



# Idaho Board of Pharmacy

Published to promote voluntary compliance of pharmacy and drug law.

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## 50-Year Pharmacists

Congratulations to the following Idaho pharmacists for fifty years of dedicated service. This is certainly a milestone they can be proud of and the Idaho Board of Pharmacy wishes them the very best in their future endeavors.

James Doss .....Las Vegas, NV  
 Robert Parsons.....Boise, ID  
 Clarence Tanaka.....Twin Falls, ID  
 Patrick Damiano .....Pinehurst, ID  
 John Crawford .....Buhl, ID  
 Jack Walker.....Grand Junction, CO  
 Robert Smith.....Nampa, ID

## Continuing Education

Just a reminder that we are in the last third of the fiscal year and you might consider where you are with your continuing education (CE) at this point. Keep in mind that we will be offering a number of law programs in the coming months and they will be posted on the Idaho Board of Pharmacy's Web site at [www.state.id.us/bop](http://www.state.id.us/bop). You may also receive law credit by attending a Board of Pharmacy meeting. Meeting dates are posted on our Web site. Remember that June is a pivotal month so you are able to use all or part of the CE obtained at that time for either 2006 or 2007. The Idaho Board has approved the Pharmacist Self-Assessment Mechanism™ (PSAM™) offered by the National Association of Boards of Pharmacy® (NABP®) as a Board-approved program that will satisfy four (4) hours of Board-approved CE. The PSAM is an evaluation tool that will assist pharmacists in obtaining objective, non-punitive feedback on their individual knowledge of current practice therapies. This program was covered thoroughly in our June 2005 *Newsletter*. For more information about the PSAM, visit [www.nabp.net](http://www.nabp.net) or contact NABP at 847/391-4406 or via e-mail at [custserv@nabp.net](mailto:custserv@nabp.net).

## Spring Renewals

Our spring renewal season is rapidly approaching. Renewal notices will be mailed the last week of April 2006. If you have moved, please notify the Board office as soon as possible. We request notification in writing; you may fax the information to 208/334-2363. Please include your current phone number. If you do not receive a renewal notice by the second week of May 2006, you may download a renewal form from our Web site at [www.state.id.us/bop](http://www.state.id.us/bop) under "Renew a License." Remember it is **your** responsibility to obtain a renewal form and renew your license/registration prior to the expiration date of June 30, 2006.

## Legislation and Rule Changes

Even though this *Newsletter* was drafted at the end of January, we are just beginning our presentations for code and rule changes with outcomes yet to be decided. It is not always the Board that proposes changes that will affect pharmacy but other entities as well. Some-

times we are aware of these proposals and other times we are not. This always makes for an interesting time of year. In the June 2006 *Newsletter* we will give you the outcome of the 2006 legislative session. One bill that is sure to be re-introduced this year will deal with the restricted sale of pseudoephedrine. The final text of the Bill is yet to be decided. We will not know that until it has made its way through the House and the Senate.

## Board of Pharmacy Members

On June 30, 2006, Frank Casabonne, RPh will have completed his second and final five-year term on the Board. The Board has received some calls from pharmacists interested in becoming a board member. By law the Idaho State Pharmacy Association (ISPA) submits a list of names to Governor Dirk Kempthorn of possible candidates for appointment. The Idaho Society of Healthsystem Pharmacists also provide ISPA with names of pharmacists it wishes to submit. If you are interested in serving as a board member and are able to devote the time, you might wish to contact one of the associations.

## FDA Recommendation

This article was published in the November-December 2005 *NABP Newsletter* and the Board believes it is worth passing on.

### Precautions Advised for Inhaler Capsules Mistaken as Pills.

Food and Drug Administration is recommending several precautions to avoid accidental ingestion of capsules intended for use with inhalers that resemble oral medication. While the manufacturers are working on making changes to labeling and packaging to prevent further instances, FDA has issued several precautions for the interim:

- ◆ Avoid dispensing the capsules separately from the inhalation device.
- ◆ If separate dispensing of the capsules cannot be avoided, affix a cautionary label that reads "For Inhalation Use with Special Inhaler Only."
- ◆ Advise patients to store inhaler capsules with the inhaler and away from oral capsules.

## Hospital Pharmacy Staff Guidelines

If a pharmacist's clinical duties require leaving the confines of the hospital pharmacy, an Idaho-registered pharmacist intern/extern, or Idaho registered pharmacy technician can remain in the pharmacy. During this time no other hospital personnel or other persons will be allowed in the pharmacy other than the pharmacist intern/extern or pharmacy technician. No medications will be allowed to leave the pharmacy at that time except by order of and delivery to the pharmacist. If the pharmacist leaves the confines of the hospital, an intern/extern or pharmacy technician will not be allowed in the pharmacy and Board Rules 252.09, 10, and 11 become effective.

**This only applies to hospital pharmacies.**



## **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.

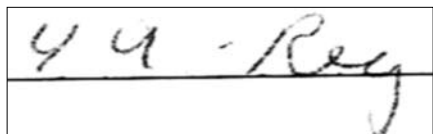
## What's wrong with "U"?



*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®) 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](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.

## Loss of Controlled Substances

The Board of Pharmacy wants to remind you that Drug Enforcement Administration Form 106 must be completed and submitted to the Idaho Board and DEA in accordance with 21 Code of Federal Regulations (CFR) 1301.74 (c) for any theft or significant loss of controlled substances (CS). Section 1301.74 (c) states "The registrant shall notify the Field Division Office of the Administration in his area, in writing, of any theft or significant loss of any [CS] within one business day of discovery of such theft or loss. The Supplier is responsible for reporting in-transit losses of [CS] of this section, within one business day of discovery of such theft or loss. The registrant shall also complete, and submit to the Field Division Office in his area, DEA Form 106 regarding the theft of loss. Thefts and significant losses must be reported whether or not the [CS] are subsequently recovered or the responsible parties are identified and action taken against them. When determining whether a loss is significant, a registrant should consider, among others, the following factors:

1. The actual quantity of [CS] lost in relation to the type of business;
2. The specific [CS] lost;
3. Whether the loss of the [CS] can be associated with access to those [CS] by specific individuals, or whether or not the loss can be attributed to unique activities that may take place involving the [CS];
4. A pattern of losses over a specific time period, whether the losses appear to be random, and the results of efforts taken to resolve the losses; and, if known,
5. Whether the specific [CS] are likely candidates for diversion;
6. Local trends and other indicators of the diversion potential of the missing [CS]."

The Board also encourages all pharmacies to install an alarm system which, upon unauthorized entry, shall transmit a signal directly to a central station protection agency or a local or state police agency, each having a legal duty to respond. The alarm should have a backup system, such as a cellular telephone, that will report the unauthorized entry in the event the telephone lines are cut.

## Rule 162. Prescription Expiration

Note the change in the language from the previous rule regarding expiration of prescription orders from one year to 15 months. "All prescription orders that are legally refillable **must have the refill instructions indicated on the face of the prescription order**. All prescription orders expire fifteen (15) months after date of issue. For long-term medication orders, a new prescription must be obtained and a new file number issued." Remember if you get a prescription

without any refill instructions there are no refills. This went into effect on April 6, 2005.

## Prescribing for Self Prohibited

Idaho Board of Pharmacy Rule 454 states that "No person shall prescribe, administer, or furnish a [CS] for himself." However, some of the medical boards have further restrictions in their statutes or rules. The Board of Medicine has language that includes spouse, child, or stepchild. The Board of Nursing's language includes anyone in the immediate family while the Board of Dentistry's language only indicates prescribing or administering to themselves. Be sure to keep in mind the fact that the dispensing of any medication must be within the practitioner's scope of practice.

## Idaho Rural Health Association

The Idaho Rural Health Association's fifth biennial conference is scheduled for May 5-6, 2006, in Sun Valley, ID. The Idaho Rural Health Association strives to improve the health of rural Idahoans through establishing access to appropriate and equitable health care services and to assist its members in providing leadership on rural issues through advocacy, communication, education, evidence-based research, and community health education. The agenda for the meeting is yet to be completed but will include a number of health care topics that should be of interest to pharmacists. For more information on the conference, you may contact Debbie Dahlquist at the Institute of Rural Health, Campus Box 8174, Idaho State University, Pocatello, ID 83209; phone: 208/282-4560; fax: 208/282-4074.

## Special Notice

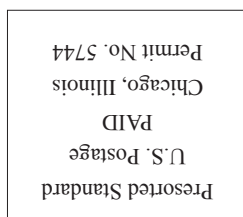
The Idaho Board of Pharmacy *Newsletter* is considered an official method of notification to pharmacies, pharmacists, pharmacy extern and/or interns, and pharmacy technicians registered/licensed by the Board. Please read them carefully. We encourage you to keep them in the back of the Idaho Pharmacy Law book for future reference.

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Page 4 – March 2006

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