

July 2008



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 March 6, 2008 and June 4, 2008.

Anderson, Dean A., License #111928. Mr Anderson petitioned the Board to have his stipulation and consent order modified so that he would be allowed to work in a pharmacy or other facility in which controlled substances are handled. The Board granted his request, on the condition that another pharmacist is on duty in the pharmacy or facility whenever Mr Anderson is on duty.

Berglund, Daniel K., License #112539. Mr Berglund admitted to the diversion of controlled substances for personal use. He also acknowledged consuming alcohol in violation of his Health Professionals Services Program participation agreement. He informed the Board that he no longer wanted to practice as a pharmacist and the Board accepted the voluntary surrender of his license.

Samuelson, John T., License #111321. Mr Samuelson admitted that he violated some of the conditions of a stipulation and consent order that was issued by the Board in 2004. He also admitted to violation of state and federal statutes and rules involving the handling and dispensing of controlled substances. The Board suspended his license for 60 days, after which time his license will be placed on probation for an additional three years. The Board also required him to complete continuing education programs covering pharmacy law, to maintain an error log for all controlled substance prescriptions, and to pay a civil penalty of \$1,500.

The following pharmacy technicians had their registrations suspended between March 6, 2008 and June 4, 2008: **Kleis, Diane M., Registration #706649; Johnson, Sarah L., Registration #715502.**

Continuing Education

Minnesota pharmacists are reminded that continuing education reporting is due no later than October 1 of every even-numbered year. There are now approximately three months left during which Minnesota pharmacists can complete and

report their continuing education for the period from October 1, 2006 to September 30, 2008. Upon completion of at least the required 30 hours of continuing education, the Certificate of Completion, which is mailed to all pharmacists, should be signed, dated, and returned to the Board of Pharmacy office.

Governor Pawlenty Appoints Two to Board of Pharmacy

On March 17, 2008, Governor Tim Pawlenty appointed Dr Stacey Jassey and reappointed Ms Kay Hanson to the Board of Pharmacy. Hanson, of Brooklyn Park, is the pharmacy regulatory affairs manager for Target, where she oversees strategies and program development in the areas of education, industry relations, government affairs, and state compliance. She is a graduate of the University of Minnesota College of Pharmacy and has been a licensed pharmacist since 1979.

Jassey, of Maple Grove, has over 20 years of experience in the pharmacy profession. She is a community clinical pharmacist for Walgreens where she also serves as one of the nationwide interpreters for Spanish-speaking Walgreens patients. She is an assistant professor at the University of Minnesota College of Pharmacy, from which she received bachelor of science and doctor of pharmacy degrees. She is replacing Betty Johnson, a member of the Board for eight years who twice served as Board president.

2008 Legislation Affecting Pharmacy

Several laws were passed this year that will have an impact on the practice of pharmacy. Most of the pharmacy provisions in Chapter 321 of 2008 Session Law were drafted by Board staff. However, the change in dispensing authority for nurses was proposed by Planned Parenthood and the provision regarding returns of drugs from jails was proposed by the Association of Minnesota Counties. The Board worked with the Minnesota Pharmacists Association (MPhA) to get the other measures enacted into law. This law has the following provisions:

- ◆ Expands the authority for registered nurses working in family planning clinics to dispense all contraceptives, rather than just oral contraceptives. The dispensing must occur

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A Community Pharmacy Technician's Role in Medication Reduction Strategies



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 Food and Drug Administration (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 publishes its recommendations. To read about the recommendations for prevention of reported errors that you can put into practice today, subscribe to **ISMP Medication Safety Alert!**[®] **Community/Ambulatory Edition** by visiting www.ismp.org. 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: 200 Lakeside Dr, Horsham, PA 19044. Phone: 215/947-7797. E-mail: ismpinfo@ismp.org.

Pharmacy technicians play a major role in community pharmacy practice. The pharmacist relies on the technician to provide an extra layer of safety. It is important for technicians to follow system-based processes and inform the pharmacist when these processes do not work or are unmanageable.

Prescription Drop Off

The date of birth should be written on every hard copy prescription so the pharmacist has a second identifier readily available during verification. Allergy information should be questioned and updated at every patient encounter. Medical condition information, such as pregnancy, communicated to the technician at drop off should be updated in the computerized profile system to help the verification pharmacist determine counseling opportunities. Knowing a person's medical conditions also helps the pharmacist determine if prescriptions are written incorrectly or for the wrong drug.

Data Entry

Medication safety is enhanced when technicians know the particular language of pharmacy when entering a prescription.

New drugs are at a particular risk because it is more likely that the technician is not aware of the new drug and a more familiar drug is selected. Pharmacists and technicians should work together to determine the best method of distributing information regarding availability of new drugs on the market.

It is important that the technician understands the safety features of the computer system and does not create work-arounds to improve efficiency at the risk of decreasing accuracy and safety. Drug alerts can be numerous, and the technician may be inclined to override the alert and not "bother" the pharmacist. A better way to resolve too many alerts would be to establish protocol between the technician and the pharmacist to determine which level and type of alert needs pharmacist intervention.

Production

Mix-ups occur primarily due to incorrectly reading the label. The problem is aggravated by what is referred to as *confirmation bias*. Often a technician chooses a medication container based on a mental picture of the item, whether it be a characteristic of the drug label, the shape and size or color of the container, or the location of the item on a shelf. Consequently the wrong product is picked. Physically separating drugs

with look-alike labels and packaging helps to reduce this contributing factor.

Point of Sale

Correctly filled prescriptions sold to a patient for whom it was not intended is an error that can be avoided by consistent use of a second identifier at the point of sale. Ask the person picking up the prescription to verify the address or in the case of similar names, the date of birth, and compare the answer to the information on the prescription receipt.

Internal errors should be discussed among all staff for training purposes. In addition, it is important to read about and discuss errors and methods of prevention occurring and being employed at other pharmacies within a chain and in other pharmacies, nationwide. ISMP Medication Safety Alert! Community/Ambulatory Edition offers this information to both pharmacists and technicians.

FDA's Effort to Remove Unapproved Drugs From the Market

Pharmacists are often not aware of the unapproved status of some drugs and have continued to unknowingly dispense unapproved drugs because the labeling does not disclose that they lack FDA approval. FDA estimates that there are several thousand unapproved drugs illegally marketed in the United States. FDA is stepping up its efforts to remove unapproved drugs from the market.

Background

There are three categories of unapproved drugs that are on the market. The first category consists of those that have been approved for safety, or that are identical, related, or similar to those drugs, and either have been found not to be effective, or for which FDA has not yet determined that they are effective. Between 1938 (passage of the Federal Food, Drug, and Cosmetic Act) and 1962, manufacturers were only required to demonstrate that drugs were safe; the requirement that they also demonstrate that drugs were effective was added in 1962. Drugs that fall in this category have been part of the DESI (Drug Efficacy Study Implementation) review, which was implemented to determine whether drugs approved between 1938 and 1962, or drugs that are identical, related, or similar to such drugs, met the new effectiveness requirements. While the DESI review is mostly completed, some parts of it are still continuing. The second category of unapproved drugs consists of those drugs that were on the market prior to 1938 (passage of the Federal Food, Drug, and Cosmetic Act). The third category, new unapproved drugs, comprises unapproved drugs that were first marketed (or changed) after 1962. Some also may have already been the subject of a formal agency finding that they are new drugs.

FDA's Concerns About Unapproved Drugs

FDA has serious concerns that drugs marketed without FDA approval may not meet modern standards for safety, effectiveness, manufacturing quality, labeling, and post-market surveillance. For example, FDA-approved drugs must demonstrate that their manufacturing processes can reliably produce drug products of expected identity, strength, quality, and purity. In addition, FDA's review of the applicant's labeling ensures that health care professionals and patients have the information necessary to understand a drug product's risks and its safety and efficacy.

Sponsors that market approved products are subject to more extensive reporting requirements for adverse drug events than sponsors of unapproved drugs. Reporting of adverse events by health care professionals and patients is voluntary, and under-reporting is well documented. FDA, therefore, cannot assume that an unapproved drug is safe or effective simply because it has been marketed for some period of time without reports of serious safety or effectiveness concerns.



Enforcement Priorities

Manufacturers of unapproved drugs are usually fully aware that their drugs are marketed illegally, yet they continue to circumvent the law and put consumers' health at risk.

Most recently, in June 2006, FDA issued a guidance entitled "Marketed Unapproved Drugs – Compliance Policy Guide" (CPG) outlining its enforcement policies aimed at bringing all such drugs into the approval process. (The CPG is available at www.fda.gov/cder/guidance/6911fnl.pdf) The agency provided industry with specific notice that anyone who markets an unapproved drug is subject to enforcement action. This CPG outlines the agency's risk-based enforcement policies aimed at bringing all such drugs into the approval process without imposing undue burdens on consumers or unnecessarily disrupting the market. For all unapproved drugs, the CPG gives highest enforcement priority to the following:

- ◆ Drugs with potential safety concerns
- ◆ Drugs that lack evidence of effectiveness
- ◆ Fraudulent drugs
- ◆ Drugs with formulation changes made as a pretext to avoid enforcement
- ◆ Unapproved drugs that directly compete with an approved drug

Table 1 lists examples of drugs or classes of drugs that, consistent with the CPG, FDA has identified as a higher priority because of safety or other concerns. For six of them, FDA has specifically announced its intention to take enforcement action against companies marketing unapproved versions of those drug products. FDA has withdrawn the approval of the seventh product.

Extended release combination drug products containing guaifenesin (competed with approved products)
Trimethobenzamide hydrochloride suppositories (lacked evidence of effectiveness)
Ergotamine-containing drug products (labeling did not include critical warnings regarding the potential for serious, possibly fatal interactions with other drugs)
Quinine sulfate drug products (665 reports of adverse events, including 93 deaths, and the labeling lacked necessary warnings and safe dosing information)
Carbinoxamine drug products (associated with 21 infant deaths)
Colchicine injectables (50 reports of adverse events, including 23 deaths)

Importance to Pharmacists

FDA is taking steps to ensure that all marketed US drugs have met approval requirements. FDA recognizes that some unapproved drugs may provide benefits; however, since these products have not undergone FDA review for safety and efficacy, the agency recommends that pharmacists, prescribers, and patients carefully consider the medical condition being treated, the patient's previous response to a drug, and the availability of approved alternatives for treatment. FDA will proceed on a case-by-case basis and make every effort to avoid adversely affecting public health, imposing undue burdens on health care professionals and patients, and unnecessarily disrupting the drug supply. More information regarding the FDA's Unapproved Drug Initiative can be found on its Web site: www.fda.gov/cder/drug/unapproved_drugs/.

NABP Educates Public on Buying from Internet Pharmacies with New Section on its Web site

On May 16, 2008, the National Association of Boards of Pharmacy® (NABP®) launched the Internet Pharmacies section of its Web site, educating patients on the potential dangers of buying medicine online and empowering them to make informed choices. As of mid-June, the site listed 250 Internet drug outlets that appear to be out of compliance with state and federal laws or NABP patient safety and pharmacy practice standards, thereby putting those who purchase from these sites in danger of purchasing drugs that could cause patients serious harm or even death.

NABP developed these standards for its new Internet Drug Outlet Identification program with input from its member boards of pharmacy, interested stakeholders, and regulatory agencies, including the FDA and the US Drug Enforcement Administration. Internet drug outlets operating in conflict with these criteria are listed on the NABP Web site as "not recommended." NABP has identified another 300 suspiciously operating Internet drug outlets and is in the process of verifying its findings before posting these sites to the "not recommended" list. Of the hundreds of sites reviewed under this program so far, only nine have been found to be potentially legitimate, pending verification of licensure and other criteria. At this time, NABP recommends that patients buying medicine online use only Internet pharmacies accredited through the VIPPS® (Verified Internet Pharmacy Practice Sites™) program. NABP has verified that these pharmacies are appropriately licensed and have successfully completed the well-recognized and rigorous VIPPS criteria evaluation and on-site inspection. These pharmacies, representing more than 12,000 pharmacies, are listed on the NABP Web site as "recommended."

These lists, along with program criteria and related patient information, are accessible in the Internet Pharmacies section of the NABP Web site.

The new program is an outgrowth of a 2007 NABP resolution, "Internet Pharmacy Public Safety Awareness," in which the Association pledges to continue collaborating with federal agencies and other interested stakeholders to educate the public and health care professionals of the dangers of acquiring drugs illegally through the Internet and from foreign sources. As part of this initiative, NABP will provide information to assist state and federal regulators in their efforts to shut down rogue Internet drug outlets.

RxPatrol Video Helps Pharmacists Address and Prevent Pharmacy Theft

Pharmacy theft is a serious crime that is on the rise, costing pharmacies billions annually in stolen medication according to the Federal Bureau of Investigation (FBI). RxPatrol® has teamed up with Crime Stoppers and other law enforcement officials to disseminate information regarding pharmacy crime. One resource that pharmacists can use to educate themselves and their coworkers is a training video that provides tips for pharmacists to address the rising issue of pharmacy robberies. The video includes interviews with law enforcement officials from the FBI and police department about what can be done to prevent such activity. The video can be found on the RxPatrol Web site at www.rxpatrol.com/videos.asp and by clicking on "Pharmacy Safety – Robbery."

RxPatrol is a collaborative effort between industry and law enforcement designed to collect, collate, analyze and disseminate pharmacy theft information. RxPatrol helps protect the pharmacy environment and ensure legitimate patients' access to life-sustaining medicines.

only pursuant to a protocol established by the medical director or with a physician. Effective August 1, 2008.

- ◆ Establishes that prescriptions or drug orders for controlled substances and certain other drugs (carisoprodol, tramadol, muscle relaxants, erectile dysfunction drugs) are not valid unless the prescriptions or orders are based on a documented patient evaluation, including an in-person examination, adequate to establish a diagnosis and identify underlying conditions and contraindications to treatment. Pharmacists are prohibited from knowingly dispensing invalid prescriptions. This provision is intended to prevent pharmacies and pharmacists from contracting or knowingly working with illegitimate Internet Web sites. This law became effective the day after it was signed by Governor Tim Pawlenty. Pharmacists should be advised that the Board has the authority to pursue disciplinary action against pharmacists and pharmacies involved in the processing of prescriptions that they know originate from illegitimate Web sites. Additional information will be provided in the next *Newsletter*.
- ◆ Officially allows a patient to designate a family member, friend, or caregiver to handle a prescription drug for the patient. Before this change, it was technically unlawful for a person (even a spouse) to pick up someone else's medication at the pharmacy. (Although it obviously occurred all of the time.) This provision is already in effect.
- ◆ Clarifies that pharmacies can redispense medications returned from jails provided certain conditions are met. This provision, which was opposed by the Board, is already in effect.
- ◆ Makes certain changes to the section of the statute involving the controlled substance prescription electronic reporting system that the Board is required to establish. Most notably, it delays implementation until January 1, 2010. The legislation was supposed to expand the program to include Schedule IV controlled substances but that change was inadvertently left out of the legislation. A technical correction to make this change will be pursued next year.

Chapter 189 of 2008 Session Law, a provision proposed by the MPhA, modifies the definition of "practice of pharmacy." Pharmacists will be allowed to administer the influenza vaccine to any person over the age of 10 and to administer any vaccine to adults. This legislation also removes the phrase "case-by-case" from language concerning protocols. (That is, protocols will no longer have to refer to specific patients.) Effective August 1, 2008.

Chapter 358 of 2008 Session Law. Effective January 1, 2011, all providers, group purchasers, prescribers, and dispensers must establish and maintain an electronic prescription drug program that complies with the national standards for transmitting, directly or through an intermediary, prescriptions and prescription-related information using electronic media. This section was developed by the Minnesota Department of Health and deals with what might be called "transactional standards" but does not address "operational

standards." That is, it deals with how electronic prescriptions are transmitted from the prescriber to the dispenser, but does not address how prescriptions are entered into and retrieved from e-prescribing systems. Board staff has been working with MPhA and others on draft legislation to address operational standards.

Chapter 348 of 2008 Session Law provides for registration of naturopathic doctors. However, it specifically **prohibits** naturopathic doctors, even those who will now be registered, from prescribing legend drugs.

Chapter 363 of 2008 Session Law reduces fee-for-service Medicaid ingredient reimbursement from average wholesale price – 12% to average wholesale price – 14%, effective July 1, 2008. It also transfers \$3.219 million from the special revenue fund to the general fund (ie, takes money from the reserve funds of the health-licensing boards, as occurred in 2003). The amount to be transferred from each board has not yet been determined.

The Health Professionals Services Program

The Board typically investigates at least a dozen complaints each year against pharmacists and technicians involved in the alleged diversion of controlled substances, the abuse of alcohol, or the inability to safely practice due to a mental illness. The Board takes such complaints seriously because, left untreated, substance abuse and other mental illnesses can put patients at risk. Fortunately, licensed and registered health professionals can get help before they become the subject of disciplinary action. Created in 1994 as an alternative to Board discipline, the state of Minnesota's Health Professional Services Program (HPSP) offers a proactive way to get confidential help for illnesses.

HPSP evaluates professionals and, if necessary, enters into treatment agreements with them. HPSP monitors treatment progress, work quality, and medications, along with attendance at support groups. Random urine screens (if alcohol or drug use is part of the illness), counseling, work limitations, or other stipulations that address both the professional's needs and public safety might also be required. Typically, agreements are for 36 months. A health professional who self-reports to HPSP and who fulfills the conditions of a participation agreement is not reported to the relevant licensing board.

To learn more about HPSP and how to refer someone who may have an illness call 651/643-2120, visit its Web site at www.hpsp.state.mn.us, or write for information at Energy Park Place, 1380 Energy Park Lane, Suite 202, St Paul, MN 55108.