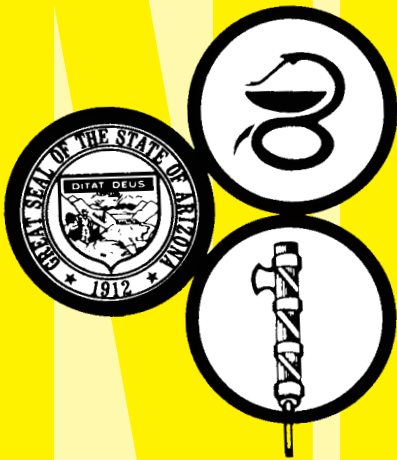


January 2006



Arizona State Board of Pharmacy

4425 W Olive Ave, Suite 140, Glendale, AZ 85302-3844

Web site: www.pharmacy.state.az.us

E-mail: info@azsbp.com

Published to promote voluntary compliance of pharmacy and drug law.

Arizona State Newsletter Switching to E-newsletter Format

Starting with the April 2006 *Newsletter*, the Arizona State Board of Pharmacy will no longer be publishing a printed version of its state *Newsletter*; instead, the *Newsletters* will be offered as an electronic *Newsletter* on the Board's Web site (www.pharmacy.state.az.us), as well as the National Association of Boards of Pharmacy's (NABP®) Web site (www.nabp.net). The reasons for the change are anticipated increased postal rates and the fact that the Board now licenses 8,500 pharmacy technicians, which more than doubles the size of its mailing list. As a result, the cost of mailing to each licensee is no longer justified by the benefits. The Board will send e-mail alerts to its *Newsletter* subscriber list with a link to the *Newsletter*. In this e-mail alert, subscribers will have the option to subscribe or unsubscribe to Arizona's state *Newsletter*; the subscribe/unsubscribe option will also be posted on the Arizona Board's section of the NABP Web site. The Arizona state *Newsletter* is published in January, April, July, and October of each year. Please inform the Board office immediately if your e-mail address has changed.

A Historic Milestone – Governor Appoints Pharmacy Technician as Board Member

On August 10, 2005, Governor Janet Napolitano appointed Louanne Honeyestewa, CPhT, to a five-year term on the Board. Ms Honeyestewa is employed as a pharmacy technician at Scottsdale Select Specialty hospital pharmacy. Ms Honeyestewa is the first technician named to the Board since its inception in 1903 when Arizona was still a territory and not yet a state. The Board and staff look forward to working with Ms Honeyestewa and anticipate that her input, which represents the largest group of Board licensees, will be valuable in discussions on Board policy and strategic planning. There are currently 8,315 licensed technicians and 6,635 licensed pharmacists in our active database.

Congratulations to Evelyn D. Timmons, RPh, FACA, FIACP

Veteran compounding pharmacist Evelyn Timmons was recently awarded an Honorary Fellowship in the International Academy of Compounding Pharmacists (IACP). The award was given in recognition of her lifetime achievements in the profession of pharmacy and especially in pharmacist compounding. The award was presented in April 2005 and was recognition for the time, talent, and treasure Evelyn has provided since the beginning of the organization. Evelyn also served on the Board of Directors, as well as on numerous committees. She has supported the Academy and the Foundation with generous financial contributions and has once again

stepped up to help us charter the IACP's Founders' Council. Evelyn is also currently serving as a member of the Board of Pharmacy's Sterile Compounding Task Force.

Online Pharmacist License Renewal Statistics

Pharmacist license renewals were processed online in 2005 as part of a test program to help the Board staff assess the cost versus the benefits of an online program and to help us prepare to convert to online renewals for additional permits and licenses in 2006. Statistics for the 2005 pilot show that almost 32% or 1,175 of the 3,772 pharmacists eligible for renewal chose to renew online using credit cards and that 423 relief certificates were ordered. The transaction and credit card fees for the service totaled \$3,437.43, which is in line with what the Board has expended on temporary personnel to process paper renewals in past years. The major benefits were reduced license renewal turnaround time and almost no errors because daily electronic reports were automatically downloaded into our database, which eliminates human error from inputting monies received, address, and employment changes. The results were very satisfying in light of the fact that we started the program almost two weeks after the renewal period began due to technical requirements from IBM®, which is the state vendor for online renewal programs. It is the intention of Board staff to expand the program in 2007.

Phoenix Methamphetamine Precursor (Pseudoephedrine) Ordinances

The Phoenix City Council passed two ordinances in September 2005 aimed at reducing production of the dangerous drug crystal methamphetamine (meth). The ordinances took effect on December 6, 2005, regulating the sale and display of some common cold and allergy medications that contain key raw materials used to make meth. The actions followed recommendations from the Crystal Meth Task Force, made up of city, state, neighborhood, and community leaders. Other Arizona cities have passed or are considering similar ordinances.

The Phoenix ordinances require retailers to remove all products containing pseudoephedrine or ephedrine from open-store shelves. Stores can sell the products at registers or behind pharmacy counters. If the products are displayed on shelves, stores may have to forfeit them to police. Stores may request a hearing if police seize the products.

Also, retailers must ask customers for photo identification and customers purchasing the products must write personal information (name, date of birth, address, quantity purchased) in a log book at the store. The log books will be shared with police.

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.

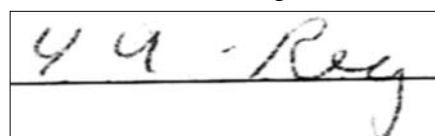
What's wrong with "U?"



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

The city of Phoenix sent letters explaining the ordinances to approximately 1,200 stores that carry the products and has worked on a public outreach campaign to inform residents and businesses of the new regulations.

Visit <http://phoenix.gov/meth>, on the city of Phoenix, Arizona's official website for more information in English and Spanish, including "frequently asked questions" for residents and businesses, log pages to print for use in stores, and the full text of the ordinances, or call 602/275-5886.

Disciplinary Actions – Board of Pharmacy (Actions Since October 2005 Newsletter)

Notice: Before making a prescription-dispensing or other decision pursuant to information in this issue, you are encouraged to verify the current condition of a license with the appropriate licensing agency (Board).

Joseph Ramos – Pharmacy Technician License revoked, Controlled Substance Violations.

Jennifer Force – Pharmacy Technician License suspended for 30 days, followed by a one-year probation, Controlled Substance violations.

Millennium Wholesale (Ivan Walker) – Full Service Wholesale Permit revoked, failure to notify of change of location and current location.

Marta Broksas, RPh – Pharmacist License suspended for 30 days, followed by probation for three years; Civil penalty of \$5,000, Controlled Substance violations.

Kevin Denick, RPh – Pharmacist License revoked, Dispensed prescription-only drugs without valid prescriptions, Controlled Substance violations.

Disciplinary Actions – Other Health Care Practitioner Boards (November 2005)

Notice: Before making a prescription-dispensing or other decision pursuant to information in this issue, you are encouraged to verify the current condition of a license with the appropriate licensing agency (Board).

James Gadd, MD (#8696) – Interim Consent Agreement for Practice Restriction, effective September 15, 2005.

Michael Millette, PA (#2866) – Order Vacating Interim Consent Agreement for Practice. Restriction.

Kenley M. Remen, MD (#30159) – Stayed Revocation and License Suspension, effective August 15, 2005.

Tammy Tadam, MD (#31547) – Summary Suspension of License, effective September 18, 2005.

David Wilbirt, MD (#9920) – Summary Suspension of License, effective September 1, 2005.

John Woods, MD (#19005) – Summary Suspension of License, effective August 31, 2005.

Deborah Golob, MD (#31682) – Lifting of Suspension, effective October 6, 2005.

George Grim, MD (#4632) – Surrender of License, effective October 12, 2005.

Timothy Klein, MD (#32213) – Termination of Non-Disciplinary Probation, effective October 12, 2005.

Paul Aupperle, MD (#30485) – Letter of Reprimand, five-year probation, effective October 12, 2005.

Paul Rodriguez, MD (#4734) – Stayed Suspension and Practice Restriction, effective October 12, 2005.

Parmeshwar Khamre, MD (#12905) – Surrender of License, effective October 12, 2005.

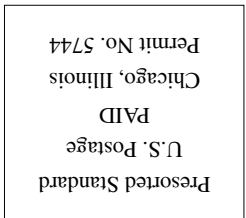
Scott Weiss, MD (#20073) – Letter of Reprimand, effective October 12, 2005.

Linda Vanderbeek, PA (#2867) – Letter of Reprimand, five-year probation, effective October 7, 2005.

Page 4 – January 2006

The *Arizona State Board of Pharmacy News* is published by the Arizona State Board of Pharmacy and the National Association of Boards of Pharmacy Foundation, Inc, to promote voluntary compliance of pharmacy and drug law. The opinions and views expressed in this publication do not necessarily reflect the official views, opinions, or policies of the Foundation or the Board unless expressly so stated.

Harlan "Hal" Wand, RPh - State News Editor
Carmen A. Catizone, MS, RPh, DPh - National News Editor
& Executive Editor
Larissa Doucette - Editorial Manager



ARIZONA STATE BOARD OF PHARMACY
National Association of Boards of Pharmacy Foundation, Inc
1600 Fehamville Drive
Mount Prospect, IL 60056