

Committee Volunteers Needed

The Board needs volunteers for upcoming committee work. We will have two (2) working committees starting in 2006: Compounding Rules Committee (United States Pharmacopeia Chapter 797) and Wholesale Pedigree Rules Committee. If you wish to work on either committee, please fax or e-mail your request to the Board.

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

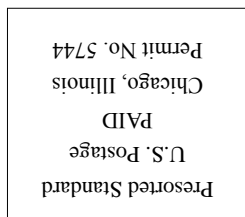
The Board welcomes your comments and questions. You may mail them to the Oklahoma State Board of Pharmacy, 4545 Lincoln Blvd, Ste 112, Oklahoma City, OK 73105, fax us at 405/521-3758, or e-mail us at:

Board e-mail: pharmacy@pharmacy.ok.gov
Board Web site: www.pharmacy.ok.gov

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