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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 actions concerning **pharmacists** between the dates of December 7, 2006 and March 31, 2007.

Lundstad, Lance. Intern Registration #807956. Mr Lundstad, licensed as a pharmacist in Wisconsin, filed an application for licensure by reciprocity. However, his license to practice pharmacy is currently under restriction in that state due to the diversion of controlled substances. The Board will allow Mr Lundstad to take the examination for reciprocal licensure provided that he successfully completes a period of internship. Mr Lundstad will be on probation during his internship, and he will also be placed on probation until December 7, 2010, if he is licensed as a pharmacist by reciprocity.

Mahlendorf, Laura Lee. License #118771. Ms Mahlendorf, licensed as a pharmacist in Montana, filed an application for licensure by reciprocity. However, her license to practice pharmacy is currently under restriction in that state due to the diversion of controlled substances. The Board allowed Ms Mahlendorf to take the examination for reciprocal licensure, which she passed. She will be on probation for a period of five years.

The Board took the following disciplinary actions concerning **technicians** between the dates of December 7, 2006 and March 31, 2007.

The following pharmacy technicians had their registrations revoked:

- **Boulden, Emily, Registration #708649**
- **Klass, Oren K., Registration #700266**
- **Mitoko, Nancy K., Registration #705941**
- **Wingfield, Lynn, Registration #700838**

The following pharmacy technicians had their registrations reinstated:

- **Dago, Stefano A., Registration #710501**
- **Londo, Tammy K., Registration #709134**

Board of Pharmacy Elects New Officers

At its meeting January 10, 2007, the Board of Pharmacy elected Pharmacist Betty Johnson, of Minneapolis, MN, as Board president for calendar year 2007. Pharmacist Gary Schneider, of Plymouth, MN was elected as vice president. Ms Johnson is a pharmacist for Prairiestone Pharmacy in Minneapolis and has been a Board member since 2000. Mr Schneider is vice president of Gallipot, Inc, a distributor of pharmacy chemicals and supplies, and has been on the Board since 2002. Cody Wiberg was also elected to serve as Board secretary (executive director) for an additional year.

Board of Pharmacy Web Site Update

The Board recently upgraded its Web site to allow for the online processing of pharmacist license and technician registration renewals. In addition, employers, licensees, and members of the public can verify the licensure or registration of most individuals and businesses licensed or registered by the Board. Approximately 75% of pharmacists and technicians renewed their license or registration online.

The Board has received a number of comments about the new online services, some positive and some negative. As a result, staff is working with the Board's vendor to make a number of improvements. As just one example, the log in procedure will be changed so that a user identification and password will be required, rather than the social security number. The general design and appearance of the online services pages will also be improved.

Proposed Rules Package

The Board of Pharmacy has been working to update Board rules in many different areas including: Definitions, License Categories, Pharmacy Satellites, Patient Access to Pharmacists, Closing a Pharmacy, Required Reference Books and Equipment, Applications for Licensure, Reciprocal Licensure, Drug Manufacturer or Wholesaler Licensure, Pharmaceutical Waste, Vending Machines, Return of Drugs and Devices, Electronic Prescriptions, Compounding and Dispensing, Transfer of Prescriptions Between Pharmacies, Prepackaging and Labeling, Pharmacy Compounding Practices, Beyond-use Dates, Prescription Labeling, Labeling of Out-patient Intravenous Admixture Drugs, Electronic Data Processing, Schedule III and V Controlled Substances,

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FD&C Act Holds Manufacturers Accountable for Availability of Medication Guides

Under the Federal Food, Drug, and Cosmetic (FD&C) Act, Food and Drug Administration (FDA) requires that Medication Guides be dispensed with products the agency deems a serious and significant public health concern. Medication Guides provide consumers with information about the risks and benefits of these drugs and are necessary for patients to use these products safely and effectively.

FDA is interested in receiving reports about all instances in which manufacturers, distributors, or packers are not complying with the Medication Guide distribution requirements as set forth in Title 21, Code of Federal Regulations (CFR), section 208.24, Distributing and dispensing a Medication Guide.

The regulation requires manufacturers, distributors, or packers to provide authorized dispensers with Medication Guides – or the means to produce Medication Guides – in sufficient numbers to provide one to each patient who receives the drug. The manufacturer is responsible for ensuring that pharmacists have the Medication Guides they need when dispensing these drugs to consumers.

Problems related to the availability of Medication Guides are a labeling concern to FDA, and pharmacists are often the first to become aware of these problems. Voluntary reporting by pharmacists of these instances would assist FDA in ensuring manufacturer, distributor, and packer compliance with the Medication Guide regulatory requirement.

In addition to reporting to FDA, the agency advises pharmacies to contact the manufacturers directly to discuss problems associated with the availability of Medication Guides.

More information is available at *www.fda.gov/medwatch/report/hcp.htm*. Reports can also be made by phone at 1-800/FDA-1088.

Infant Deaths Attributed to Cough and Cold Medications

The Centers for Disease Control and Prevention (CDC) issued a Morbidity and Mortality Weekly Report article describing three deaths of infants ranging in age from one to six months associated with cough and cold medications. These medications were determined by medical examiners or coroners to be the underlying cause of death.

According to the report, the three infants – two boys and one girl – had what appeared to be high levels (4,743 ng/mL to 7,100 ng/mL) of pseudoephedrine in postmortem blood samples. One infant had received both a prescription and an over-the-counter (OTC) cough and cold combination medication at the same time; both medications contained pseudoephedrine.

During 2004-2005, an estimated 1,519 children younger than two years were treated in emergency departments in the United States for adverse events, including overdoses, associated with cough and cold medications.

Because of the risks, parents and caregivers should consult a health care provider before administering cough and cold medications to children in this age group. Clinicians should use caution when prescribing cough and cold medications to children younger than two years. In addition, clinicians and pharmacists should always ask caregivers about their use of OTC combination medications to avoid overdose from multiple medications containing the same ingredient.

The complete article is available at *www.cdc.gov/mmwr/preview/mmwrhtml/mm5601a1.htm.*

Changes in Medication Appearance Should Prompt Investigation

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) 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.

As the number of generic products continues to increase, it seems that both patients and practitioners have become desensitized to changes in medication appearance. So much so that patients may not question a change or, when they do, practitioners may simply reassure them that it was due to a change in manufacturer without actively investigating the reason. It is not uncommon for ISMP to receive reports from both practitioners and consumers where a change in medication appearance was not fully investigated and subsequently contributed to an error.

In one case, a man shared an account of what his 86-year-old father experienced over the course of nine days after his prescription for minoxidil was mistakenly refilled with another medication. He had been taking minoxidil 2.5 mg for years at a dose of 5 mg (2 tablets) twice daily. Due to failing vision, he did not realize that his minoxidil tablets looked different. His daughter noticed the change, but was unconcerned since the tablets had previously changed appearance. Within a few days of taking the medication, his appetite began to fade, he complained of a sore throat, and felt like he was coming down with a cold. Soon after, he developed a red rash on his face, had trouble maintaining his balance, needed assistance with his daily activities, and wished to remain in bed. When a family friend (a nurse) came to see him, she noticed a very red, raised rash on his abdomen that looked like a medication rash. She asked his daughter if he was taking any new medications and was informed that there were no new medications, but the minoxidil tablets looked different than before. The pharmacy was contacted about the change and a staff member explained that it was a different generic for minoxidil, and that the pills could be exchanged for those that he usually received. There was no mention of a mistake being made when the medication was exchanged. He was taken to the hospital the following day, when he could barely walk.

After this incident was explained to hospital staff, they contacted the pharmacy. It was then revealed that he was given methotrexate by mistake because the bottles were stored next to each other. By this time, the man had taken 36 methotrexate 2.5 mg tablets, his white blood cell and platelet counts were extremely low, and he was in critical condition. We later learned that he passed away during that hospital visit.

In another case, a breast cancer patient went to her pharmacy to pick up a refill for **Femara**® (letrozole) but instead received the estrogen replacement product **femhrt**® (norethindrone and ethinyl estradiol). The patient recognized that the tablets were different, but after she read the label on the prescription bottle, which indicated Femara, she proceeded to use the tablets thinking the pharmacy used another manufacturer's product. After some time, she began to experience bloating, low back pain, and menstrual spotting. The error was discovered when she visited the clinic and the practitioner asked to see her medication. It is believed that disease progression had occurred secondary to the estrogen exposure, as evidenced by increased tumor markers. As a result of the error, chemotherapy was restarted.

The nature of these errors (wrong product dispensed on a refilled prescription despite a correct interpretation of the prescription) reinforces the need for the prescription verification process to be standardized. Verification should include comparisons of the pharmacy label with the selected manufacturer's product and the original prescription (whenever possible). In addition, the national drug code (NDC) number on the manufacturer's product should be compared to the NDC number in the pharmacy computer system. Pharmacies that utilize drug-imaging technology or bar code scanners as part of their verification process experience fewer of these errors.

Patients should be made aware of what their medication will look like and be educated to always question any change in its appearance. Pharmacies could consider software that allows a description of the medication's appearance to be printed on either the pharmacy label or receipt. Staff and patients should then be educated about proper use of this method. Ideally, pharmacists should proactively communicate with patients about the appearance of their medication by showing the medication to them during counseling and alerting them whenever a change occurs. Pharmacists should thoroughly investigate questions raised by patients or caregivers. Consider making it mandatory for pharmacists to investigate all inquiries related to changes in medication appearance. Although an auxiliary label can be placed on the medication container or the pharmacy receipt to alert the patient or caregiver that a change in appearance has occurred, the label may go unnoticed.

FDA Launches CDERLearn Educational Tutorial on MedWatch

FDA's Center for Drug Evaluation and Research (CDER) has launched its new Web-based self-learning tutorial, FDA MedWatch and Patient Safety, available at *www.connectlive.com/events/fdamedwatch*. This tutorial is intended to teach students in the health care professions and practicing health care professionals about FDA's Safety Information and Adverse Event Reporting Program, known as MedWatch.

The module explains how MedWatch provides important and timely clinical safety information on medical products, including prescription and OTC drugs, biologics, medical and radiation-emitting devices, and special nutritional products (eg, medical foods, dietary supplements, and infant formulas). It also describes how the reporting of serious adverse events, product quality problems, and product use errors to MedWatch is essential to FDA's safety monitoring process and to improving patients' safe use of medical products. The module consists of a 30-minute video and PowerPoint program with optional quiz and certificate of completion.

Three additional free programs for health professionals are available on the CDERLearn site, on the topics of the drug development and review process, the generic drug review process, and osteoporosis. Continuing education credit for these three programs may be awarded after completion of a quiz and evaluation form.

More information is available at *www.fda.gov/cder/learn/CDERLearn/default.htm*.

ONDCPRA Increases Patient Limit for Physicians Authorized under DATA 2000

The Office of National Drug Control Policy Reauthorization Act of 2006 (ONDCPRA) has modified the restriction on the number of patients a physician authorized under the Drug Addiction Treatment Act of 2000 (DATA 2000) may treat.

Under DATA 2000, physicians were restricted to treating no more than 30 patients at any one time. Under ONDCPRA, which became effective on December 29, 2006, physicians meeting certain criteria may notify the Secretary of Health and Human Services of their need and intent to treat up to 100 patients at any one time.

To be eligible for the increased patient limit: (1) the physician must currently be qualified under DATA 2000; (2) at least one year must have elapsed since the physician submitted the initial notification for authorization; (3) the physician must certify his or her capacity to refer patients for appropriate counseling and other appropriate ancillary services; and (4) the physician must certify that the total number of patients at any one time will not exceed the applicable number.

DATA 2000 allows qualified physicians to dispense or prescribe specifically approved Schedule III, IV, and V narcotic medications for the treatment of opioid addiction in treatment settings other than the traditional opioid treatment program (ie, methadone clinics). In addition, DATA 2000 allows qualified physicians who practice opioid addiction therapy to apply for and receive waivers of the registration requirements defined in the Controlled Substances Act.

More information is available by phone at 866/287-2728, via e-mail at info@buprenorphine.samhsa.gov, or online at *www.buprenorphine.samhsa.gov*.

Deadline Approaches for Pharmacists to Use NPI Numbers

The Administrative Simplification provisions of the Health Insurance Portability and Accountability Act of 1996 (HIPAA) require pharmacists to begin using the National Provider Identifier (NPI) by May 23, 2007. These provisions are intended to improve the efficiency and effectiveness of the electronic transmission of health information. Pharmacists can apply online or print an application for an NPI at *https://nppes.cms.hhs.gov*.

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Registration of Controlled Substance Researchers, Prescription Order Communication, Hospital Pharmacist-in-Charge (PIC), Patient Care, Pharmaceutical Service Policies, Policy and Procedures Manuals, Physical Requirements, Service and Filing of Papers, Variances, Registration of Medical Gas Retailers, and Continuing Pharmaceutical Education.

A hearing on these rules was held on November 14, 2006, before Administrative Law Judge Kathleen Sheehy. Judge Sheehy issued a report of her findings and the Board adopted the report at a special meeting that took place on February 7, 2007. The Office of the Governor has given the Board approval to adopt the rules as amended. The rules still need to be reviewed by the administrative law judge and once again by the Office of the Governor, but formal adoption of the rules should occur very soon. Some of the rule changes are significant, so please visit the Board's Web site for updates.

Pharmacist Interns and Preceptors

Approximately 150 pharmacy students will become eligible to work as pharmacy interns this summer. Many of these students will be seeking employment in order to obtain their required internship hours. Minnesota pharmacists who will be hiring pharmacy students as pharmacist interns over the summer must be sure that students are registered with the Board of Pharmacy as interns and that the pharmacists under whose supervision the interns will be working are properly registered with the Board as pharmacist preceptors. Failure of students to properly register as interns and failure of pharmacists to properly register as preceptors will result in loss of intern hours for the student and the potential for disciplinary action involving the pharmacist.

Please also note that every year individuals are found to be working in Minnesota as interns based on intern registration in another state. Registration as an intern in another state is not valid in Minnesota. A student of a college of pharmacy located in another state, who is employed in a Minnesota pharmacy as an intern, must be registered as an intern in Minnesota.

In order to renew registration as a preceptor, a pharmacist must have participated in an instructional program specifically for preceptors, provided or approved by the Board, within the previous 24 months. At its January 10, 2007 meeting, the Board designated additional continuing education programs as being acceptable for this purpose. Please refer to the "Interns and Preceptors" portion of the Board's Web site for additional information.

Technicians

Board of Pharmacy inspectors continue to report finding pharmacy technicians working without a current technician registration. In some cases, individuals have been allowed to work as technicians for months without being registered. Technicians are reminded that they are **not** allowed to work as pharmacy technicians without valid registration with the Board. For new technicians, original registration must take place **before** employment as a technician commences.

PICs of pharmacies in Minnesota are responsible for assuring that **all** pharmacists, pharmacy technicians, and pharmacist interns are properly licensed or registered with the Board at **all** times. If an individual works in one of those capacities without proper licensure or registration, disciplinary action can be taken against both the PIC and the unlicensed or unregistered individual.

While a PIC no longer has to submit copies of policies and procedures relating to the use of pharmacy technicians to the Board for approval, these documents are still required to be up-to-date and readily accessible to Board of Pharmacy inspectors at the time of their regular inspection visits. In the experience of the Board inspectors, pharmacists frequently cannot find their policies and procedures, the procedures do not accurately reflect what the technicians are actually doing, or the policies and procedures have not been updated within the last five years, as required. Sometimes all of the above are found to be true.

A PIC must make sure that the policies and procedures for the use of technicians at their pharmacy are up-to-date, are readily retrievable, and have been read by all of the pharmacists and technicians employed at the pharmacy.

Scanning Prescription Orders into Computer Systems

Some pharmacies use systems that allow prescription orders to be scanned into computer systems. The scanned image is then used to process the prescription and to verify its validity. Pharmacists are reminded that the use of such systems requires Board approval of a variance to Minnesota Rules 6800.3100, subpart 2. That rule requires that verification of the validity and propriety of a prescription must be of the original prescription. A copy that is rewritten or electronically produced is not acceptable under most circumstances. The Board usually approves variances to this rule, but a pharmacy cannot use such a system before obtaining that approval.

Variance Requests

The Board's Variance Committee, which makes recommendations to the full Board concerning variance requests, meets approximately one week prior to regularly scheduled business meetings. Staff provides copies of the variance requests and supporting documentation to the committee members two weeks prior to the committee meeting. Consequently, variance requests and all supporting documentation must be received in the Board office at least 30 days prior to the Board meeting at which the requestor would like the variance heard. Variances received after the cutoff date will not be heard until the following meeting.

The *Minnesota Board of Pharmacy News* is published by the Minnesota 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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