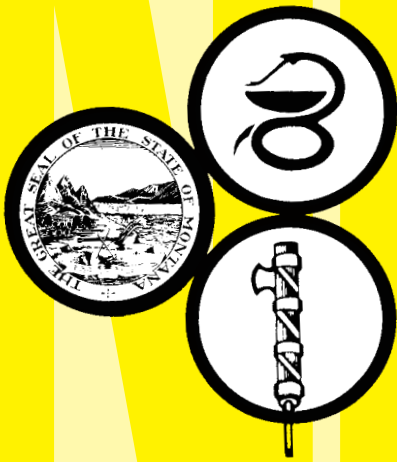


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Montana Board of Pharmacy

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We Extend Our Sincere Sympathy to Tom Mensing

There are few if any pharmacists in Montana who have not been touched in a positive way by Tom Mensing's kindness, dedication, wisdom, and gentle humor, especially during the years Tom, Karen, and the "brown dog" spent visiting the pharmacists and pharmacies of Montana as he served as compliance officer for the Montana Board of Pharmacy. Karen was truly the other half of Tom's soul. She was killed in a vehicle-pedestrian accident in Helena on November 11, 2005. If desired, memorials can be sent to the Red Lodge Community Church, PO Box 786, Red Lodge, MT, 59068 or the Beartooth Cupboard Food Bank, PO Box 665, Red Lodge, MT, 59068. Our thoughts of sympathy go out to Tom and his family.

A Thorny Problem to Ponder

What is the best way to proceed when a patient is admitted to your facility and his or her medications are found to include contraband products? An attorney in the Montana Attorney General's office recently gave a verbal opinion stating that any illicit drug product encountered in the normal course of business should be turned over to local law enforcement personnel. Storing contraband products and returning them to the patient upon discharge is definitely not desirable, nor is wasting and disposing of contraband products within the pharmacy, as you would possibly be implicated in the destruction of potential criminal evidence. If contraband products are turned over to law enforcement, it would be advisable to get a signature of the officer/agency picking them up and a pharmacist signature as well as a description and quantity of the contraband products. Institutional guidelines should be followed regarding patient identification. A subpoena can be requested by law enforcement if necessary.

Controlled Substance Prescriptions

Pharmacists have a responsibility to ensure that controlled substances (CS) are dispensed pursuant to legitimate medical needs while preventing their diversion into the illicit market. Prescription pads can be stolen, quantities on legitimate prescription blanks can be altered, and diverters can occasionally attempt to call in their own prescriptions, giving their own

number as a call back number. Legitimate prescriptions are occasionally copied, and computers can be used to create prescription blanks for nonexistent practitioners, or legitimate practitioners with a different call back number that is answered by an accomplice to verify the "authenticity" of the prescription. The Board of Pharmacy is considering rule wording that would require prescriptions for CS, if written, to be written on a safety blank which would be resistant to tampering and on which "VOID" or a similar message would appear when the original prescription is photocopied. Many states have passed similar rules to date.

In the meantime, continue to be aware of unusual prescription characteristics such as writing that is too neat, a lack of abbreviations, unusually large quantities, or drugs that do not fit into a practitioner's usual prescribing pattern, blanks that appear to have been hand-cut or photocopied, and called-in prescriptions that seem unusual or do not feel "right" in some way. If you believe that you have a forged, altered, or counterfeit prescription, do not dispense it – call the police. An obviously forged or altered prescription should be held for the police, not returned to the patient, unless doing so would jeopardize your safety.

When there is a question concerning any part of a prescription, call the prescriber for verification or clarification. It is good practice to consult the phone book or your pharmacy prescriber list rather than dialing the number printed on the prescription blank. Although not presently required, it is wise to ask for identification when an unknown patient picks up any prescription.

A practitioner who writes significantly more CS prescriptions (or in larger quantities) compared to other practitioners in your area is not necessarily "the enemy." Practitioners who specialize in pain management tend to . . . surprise . . . write large quantities of CS more frequently than most. As long as the practitioner is licensed to prescribe CS and legitimate medical need exists, this should not cause concern. Pharmacists share a corresponding liability with the prescriber to ascertain that CS are not dispensed to patients that do not have a legitimate medical need, and a pharmacist is definitely within his or her authority to call any prescriber to ask about

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.

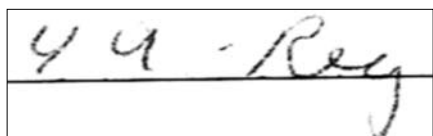
What's wrong with "U"?



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

a patient's treatment plan or offer suggestions regarding drug therapy. The Board of Nursing and the Board of Medical Examiners acknowledge this as well. In legitimate situations, practitioners should be willing to engage with pharmacists whenever a legitimate question or concern exists. The boards of Pharmacy (402/841-2355), Medical Examiners (402/841-2360), and Nursing (402/841-2341) are there to help if you encounter problems. If you believe that you have discovered a pattern of prescription abuse, contact the appropriate board and/or law enforcement promptly.

If patients appear within a short period of time, all bearing similar prescriptions from the same practitioner, that practitioner would appreciate a phone call, just as he or she would if a patient is asking for refills with ever-increasing frequency, even offering to pay with cash if the third-party payer rejects the claim. Consistent requests for early refills could be caused by abuse or diversion, but it is important to remember that the patient who requests refills more frequently than expected could also be suffering from unresolved pain or worsening disease. Avoid knee-jerk reactions. A pharmacist would be wise to talk the situation over with both the patient and the prescriber in such cases, and could make a dramatic difference in the lives of selected patients in doing so.

Pharmacists and physicians within an area should strive to develop a network, or at least a working relationship, to promote teamwork and camaraderie. Discussing potential abuse problems with other pharmacists and physicians in the community is not a violation of the Health Insurance Portability and Accountability Act if done on a need-to-know basis, and such interventions are a vital part of good patient care.

Final Rule: Drug Addiction Treatment Act

On June 23, 2005, a final rule on the Drug Addiction Treatment Act was published. Pursuant to this rule, qualifying physicians (doctor of medicine or doctor of osteopathy) may prescribe a Schedule III-V medication for detoxification and maintenance purposes. Currently, buprenorphine is the only qualifying drug used in this manner. When a physician applies for a waiver, the Department of Health and Human

Services has 45 days to review the application before sending it to Drug Enforcement Administration (DEA). DEA then assigns each qualifying physician a certification DEA number in which the alpha character is replaced with an "X" in the physician's original DEA number. Prescriptions written for buprenorphine for detoxification or maintenance purposes must include both numbers. It is possible for a physician to start treatment of one patient before the 45-day period has expired, provided the physician requested that ability on the original waiver. Pharmacists needing to verify a physician's status can log onto www.buprenorphine.samhsa.gov and click on "physician locator," or call 240/276-2716, as some physicians may not yet have been listed. Practitioners and group practices are limited to treating 30 patients at any one time.

Welcome Jim MacKenzie, Our New Board Member

Jim MacKenzie, RPh, of Whitefish, MT, has accepted an appointment from Governor Brian Schweitzer to serve on the Montana Board of Pharmacy. His term will expire July 1, 2010, and he may be reappointed once at the pleasure of the Governor. Jim replaces Bob Mann, RPh, of Plentywood, who has served the Board with distinction since July 2000. We thank Bob for his time and energy, his common sense approach, and the professional manner in which he has served the citizens of Montana for the past five years. We will miss you, Bob, and we offer a hearty welcome with thanks to Jim MacKenzie, our newest Board member.

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