

April 2006



# Minnesota Board of Pharmacy

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Published to promote voluntary compliance of pharmacy and drug law.

## **Disciplinary Activity**

The Minnesota Board of Pharmacy took the following disciplinary action concerning a **pharmacist** between the dates of December 1, 2005 and March 1, 2006.

**Schroeder, Clifford E., License #113941-7.** Mr Schroeder successfully completed his probation and the Board granted his petition for an unrestricted license.

The following **pharmacy technicians** had their registration suspended or revoked:

**Cervantes, Joseph R.,** Registration #702251-5

**Dago, Stefano A.,** Registration #710501-8

**Doheny, Dawn G.,** Registration #705406-2

**Wicklund, Byron,** Registration #712308-7

The following **pharmacy technicians** had their registration reinstated: **Coolidge, Nancy J.,** Registration #700376-7; and **Galagher, Mary P.,** Registration #703126-3.

## **Board of Pharmacy Elects New Officers**

At its meeting of January 11, 2006, the Board of Pharmacy elected Pharmacist Vern Kassekert, of White Bear Lake, MN, as Board president for calendar year 2006. Public Member Carleton Crawford, of Minneapolis, MN, was elected as vice president. Mr Kassekert is a pharmacist for Walgreen's in White Bear Lake and has been a Board member since 1999. Mr Crawford is employed as an architect and has been on the Board since 2003.

## **Rural Pharmacy Planning and Transition Grant Program**

During the 2005 session, the Legislature passed, and Governor Tim Pawlenty signed into law, a bill that established a Rural Pharmacy Planning and Transition Grant Program (RPPTGP). The program, which is administered by the Minnesota Department of Health, is designed to preserve access to prescription medication and the skills of a pharmacist in rural areas. Funding is available to support the planning or implementation of projects that improve community access to prescription medication and the skills of a pharmacist. Board Member Betty Johnson, a pharmacist from Elbow Lake, MN, will be the Board's representative on the RPPTGP Review Committee.

## **Continuing Education**

Minnesota pharmacists are reminded that continuing education (CE) reporting is due no later than October 1 of every even-numbered year. There are now approximately six months left during which Minnesota pharmacists can complete and report their CE for the period from October 1, 2004 to September 30, 2006.

Upon completion of at least the required 30 hours of CE, the Certificate of Completion, which was previously mailed to all

pharmacists, should be signed, dated, and returned to the Board of Pharmacy office.

The **Pharmacist Self-Assessment Mechanism™ (PSAM™)** is an online evaluation tool offered by the National Association of Boards of Pharmacy® (NABP®). It consists of 100 multiple choice questions, divided into three sections of equal length. Each section can be completed in as little as one hour; a maximum of three hours per section is allowed. After completing each section, the examinee has the option of completing a "feedback loop." The loop displays each question, the answer chosen by the examinee, the correct answer, a brief explanation justifying the correct answer, and a reference from which additional information can be obtained. Additional information about the PSAM can be found on the NABP Web site at [www.nabp.net](http://www.nabp.net).

At its January 2006 meeting, the Board decided that pharmacists completing the PSAM may be granted six hours of CE credit. However, pharmacists will be granted credit only once every biennial reporting period.

**CE programs sponsored by drug companies.** As of October 1, 2006, the Board of Pharmacy will no longer approve CE programs that are directly conducted or sponsored by drug companies or drug company representatives. Also, the Board will no longer accept drug companies or drug company representatives as Minnesota-approved providers. This change aligns Board policy with the decision of Accreditation Council for Pharmacy Education to no longer approve pharmaceutical and biomedical device manufacturers seeking accreditation as providers of CE.

**Licensure and CE requirements for individuals called to active military duty.** Per Minnesota law, individuals called to active military duty are exempt from the payment of all renewal fees and from the filing of any application for renewal during the time they are on active duty in the armed forces and for a further period of six months after release from active duty. While the law does not specifically mention other licensing requirements such as completion of CE, the Board has concluded that it is probable that the legislature intended that licensing agencies make reasonable accommodations for individuals called to active duty. Therefore, at its November 2005 meeting, the Board decided that individuals called to active military duty will be exempt from the normal CE requirements for the period during which they are on active duty and for a further period of six months after release from active duty.

## **Registration of Pharmacist Interns as Technicians**

In the past, pharmacist interns who on occasion also worked as pharmacy technicians had to be registered as both technicians and

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## **FDA Cautions Consumers About Filling US Prescriptions Abroad**

Food and Drug Administration (FDA) issued a warning to health care professionals and consumers that filling their prescriptions abroad may have adverse health consequences due to the confusion with drug brand names that could inadvertently lead consumers to take the wrong medication for their condition. In an investigation, FDA has found that many foreign medications, although marketed under the same or similar-sounding brand names as those in the United States, contain different active ingredients than in the US. Taking a different active ingredient could potentially harm the user.

FDA found 105 US brand names that have foreign counterparts that look or sound so similar that consumers who fill such prescriptions abroad may receive a drug with the wrong active ingredient. For example, in the United Kingdom, Amyben<sup>®</sup>, a brand name for a drug product containing amiodarone, used to treat abnormal heart rhythms, could be mistaken for Ambien<sup>®</sup>, a US brand name for a sedative. Using Amyben instead of Ambien could have a serious adverse outcome. For more information on this topic visit [www.fda.gov/oc/opacom/reports/confusingnames.html](http://www.fda.gov/oc/opacom/reports/confusingnames.html).

## **Safety Can Not be Sacrificed For Speed**



*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, 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).*

**Problem:** Typically, pharmacies have developed well-established methods for monitoring the accuracy of the dispensing process. But today, pharmacy work is increasingly stressful and these checks and balances can easily be strained beyond capacity. With an increasing number of prescriptions and a shortage of qualified pharmacists, conditions are ripe for potentially unsafe working conditions – long hours without breaks; multitasking between answering phones, overseeing other pharmacy staff, dispensing prescriptions, and counseling patients; and ever-increasing time spent attending to insurance issues. Inevitably, these conditions can increase the chance for dispensing errors.

One pharmacy knows this all too well after a five-year-old boy died as a result of an order entry and medication compounding error that was not caught by the usual verification process. In this case, imipramine was dispensed in a concentration five times greater than prescribed. Imipramine is a tricyclic antidepressant used to treat adults, but it is also used to treat childhood enuresis.

An extemporaneous solution was to be prepared at this pharmacy that specialized in compounded prescriptions since a liquid formulation was not commercially available. A pharmacy technician incorrectly entered the concentration of the prescribed solution into the computer as **50 mg/mL** instead of **50 mg/5 mL**, along with the prescribed directions to give 2 tsp at bedtime. He then proceeded to prepare the solution using the incorrect concentration on the label rather than the concentration indicated on the prescription. When the compound was completed, the technician placed it in a holding area to await a pharmacist's verification. At this time, one of the two pharmacists on duty was at lunch and the high workload of the pharmacy made it difficult for the pharmacist to check the prescription right away. When the child's mother returned to pick up the prescription, the cash register clerk retrieved the prescription from the holding area without telling a pharmacist, and gave it to the mother, unaware that it had not yet been checked. At bedtime, the mother administered 2 tsp of the drug (500 mg instead of the intended 100 mg) to the child. When she went to wake him the next morning, the child was dead. An autopsy confirmed imipramine poisoning.

There are many factors that contributed to this error including inaccurate order entry and issues related to high workload. However, a critical breakdown in safety processes occurred when the cash register clerk took the prescription from the pharmacy holding area (to prevent the mother from waiting any longer for the prescription), thereby circumventing the usual pharmacist verification process.

While this error underscores a growing problem in health care, the problem was clearly evident to this pharmacy owner – even a year before the error occurred. When interviewed for an article that appeared in a national publication, he vented his frustrations about the scant attention paid in our society to pharmacist workload difficulties faced in today's health care environment. On the day of the interview, 49 prescriptions were in the process of being prepared and about a dozen patients were standing in line or wandering around the store waiting for prescriptions. Yet this was a slow day. The owner also said that, while managed care had reduced profits considerably over the past several years, prescription volume had increased 50% (at the time of the error, the pharmacy was dispensing about 10,000 prescriptions per month versus 7,000 per month during the prior year, without an increase in staff) and medication regimens and drug interactions were more complex. To overcome these barriers, the owner added private consultation areas for patient counseling; installed a \$175,000 robot that accurately dispenses the 200 most common drugs; and diversified sales to offset full-time pharmacists' salaries. But these efforts could not have prevented this tragic fatal error that circumvented the normal safety processes.

**Safe Practice Recommendations:** The environment and demands placed on health professionals significantly affect their ability to provide safe health care services. While technology such as robots can help, overstressed professionals cannot consistently perform at the maximum level of safety. Therefore, it is important that the public and health care leadership understand this problem so they can be more open to tradeoffs, such as working

# Compliance News

Compliance News to a particular state or jurisdiction should not be assumed. The law of such state or jurisdiction.)



with one patient at a time and incurring longer turnaround times, which are necessary to enhance patient safety. With a shortage of qualified professionals, we need to demand more rapid adoption of computerized prescribing to reduce time spent with prescription transcription. We should identify the biggest distractions that occur in our workplaces and eliminate or reduce the source by batching common interruptions and reorganizing work areas. Staff members need to be properly trained to understand safety procedures that are in place and know the limits of their specific duties. Fail-safe processes to ensure an independent double check before dispensing medications and performing other critical processes are a must. The pharmacy where this error occurred now requires two pharmacists to check every prescription. Unfortunately, this level of vigilance is typical after a patient has been harmed from an error. In other pharmacies, especially where there is only one pharmacist on duty, technicians may be involved in the double-check process.

A few other strategies can be used to prevent similar errors:

- ◆ Have one person perform order entry and a different person prepare the prescription, if possible, to add an independent validation of the order entry process.
- ◆ Do not prepare prescriptions using only the computer-generated label, as order entry may have been incorrect.
- ◆ Ensure that the original prescription, computer-generated label, prepared product, and manufacturer's product(s) remain together throughout the preparation process.
- ◆ Verify dispensing accuracy by comparing the original prescription with the labeled patient product and the manufacturer's product(s) used.

## **NIH Develops Community Drug Alert Bulletin**

The National Institute on Drug Abuse, as part of the National Institutes of Health (NIH), has developed a new Community Drug Alert Bulletin that addresses the latest scientific research on the non-medical use of prescription drugs of abuse and addiction.

This bulletin is geared toward parents, teachers, counselors, school nurses, and health professionals who are associated with those at risk from prescription drug abuse for non-medical purposes. It summarizes the growing problem in the US and the trend of non-medical use of prescription drugs. For more information on this bulletin visit [www.nida.nih.gov/PrescripAlert/index.html](http://www.nida.nih.gov/PrescripAlert/index.html).

## **Implementation of the Anabolic Steroid Control Act of 2004**

According to the December 16, 2005 *Federal Register*, effective January 20, 2005, the Anabolic Steroid Control Act of 2004 amended the Controlled Substances Act (CSA) and replaced the existing definition of "anabolic steroid" with a new definition. This new definition changed the basis for all future administrative scheduling actions relating to the control of the anabolic steroids as Schedule III controlled substances (CS) by eliminating the requirement to prove muscle growth. Also, the Act lists 59 substances as being anabolic steroids; these substances and their salts, esters, and ethers are Schedule III CS. The Act also revised the language of the CSA requiring exclusion of certain over-the-counter products from regulation as CS.

According to the House Report, the purpose of the Act is "to prevent the abuse of steroids by professional athletes. It will also address the widespread use of steroids and steroid precursors by college, high school, and even middle school students."

The changes to the definition include the following:

- ◆ Correction of the listing of steroid names resulting from the passage of the Anabolic Steroid Control Act of 1990.
- ◆ Replacement of the list of 23 steroids with a list of 59 steroids, including both intrinsically active steroids as well as steroid metabolic precursors.
- ◆ Automatic scheduling of the salts, esters, and ethers of Schedule III anabolic steroids without the need to prove that these salts, esters, or ethers promote muscle growth.
- ◆ Removal of the automatic scheduling of isomers of steroids listed as Schedule III anabolic steroids.
- ◆ Addition of dehydroepiandrosterone to the list of excluded substances.

## **FDA Unveils New Package Insert Format**

On January 18, 2006, FDA unveiled a major revision to the format of prescription drug information, commonly called the package insert, which will give health care professionals clear and concise prescribing information. This new format was developed in order to manage the risks of medication use and reduce medical errors; the new package insert will provide the most up-to-date information in an easy-to-read format. This new format will also make prescription information more accessible for use with electronic prescribing tools and other electronic information resources.

Revised for the first time in more than 25 years, the new format requires that the prescription information for new and recently approved products meet specific graphical requirements and includes the reorganization of critical information so physicians can find the information they need quickly. Some of the more important changes include:

- ◆ A new section called *Highlights* to provide immediate access to the most important prescribing information about benefits and risks.
- ◆ A table of contents for easy reference to detailed safety and efficacy information.
- ◆ The date of initial product approval, making it easier to determine how long a product has been on the market.
- ◆ A toll-free number and Internet reporting information for suspected adverse events to encourage more widespread reporting of suspected side effects.

This new format will be integrated into FDA's other e-Health initiatives and standards-settings through a variety of ongoing initiatives at FDA. For more information please visit [www.fda.gov/cder/regulatory/physLabel/default.htm](http://www.fda.gov/cder/regulatory/physLabel/default.htm).

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interns. At its January 2006 meeting, the Board of Pharmacy approved a change in this policy. As of January 11, 2006, individuals registered as interns in the state of Minnesota no longer need to be registered as technicians in order to work as technicians. Interns cannot receive credit for internship hours while they are working as technicians. If two interns are working at the same time, only one of them can be counted as an intern, unless the pharmacy has received a variance to the 1:1 intern-to-pharmacist ratio. The other must be counted as a technician when determining the technician-to-pharmacist ratio.

### **Cancer Drug Repository Program**

During the 2005 session, the Minnesota Legislature passed, and Governor Pawlenty signed into law, a bill requiring the Board of Pharmacy to establish and maintain a cancer drug repository program (CDRP). Under the CDRP, any person may donate a cancer drug or supply for use by an individual who meets the eligibility criteria specified in the law. Donations must be made to a medical facility or pharmacy that elects to participate in the program and meets the requirements in the law.

Board of Pharmacy surveyors Stu Vandenberg and Les Kotek drafted guidelines for the CDRP and prepared forms titled "Cancer Drug Repository Program Notice of Participation or Withdrawal," "Cancer Drug Repository Program Donation, Transfer, and Destruction Record," and "Cancer Drug Repository Program Recipient Record." The Board of Pharmacy approved the guidelines and forms at its January 2006 meeting. The guidelines and forms can be obtained from the Board's office or downloaded from the Board's Web site at [www.phcybrd.state.mn.us](http://www.phcybrd.state.mn.us).

### **Methamphetamine Precursors – An Update**

In 2005, Minnesota joined the ranks of states that have placed additional restrictions on the methamphetamine precursor drugs ephedrine and pseudoephedrine. Most products containing these drugs, either alone or in combination with other drugs, must now be kept behind the counter and sold only by pharmacists, pharmacy technicians, or pharmacy clerks. Liquid products, liquid-filled gel capsules, and pediatric products labeled for administration to children do not have to be kept behind the counter.

Packages must contain no more than 3 grams of ephedrine or pseudoephedrine, calculated as the base drug, not the salt. For example, Claritin-D® 24-Hour contains 240 mg of pseudoephedrine sulfate, but only 181.8 mg of the base. Consequently, 15 tablets contain 181.8 mg\* 15 = 2727 mg or 2.727 grams of pseudoephedrine base. Two of the 15-count packages of this product would contain about 5.5 grams of pseudoephedrine.

No more than two packages of products containing ephedrine or pseudoephedrine may be sold in a single over-the-counter (OTC) transaction. No person may make OTC purchases of more than two packages, or more than 6 grams, per month. Licensed practitioners who are authorized to prescribe drugs may issue a prescription for larger quantities.

For OTC sales, the pharmacy must require the buyer to provide photographic identification showing the buyer's date of birth. Individuals must be at least 18 years old to purchase products that contain ephedrine or pseudoephedrine. The buyer must sign a paper or electronic document listing the date of the sale, the name of the buyer, and the amount of drug sold. Please be aware, however, that on April 8, 2006, a new federal law regulating pseudoephedrine and ephedrine sales became effective. We will be reviewing this law for conflicts with our state law and reporting back to you with our findings in a future issue of this *Newsletter*.

### **Packaging for Iron-Containing Dietary Supplement and Drug Products**

In 1997, Food and Drug Administration (FDA) issued a rule that required unit-dose packaging for dietary supplement and drug products that contain 30 mg or more of iron per dosage unit. That rule was challenged by the Nutritional Health Alliance, an association including manufacturers and distributors of dietary supplements containing iron. On May 9, 2003, the United States District Court for the Eastern District of New York signed a final judgment declaring the rule to be invalid and without legal force or effect. Therefore, FDA issued a rule on October 17, 2003, removing those parts of the 1997 final rule that required unit-dose packaging for dietary supplement and drug products that contain 30 mg or more of iron per dosage unit. This topic is being included in this *Newsletter* because Board surveyors have received questions from pharmacists about the legal status of bulk packages of products containing iron.

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