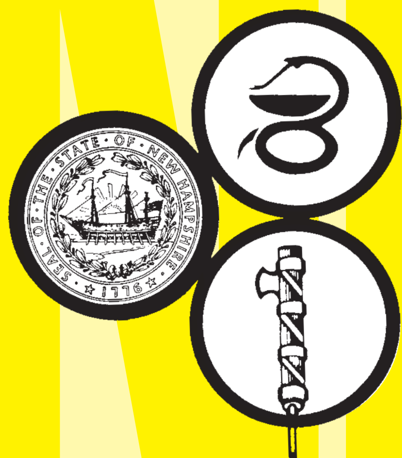
April 2006



New Hampshire Board of Pharmacy

Health and Human Services Bldg
57 Regional Dr, Concord, NH 03301-8518
www.nh.gov/pharmacy

Published to promote voluntary compliance of pharmacy and drug law.

Frank C. Maynard and Board of Pharmacy President Tina Genovese.

Recognition for 50 Years of Service

On December 21, 2005, at a reception hosted by the New Hampshire Board of Pharmacy, two New Hampshire pharmacists were honored for their individual licensure of 50 years. **Frank C. Maynard, Jr, RPh,** West Lebanon, NH, and **Fred N. Oliver, Jr, RPh,** Manchester, NH, both 1955 graduates of the Massachusetts College of Pharmacy and Health Sciences, were presented with a Gold Certificate and a Citation signed by Governor John Lynch.

Bronchodilators – Labeling Aerosols

Pharmacists are reminded that when dispensing bronchodilator aerosols, both the outside carton and the **canister itself** should be labeled. This procedure is especially important when the prescription is issued for younger patients who carry their inhalers in shirt or pant pockets. School Health Services representatives are again reporting "found" canisters on school property (hallways, etc) without any patient-specific identification attached. While it may be easier to affix a label to the outside carton, few, if any, patients — especially children — carry their inhalers in the box.

'Authorized' Technician

With the passage of HB 114, effective July 1, 2005, a number of sections of the New Hampshire Pharmacy Act (RSA 318) and the New Hampshire Controlled Drug Act (RSA 318-B) were amended*.

Of note, the Board wishes to call to your attention an amendment to RSA 318:47-c, Prescriptions, which in part, now reads: "A prescription may be written, oral, or electronically transmitted. All oral prescriptions shall be immediately reduced to writing by the pharmacist **or authorized technician** receiving the oral prescription. . . ."

This amendment was sought in order to provide certain technicians with the authority to accept oral prescription information via the telephone. This authority, once the Board establishes the recognition of **certified** pharmacy technicians and related standards, will allow pharmacists (on duty), to designate **eligible** technicians to accept telephone orders. However, until the Board implements appropriate rules to recognize the certification of certain registered pharmacy technicians, pharmacists are reminded that they are ultimately responsible for any errors resulting from incorrect information entered by technicians directly from the prescriber (or his/her agent) over the telephone.

*A new *New Hampshire Pharmacy Laws and Rules* handbook is currently in production and will be distributed to all New Hampshire licensed pharmacies as soon as it becomes available.

Amended Rules Finalized

A comprehensive initiative to update and amend the Administrative Rules of the Board has been finalized and made effective as of February 23, 2006. Please note, however, that the application of those amendments will not be enforced until all pharmacies have received a current copy of the *New Hampshire Pharmacy Laws and Rules* handbook. Several new and/or amended sections follow:

Ph 704.03 Transmission of Prescription Drug Order by Prescriber

(a) A prescription drug order may be transmitted to a pharmacy by an authorized prescriber or his designated agent in writing, orally or electronically.

(b) An electronically transmitted* prescription drug or device order shall:

(1) Be sent to the pharmacy of the patient's choice;

(2) For a non-controlled substance prescription drug or device order, include:

a. The name of the patient;
b. The name, strength, and quantity of the drug prescribed;
c. Any directions specified by the prescribing practitioner;
d. The name and address of the prescribing practitioner which shall be printed or typewritten;
e. The prescribing practitioner's phone number for verbal confirmation; and
f. The date the prescription was ordered.

***Means by fax or modem-to-modem.**

(3) For a schedule III–IV controlled substance prescription drug order, as defined in RSA 318-B:1-b and transmitted by **facsimile***, include:

a. The name and address of the patient;
b. The name, strength, and quantity of the drug prescribed;
c. Any directions specified by the prescribing practitioner;
d. The full name of the prescribing practitioner, which must be printed, rubber stamped, or typewritten above or below his or her handwritten signature;
e. The address of the prescribing practitioner;

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 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.

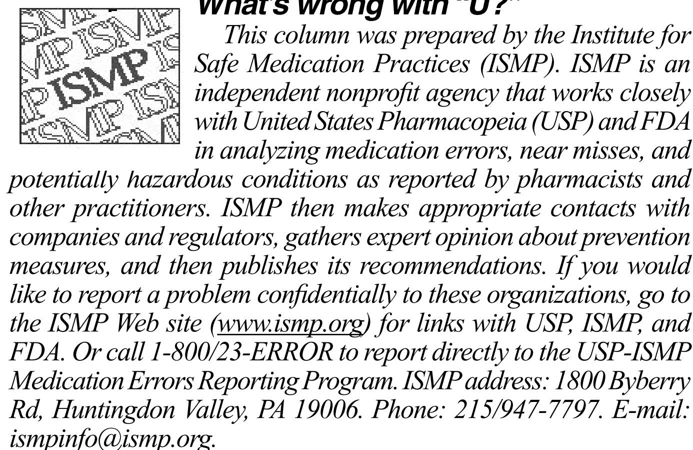
How Can You Help?

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.

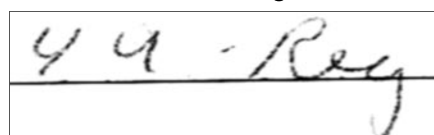
What's wrong with "U?"



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.

Continued from page 1

f. The federal Drug Enforcement Administration (DEA) number assigned to the prescribing practitioner; and
g. The date the prescription was ordered.

***Means by fax only (modem-to-modem is not allowed).**

Ph 704.06 Drug Product Selection is Amended to Read

(b) Therapeutically equivalent drugs shall include only those drug products listed in "Approved Prescription Drug Products with Therapeutic Equivalence Evaluations" published by the United States Department of Health and Human Services, according to RSA 146-B:2, I, **or any written notification or confirmation from the federal Food and Drug Administration (FDA) that a drug product is a therapeutically equivalent drug product.**

(c) The pharmacist shall not select an equivalent drug product:

(1) If the prescriber handwrites "medically necessary" on the written prescription;

(2) If when ordering a prescription orally, the prescriber specifies that the prescribed drug is medically necessary; or

(3) **If the prescription is electronically transmitted, the prescriber includes a statement on the face of the prescription indicating medically necessary.**

(f) Unless the prescriber instructs otherwise, the label for every drug product dispensed shall include the product's trade or brand name, if any, or its established generic name and the name of the manufacturer, packer or distributor, using abbreviations such as the National Drug Code (NDC) number if necessary. In the interest of public health and safety, the pharmacist may, when dispensing a generic drug, include the brand name on the prescription label following the generic name. The brand name, however, shall be preceded or followed with the word "sub", indicating substituted for, or "I.C.", indicating interchanged for, **or "generic for."**

Ph 800 Pharmacy Technicians

Amended Ph 803.01 by adding paragraph (c) to read as follows:

(c) An applicant for registration as a registered pharmacy technician shall meet the following requirements:

(1) Be at least 18 years of age or have a high school or equivalent diploma, or be working to achieve a high school or equivalent diploma;

(2) Be of good moral character;

(3) Shall not have been convicted of a drug-related felony or admitted to sufficient facts to warrant such findings; and

(4) Shall have training or experience as determined by the pharmacist-in-charge.

Amend Ph 807.01 by amending paragraphs (a), (b), (c), and (e) to read as follows:

(a) It shall be the responsibility of the pharmacist-in-charge to identify pharmacy technicians and to [en]sure that such persons are registered with the board as pharmacy technicians within 30 days of employment.

(b) All pharmacy technicians shall wear a name tag, identifying them as a "Pharmacy Technician" while on duty.

(c) The pharmacist on duty shall determine the duties of the pharmacy technician based upon the needs of the pharmacy. Pharmacy technicians shall be limited to performing tasks in the preparation of legend drugs and devices and to provide nonjudgmental technical support services, as defined in Ph 807.01.

(e) The pharmacist shall verify and confirm the correctness, exactness, accuracy, and completeness of the acts, tasks, and functions undertaken by the pharmacy technician who assists the pharmacist in the practice of pharmacy.

The *New Hampshire Board of Pharmacy News* is published by the New Hampshire 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.

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