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Arkansas State Board of Pharmacy

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2005 Gold Certificate Recipients

The following pharmacists were honored in 2005 for completing 50 years of licensed service to the citizens of Arkansas and the profession of pharmacy.

Harold J. Ford, PD #4733
Alan Dale Harris, PD #4757
Frank J. Brunner, Jr, PD #4768
Maurice E. Reisz, PD #4774
Donald B. Gatewood, PD #4779
Paul E. Maples, PD #4780
Jack E. Coggins, PD #4781
Nathan Monroe Barrett, PD #4782
Phillip W. Ball, PD #4785
George J. Edwards, PD #4786
James Murray, PD #4787
Charles J. Smets, PD #4797

In addition to being honored during the June 2005 Arkansas Pharmacists Association (APA) Convention, these pharmacists also have seen the last days of having to pay licensing fees to renew their pharmacist licensure. Although these pharmacists must keep up-to-date with their continuing education requirements to continue working in a pharmacy, the APA and the University of Arkansas for Medical Sciences College of Pharmacy have traditionally provided a free, annual Golden Certificate CE program to all pharmacists who have reached this milestone.

The **Pharmacy Practice Act** covers this honor in ACA §17-92-309: Registration and certificate.

(c) The Board may provide by regulation for issuing and waving the renewal fee for pharmacy certificates denoting special recognition for pharmacists who have the following qualifications:
  (1) The pharmacist graduated from a college of pharmacy approved by the [b]oard fifty (50) or more years before the date on which the certificate will be issued; or
  (2) (A) The pharmacist has held an Arkansas pharmacist license for forty-nine (49) continuous years before the date on which the certificate will be issued with out any lapse in the payment of licensure fees.
  (B) However, a pharmacist who has paid fees to reinstate an expired license shall not be deemed to have held a license for continuous years.

Web Site Changes

The Arkansas State Board of Pharmacy Web site at www.arkansas.gov/asbp has had several updates throughout the various links on the home page including recent disciplinary actions and approved minutes added under the "Board News & Events" link and links to Board *Newsletters* for the past five years under the "Pharmacist Information" section. Furthermore, the "Pharmacy Lawbook" area has the most recent copies of every Board Regulation in its current form. Many of you have visited the Web site recently to renew your pharmacist license or pharmacy permit and we hope that you took this chance to look at the things available through the Web site. The Board is currently working toward incorporating the ability to update your contact information through the Board's Web site and also verify licensure status of businesses and individuals. We will notify you when these options are available.

Pharmacist and Pharmacy Renewals

The Board of Pharmacy has been very pleased with the success of online renewal processing through our new licensing software. In fact, as of January 3, 2006, 59% of the pharmacies and 68% of the pharmacists who have renewed have done so online. These totals come in with approximately 61% of all the pharmacies and pharmacists who were sent renewal notices having completed their renewals. For those of you who have taken advantage of this feature, you should have found that the turnaround time for processing online renewals is much shorter as we usually have the permits printed and mailed the business day immediately following the online processing. Many pharmacists have commented that they have received their renewed permit in two or three days after renewing them online.

Reciprocity

During the October 2005 meeting of the Arkansas State Board of Pharmacy, the Board discussed changes to the National Association of Boards of Pharmacy®'s bylaws, which will no longer require licensure transfer applicants to maintain their license by original examination. This practice is often referred to as reciprocating off of a reciprocated license. After discussing the possibility of allowing this practice in Arkansas, the Board decided that Arkansas will continue to allow pharmacists to reciprocate into Arkansas only from an original license obtained by examination and would not allow reciprocation from a reciprocated license. It is important to note that once a license is obtained in Arkansas by reciprocity, the original license used for reciprocity does not have to remain active for the reciprocated license to be valid.

Pharmacy/Wholesaler Ordering

The Arkansas State Board of Pharmacy would like to remind Arkansas pharmacists that you are responsible for making sure that the wholesale companies from which each pharmacy orders are licensed in the state of Arkansas. This responsibility includes generic houses, Internet companies, companies using phone solicitations, and any other companies wanting to sell prescription drug products to a pharmacy. This is the same responsibility that wholesalers have when ensuring a pharmacy is appropriately licensed to receive

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National Pharmacy C

(Applicability of the contents of articles in the National Pharmacy Compli
and can only be ascertained by examining

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 ammended 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 acceptablilty 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); relevent 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.

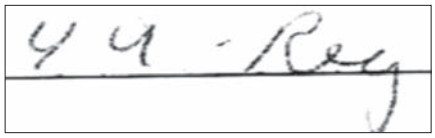
We also encourage you to include your suggestions for preventing errors. With your contributions to increased reporting and the new processes implemented by OPDRA, the agency can provide effective intervention strategies that will minimize the risks associated with medication errors.

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.

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prescription products and controlled substances (CS). Pharmacies may request a copy of the wholesaler's Arkansas Permit or call the Board office to verify licensure.

Provision of Medication Carts to Long-term Care Facilities

The Board office has received inquiries regarding what constitutes the provision of a medication cart by a pharmacy to a long-term care facility "obviously below cost." According to Regulation 02-04-0002 – *Definition of unprofessional or dishonorable conduct by a pharmacist shall mean, among other things, but not limited to:*

(o) The provision of medication carts, printing and maintenance of the [database] to produce the doctor's order sheet or medication administration record, consultation and related services by provider pharmacists to long-term care facilities free of charge or obviously below cost.

A reasonable approach for those facilities that do not desire to purchase the cart on the front end would be to construct a monthly payout schedule in which the initial purchase price plus appropriate interest is recovered over a three-to-four-year billing period. Invoice evidence of these payout schedules must be available to Board inspectors upon request. Total payout should reflect a minimum of acquisition cost plus appropriate interest.

Change of Pharmacist-in-Charge

Regulation 04-02-0005 addresses the requirements for notification of a change in pharmacist-in-charge (PIC). What is often overlooked is that when a pharmacist ceases to be the PIC of a pharmacy, they are required to do the following three things:

1. Notify the Board of Pharmacy within five days that they will no longer be the PIC of that facility;
2. Surrender the permit issued in their name for cancellation; and
3. Provide the Board of Pharmacy with an inventory of controlled drugs for the pharmacy as the ending inventory under their time as PIC. If a new PIC is being identified and submitted simultaneously with the departure of the current PIC, this inventory can serve as the inventory for both the departing and incoming PIC.

The Change of PIC form is the very first form located in the Forms and Instructions section of the Arkansas State Board of Pharmacy Web site.

Lost in Transit

Many pharmacies today are sending medications through a carrier service such as the United States Postal Service, United Parcel Service, Federal Express, or DHL. Any CS sent through these national carrier services, a local delivery service, or a pharmacy owned delivery service is the pharmacy's responsibility until it gets to the patient. If a CS is lost or stolen while in route, you must fill out Drug Enforcement Administration (DEA) Form 106 and notify all concerned agencies in accordance with Arkansas Pharmacy Law and Regulations. This form can be downloaded at www.deadiversion.usdoj.gov; or it can be obtained by contacting the Board office. Specific guidelines on reporting of the theft or loss of CS have been previously published in the December 2005 *Newsletter*.

Special Notice about the Arkansas State Board of Pharmacy Newsletter

The Arkansas State Board of Pharmacy has designated this *Newsletter* as an official method to notify pharmacists licensed by the Board about information and legal developments. Please read this *Newsletter* and keep it for future reference because this *Newsletter* will be used in hearings as proof of notification of the *Newsletter's* contents. Please contact the Board Office (501/682-0190) if you have questions about any of the articles in this *Newsletter*.

Arkansas Pharmacy Support Group Help Line
870/636-0923

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