

February 2006



# Missouri Board of Pharmacy

Published to promote voluntary compliance of pharmacy and drug law.

PO Box 625, Jefferson City, MO 65102

## Special Notice

The Missouri Board of Pharmacy's *Newsletter* is considered one of the Board's official methods of notification to pharmacists and pharmacies. They have been and will continue to be used in hearings as proof of notification. It is important to read the *Newsletters* carefully and to retain them for future reference.

## Compliance Notes

**Delivery of Drugs:** Observations are being made concerning the delivery of drugs by pharmacies to locations that are not supervised by or involve pharmacy personnel in maintaining control of the drugs until ultimate delivery to the patient or caregiver. Allowing drug deliveries to unregulated locations or to persons who are not designated a caregiver is, in effect, condoning the use of drop sites for deliveries, which is not considered an acceptable practice.

**Audits by Third Parties:** Pharmacies will from time to time be subject to audits of prescription records concerning reimbursement of the pharmacy by third-party entities or their designated representatives such as a pharmacy benefit manager or private consultant. It is important to remember that only those records within the jurisdiction of the third party, due to prior involvement with the ultimate delivery of a prescription, can be legally reviewed. Federal and state confidentiality laws protect patient records from any review process where there is no prior relationship with the third party. Pharmacists and pharmacy permit holders have a duty to safeguard the confidential nature of their records from **any** unauthorized use or review from outside individuals or entities.

**Technician Registrations:** Renewal time for registrations is approaching. Pharmacists-in-Charge (PIC) need to make sure that all technician address changes are updated. Submit changes to the Board via [www.pr.mo.gov/pharmacists-coa.asp](http://www.pr.mo.gov/pharmacists-coa.asp).

**NDC Number:** When using National Drug Code (NDC) numbers within dispensing records of the pharmacy, care must be taken to ensure that only the correct NDC number indicating the proper drug and packaging size is used.

## Ephedrine/Pseudoephedrine

As most readers already know, a law dealing with added controls on ephedrine and pseudoephedrine products went into effect in June 2005. Pure ephedrine and pseudoephedrine were classified under state law as a C-IV substance and products in combination with these drugs in tablet or capsule form were classified as C-V substances. Two issues

of primary importance for pharmacies are the need to maintain a log book of all transactions involving C-V substances and the need to add to the annual controlled substance (CS) inventory all products now falling within the C-IV and C-V classifications. For more information concerning the new law you can check out the Department of Health Web site at [www.dhss.mo.gov/BNDD/index.html](http://www.dhss.mo.gov/BNDD/index.html). Click on the icon "What's New!" for specific information.

## Licensing Actions

### Pharmacists

**Sarah R. Bartelt, #045277**, Maryland Heights, MO—October 23, 2005.

License revoked, cannot reapply for seven (7) years. Violation of previous discipline. Altered a prescription for a C-II CS for her own use. Admitted addiction to CS drugs and continued diversion for personal use. Section 338.055.2 (1), (5), (6), (13), and (15), RSMo 2000.

**Gary W. Grove, #029241**, Springfield, MO – December 1, 2005.

License placed on three (3) years probation. Compounded and dispensed, or supervised the compounding and dispensing of testosterone in oil for injection, and inhalation solutions where patient specific prescriptions did not exist for all the compounded products, nor were they compounded in reasonable anticipation of demand. Required end product testing was not performed on certain compounded products and failed to maintain adequate records on compounded products. Section 338.055.2(5), (6), and (13), RSMo Supp. 2001.

**Stanley J. Martka, #029464**, Wildwood, MO – October 15, 2005.

License placed on five (5) years probation. Participated in defrauding drug manufacturers by falsely claiming that unidentified drugs sent back to the manufacturers for credit had been purchased or possessed by the pharmacy where he served as PIC. Section 338.055.2 (4).

**Thomas J. Mayer, #041915**, Sullivan, MO – October 23, 2005.

License revoked, cannot reapply for seven (7) years. Violation of previous discipline. Drugs and drug paraphernalia were seized by the Franklin County Sheriff's Department from a house he owned; Section 338.055.2 (6) and (15), RSMo 2000.

**Ira R. McCracken, #2001018846**, Billings, MO – September 26,

2005. License placed on six (6) months suspension, followed by five (5) years probation effective October 6, 2005. Violation of discipline; failed to attend counseling appointment, failure to comply with urinalysis testing program, positive urinalysis results,

*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](http://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.

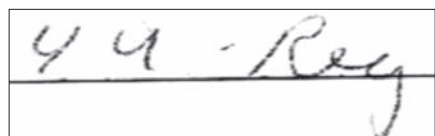
## What's wrong with "U"?



*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](http://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](mailto: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<sup>®</sup>) 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<sup>™</sup> 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](http://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

failed to disclose discipline to employers, failed to conduct initial CS inventories at places of employment, failure to comply with continuing education requirements.

**Gary R. Potts, #029537**, Springfield, MO – October 23, 2005. License suspended for one (1) year followed by probation for five (5) years. Violation of a previous discipline. Did not inform some pharmacies where employed about the terms of his discipline; theft of tramadol from a pharmacy in which he was employed; did not conduct a perpetual inventory of C-II CS at all his places of employment. Section 338.055.2(13), (15), and (17), RSMo 2000.

**Gerald W. Roberts, #029422**, St Louis, MO – October 15, 2005. License placed on five (5) years probation. Participated in defrauding drug manufacturers by falsely claiming that unidentified drugs sent back to the manufacturers for credit had been purchased or possessed by his pharmacy. Section 338.055.2 (4).

**Ashton T. Stute, #043662**, Kearney, MO – December 1, 2005. License placed on two (2) years probation. Compounding violations, recordkeeping violations, compounded a commercially available product, failure to receive physician authorization to compound a particular prescription, unauthorized dispensing. Section 338.055.2(6), (13), and (15), RSMo Supp. 2002.

**Brett F. Williams, #040486**, Chesterfield, MO – October 15, 2005. License suspended for one (1) year followed by five (5) years probation. Owned four Missouri pharmacies that participated in defrauding drug manufacturers by falsely claiming that unidentified drugs sent back to the manufacturers for credit had been purchased or possessed by those pharmacies. Section 338.055.2 (4).

#### Pharmacies

**Clarkson Square Pharmacy, #004170**, Chesterfield, MO – October 15, 2005. License placed on three (3) years probation. Pharmacy participated in defrauding drug manufacturers by falsely claiming that unidentified drugs sent back to the manufacturers for credit had been purchased or possessed by the pharmacy. Section 338.055.2 (4).

**Grove Pharmacy-Home Infusion Division, #005915**, Springfield, MO – December 1, 2005. License placed on three (3) years probation. Compounded and dispensed testosterone in oil for injection, and inhalation solutions where patient-specific prescriptions did not

exist for all the compounded products, nor were they compounded in reasonable anticipation of demand. Required end product testing was not performed on certain compounded products and failed to maintain adequate records on compounded product. Section 338.055.2(5), (6), and (13), RSMo Supp. 2001

**Ladue Pharmacy, #006534**, Ladue, MO – October 15, 2005. License placed on three (3) years probation. Pharmacy participated in defrauding drug manufacturers by falsely claiming that unidentified drugs sent back to the manufacturers for credit had been purchased or possessed by the pharmacy. Section 338.055.2 (4).

**Prescription Plus, Inc, #005326**, St Louis, MO – October 15, 2005. License placed on three (3) years probation. Pharmacy participated in defrauding drug manufacturers by falsely claiming that unidentified drugs sent back to the manufacturers for credit had been purchased or possessed by the pharmacy. Section 338.055.2 (4).

**Standard Drug Company #5, #004712**, St Louis, MO – October 15, 2005. License placed on three (3) years probation. Pharmacy participated in defrauding drug manufacturers by falsely claiming that unidentified drugs sent back to the manufacturers for credit had been purchased or possessed by the pharmacy. Section 338.055.2 (4).

**Williams Pharmacy, Inc, #004884**, University City, MO – October 15, 2005. License placed on three (3) years probation. Pharmacy participated in defrauding drug manufacturers by falsely claiming that unidentified drugs sent back to the manufacturers for credit had been purchased or possessed by the pharmacy. Section 338.055.2 (4).

Page 4 – February 2006

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1600 Feehanville Drive  
Mount Prospect, IL 60056

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