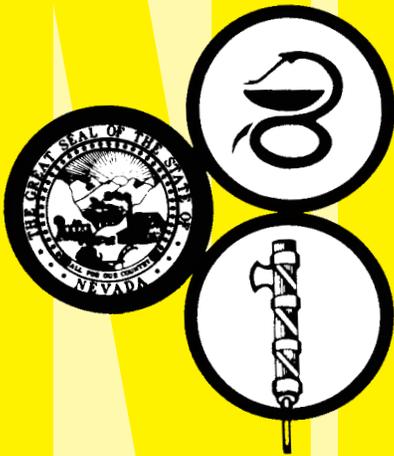


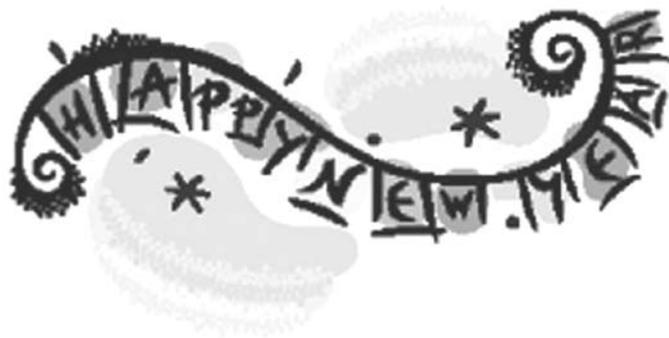
January 2006



Nevada State Board of Pharmacy

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Published to promote voluntary compliance of pharmacy and drug law.



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 Raymond J. Seidlinger, RPh, Las Vegas..... Board Member
 Leo Basch, RPh, Las Vegas Board Member
 Kathryn Craven, RPh, Las Vegas..... Board Member
 J. David Wuest, RPh, Reno Board Member
 Ann Peterson, Reno Board Member

Schedule of 2006 Board Meetings

January 11-12..... Las Vegas
 March 1-2..... Reno
 April 19-20..... Las Vegas
 June 7-8..... Reno
 July 19-20..... Las Vegas
 September 6-7 Reno
 October 25-26 Las Vegas
 December 6-7..... Reno

Board Member Appointments by Governor Guinn

Governor Kenny C. Guinn has reappointed to the Nevada State Board of Pharmacy Raymond J. Seidlinger, RPh, Las Vegas, for a third term. Ray, who is employed by Albertsons/Sav-On, has served the Board for the past six years, unselfishly contributing time, professional knowl-

edge, and some really bad jokes. The Board members and staff welcome him back for yet another stint.

Governor Guinn also appointed to the Board of Pharmacy an old friend of pharmacy for many years, Keith W. Macdonald, RPh, the retired executive secretary of the Board. He replaces Michael A. Triolo, RPh, who elected to not re-apply. The Board and staff acknowledge Michael's contributions to the Board over the past three years and wish him the best in his future endeavors. Keith, a graduate of the University of Utah School of Pharmacy, comes with a storied and fruitful career in pharmacy. A long-time resident of Carson City, Keith began his career in his father's store, Muller's Drug, later opening The Drug Center in 1965. After 25 years serving the public in retail pharmacy, Keith sold his stores and became the chief of Medicaid and later a deputy administrator for the Welfare Division in Nevada. In 1988 he was selected as executive secretary for the Board of Pharmacy, a position he held until his retirement in 2005. The Board and staff feel privileged to have such an experienced professional as a Board member, and look forward to drawing upon his vast knowledge and expertise. Welcome Keith!

Directions for Use

Nevada Administrative Code 453.015 interprets "directions for use" to require a prescription label to specify the dosage, frequency, and route of administration in which a **controlled substance** (CS) is to be taken. Use of the phrase "take as directed" or similar phrase does not satisfy this requirement. Though this requirement applies to CS, it generates frequent inquiries of the Board of Pharmacy office by pharmacists who believe it applies, or should apply, to all prescriptions, not just CS, particularly in our environment where more than 90% of all prescriptions are paid for by a third-party requiring a days' supply for adjudication. The pharmacist must always contact the physician for directions of "as directed" on a CS

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.

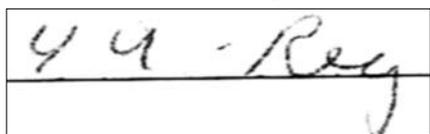
What's wrong with "U"?



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

prescription written, and often he or she must do so to determine days' supply. The Board of Pharmacy recently heard a case involving the death of a patient who overdosed on an narrow therapeutic index drug that was labeled "take as directed." The patient clearly did not understand what was "directed," nor was the counseling adequate. Board staff has communicated this concern to the Nevada Medical Society, where it was included in a recent newsletter, hopefully clarifying the use and dangers of using the sig code "u.d." or "as directed."

Label Expiration Dates

The Board office is still fielding many calls regarding what is now required on a prescription label for an expiration date. There are now two choices: (1) the actual manufacturer's expiration date that appears on the product from which the prescription is dispensed or (2) a date one year from the date of dispensing, if that date is within the actual manufacturer's expiration date. Board staff recommends that the actual manufacturer's expiration date be used on all prescriptions dispensed in an original container to alleviate patient confusion (ie, one date on the label and a different one on the package).

Prescription Transfer

Recent legislation (AB276) requires a registered pharmacist, upon request by a patient, to transmit prescriptions for that patient to another registered pharmacist as long as the prescription is legally transferable. In other words, a pharmacist may **not** refuse to transfer a prescription.

Did You Know?

The most common complaint consumers have to Board staff is not about quality of care, but is related to the conduct of pharmacy staff (pharmacist, technician, or clerk). Lack of attention, disinterest, rudeness, lack of

sensitivity, and lack of counseling are often cited. Board staff recognizes how busy you all are; however, giving some attention and showing some compassion to one's patient goes a long way and certainly will result in fewer complaints to us.

ACPE Accreditation

This is simply to clarify some confusion on Accreditation Council for Pharmacy Education (ACPE) accreditation and drug companies. ACPE has basically decided to not allow a drug company to be an official "ACPE Provider" of continuing education (CE), to eliminate bias. Drug companies, however, may work through other ACPE providers to offer programs with support as a "sponsor," leaving it up to the provider to ensure that no bias exists. In the case of locally sponsored programs where the drug company sets up a program, provides a speaker and refreshments or dinner, it will be up to the drug company to petition the CE Committee of the Board of Pharmacy for accreditation within a 60-day time frame from the offering of the program.

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