January 2006

North Carolina Board of Pharmacy

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Item 2093 – Disciplinary Actions

For many years the North Carolina Board of Pharmacy published disciplinary actions in each *Newsletter*. Beginning a few years ago the members instructed staff to list summaries of Board disciplinary actions on the Web site.

Some concern was expressed that these summaries provided insufficient or misleading information and in the fall of 2005 the members instructed staff to begin placing the text of Board orders on the Web site. In December 2005 staff placed copies of orders between 2003 and 2005 on the Web site under "Disciplinary Actions." Any Board action prior to 2003 will be listed as "Past Board Action – Call the Board office for Details." The time period for these actions will be 1985-2002. This will, in essence, list Board history for any pharmacist, technician, pharmacy, or Durable Medical Equipment (DME) facility over a 20 year period.

Item 2094 – Pneumococcal Vaccine

Reports have arrived in the Board office of the potential misuse or overuse of pneumococcal vaccine. The current accepted practice in using this drug is for the administration as a one-time dose if previous vaccination history is unknown. One time re-vaccination is recommended five years later for persons at highest risk of fatal infections. This would include persons with renal disease and persons aged 65 years and older if the first dose was given prior to age 65 and five years or more have elapsed since the previous dose. Ordinarily, there is no need to re-vaccinate after five years.

Reports have arrived in the Board office of more frequent use of this product that would not be justified under current standards.

Item 2095 – Prescription Order Expiration Date

The question has arrived in the Board office as to the existence of an "expiration date" for prescription orders. The only Regulation that would apply to this situation is the one for prescriptions in Schedules III and IV. Federal Regulation 21 CFR Part 1306.22 provides that no prescription for a controlled substance (CS) listed in Schedules III or IV shall be filled or refilled more than six months after the date on which it was issued.

For Schedule II drugs and other prescriptions for non-controlled substances, there is no limit from the date of the prescription's issue and the date of its filling. Therefore, it is possible for a practitioner to issue a prescription for emergency contraception, and this document would still be legal indefinitely. There is, of course, always a judgment factor in the decision by the pharmacist to dispense any prescription.

Item 2096 – New Statutes That Apply to Pharmacy

Three statutes were adopted during the last session of the General Assembly that affect pharmacists and pharmacies. The Pharmacy Quality Assurance Protection Act legislation effective January 1, 2006, provides that each pharmacist-manager must have in place a quality assurance program with records of dispensing errors and measures taken to prevent future errors.

Another statute adopted by the General Assembly is the Methamphetamine Lab Prevention Act of 2005. This new law takes steps to control pseudoephedrine and prevent the conversion of that chemical into methamphetamine. Provisions are made to control the sale of this product in a very similar way to Schedule V over-the-counter products.

The North Carolina Controlled Substance Reporting Act was adopted with an effective date in January 2006. As a practical matter, the system for reporting these transactions is not expected to be up and running until the fall of 2006 at the earliest. This law will require pharmacies to report the dispensing of all prescriptions for CS in Schedules II through V along with 10 pieces of information about each order. Reports are expected monthly with a move to biweekly submissions in the future.

Details on each of these new laws can be found on the Board's Web site under "New Developments."

Item 2097 – Manufacturers and Continuing Education

Several questions have arisen over the ability of pharmaceutical manufacturers to sponsor continuing education (CE). The Accreditation Council for Pharmacy Education (ACPE) has changed its policy and pharmaceutical manufacturers are no longer accredited by ACPE to conduct CE programs. Manufacturers can issue grants for CE programs but cannot control program content or influence speakers.

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and can only be ascertained by examining

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.

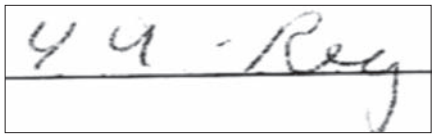
We also encourage you to include your suggestions for preventing errors. With your contributions to increased reporting and the new processes implemented by OPDRA, the agency can provide effective intervention strategies that will minimize the risks associated with medication errors.

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

Item 2098 – Employers See Merit in Board-Certified Technicians

A recent study by the Pharmacy Technician Certification Board reveals that 52% of Board certified technicians are reimbursed by their employer for the certification examination fee.

Item 2099 – Renewal Reminder

The "official" renewal period for 2006 ended December 31, 2005. We are now in the 60-day grace period, which ends February 28, 2006. Be sure to renew your license, permit, or registration in a timely manner (by February 28) to avoid penalty and/or disciplinary action. Pharmacists, technicians, pharmacies, and DME facilities should take advantage of online renewal, which is the fastest way to renew. Go to the Board's Web site at www.ncbop.org and follow the instructions for renewing online.

Item 2100 – Address Changes

It is required by law that any change in residence or work address be reported to the Board within 30 days of the change. Forms are available on the Board's Web site for this purpose or you can send an e-mail to Board staff.

Item 2101 – New Rules

Several new rules have recently become effective and pharmacists should go to the Board's Web site and click on "Law Book" for the latest up-to-date copy which includes rules that have become effective through January 1, 2006.

Item 2102 – Tapered Dosing and Labels

It has been brought to the attention of Board staff that some software programs have reproduced a prescription label for taper dosing in such a way that the patient could begin that cycle anew upon refilling a prescription that is intended to continue as a maintenance dose. Please check your system to be sure that any refills would be at the maintenance dose and not repeat a loading dose instruction.

Item 2103 – Newsletter *as Official Notice*

The North Carolina Board of Pharmacy has designated this *Newsletter* as an official method to notify pharmacists licensed by the Board about information, regulation changes, and legal developments. Please read this *Newsletter* and be aware that it is available on the Board's Web site for reference purposes.

The Board's Web site has copies of this *Newsletter* beginning with January 1997. Information also contains an index of items published in this *Newsletter*.

Item 2104 – New Labeling Law

This is another reminder that beginning in January 2006 Board rules now require the generic name of the product on the label even if no generic product is available.

Board staff also reminds pharmacists dispensing compounded prescriptions that the name of active ingredients needs to be included on the label in generic form. One recent report described a compounded product that contained the name of the drug but not its concentration. This information is essential for treatment by other health care providers.

The *North Carolina Board of Pharmacy News* is published by the North Carolina 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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