



Minnesota Board of Pharmacy

Published to promote compliance of pharmacy and drug law

University Park Plaza • 2829 University Ave SE, Suite 530 • Minneapolis, MN 55414-3251
www.pharmacy.state.mn.us

Disciplinary Activity

The Minnesota Board of Pharmacy took the following disciplinary actions concerning pharmacists between the dates of March 20, 2012 and June 20, 2012:

Gilberts, Mark E., License #115330. Mr Gilberts petitioned the Board to have his license reinstated. The Board suspended his license in January 2011 after he admitted to diverting controlled substances from his employer for his personal use. He also admitted that he consumed alcohol while on duty. In support of his petition, Mr Gilberts supplied evidence to the Board demonstrating that he had complied with all of the conditions of his order. Consequently, at its June 20, 2012 meeting, the Board rescinded the January 5, 2011 order and issued a new order for reinstatement. Mr Gilberts must successfully participate in and complete the Health Professionals Services Program (HPSP) before he can petition the Board for an unrestricted license.

Schimming, Angie L., License #116034. Ms Schimming admitted that she violated the terms of her HPSP agreement by failing to provide toxicology screens, failing to provide HPSP with copies of her prescriptions, and by abusing lorazepam by taking doses in excess of the prescribed amount. As a result of these violations, Ms Schimming was unsatisfactorily discharged from HPSP. Discharge from HPSP violated the conditions of an order that the Board had previously imposed. Ms Schimming further admitted that she was charged with gross misdemeanor driving while impaired and felony credit card fraud. Consequently, the Board adopted a stipulation and consent order at its April 4, 2012 meeting, suspending her license for an indefinite period of time.

Swanson, Amy L., License #116161. Ms Swanson admitted to incorrectly certifying a prescription, resulting in a patient receiving mefloquine instead of chloroquine. The pharmacy did not have chloroquine in stock and mefloquine was substituted without the approval of the prescriber. In addition, Ms Swanson admitted that the mefloquine that was initially dispensed had expired before the date of dispensing and was thus an adulterated drug. The patient returned the expired product and it was replaced with unexpired mefloquine, again without the permission of the prescriber. The patient ingested the mefloquine and experienced significant adverse reactions. Consequently, the Board adopted a stipulation and consent order at its May 9, 2012 meeting, reprimanding Ms Swanson and imposing a \$1,000 civil penalty.

Wachtl, Jason R., License #119029. Dr Wachtl petitioned the Board to have certain limitations on his license removed. The Board issued a stipulation and consent order on February 25, 2011, based upon his use of fraudulent prescriptions to obtain controlled substances. In support of his petition, Dr Wachtl supplied evidence to the Board demonstrating that he had complied with all of the conditions of his order. Consequently, at its April 4, 2012 meeting, the Board issued an order of partial reinstatement that removed certain limitations that had been placed on his license. Dr Wachtl may now serve as a preceptor, work as a pharmacist-in-charge, and is not required to have another individual on duty when working in a setting with controlled substances.

The Board took the following disciplinary action concerning a licensed drug wholesaler between the dates of March 12, 2012 and June 20, 2012:

Minnesota Independent Cooperative, License #361687. Minnesota Independent Cooperative admitted that it purchased drugs from B&Y Wholesale Distributors, Inc, a company located in Puerto Rico that was not licensed by the Board as a nonresidential wholesaler at the time that the purchases were made. Consequently, the Board adopted a stipulation and consent order at its April 4, 2012 meeting, reprimanding Minnesota Independent Cooperative and imposing a \$10,000 civil penalty.

Board Member Appointments

On April 20, 2012, Governor Mark Dayton reappointed Kay Hanson as a pharmacist member of the Minnesota Board of Pharmacy. Ms Hanson has over 33 years experience as a registered pharmacist in both independent and chain retail pharmacy. She is currently the pharmacy regulatory affairs manager for Target Corporation. Her focus is business consultation and strategy development for pharmacy programs, analyzing and tracking board of pharmacy proposals and regulations across 48 states, as well as industry relations for Target. She received her bachelor of science degree in pharmacy from the University of Minnesota. She was first appointed in 2004 by Governor Tim Pawlenty.

Governor Dayton also reappointed Bob Goetz as a pharmacist member of the Board. Mr Goetz was initially appointed to the Board on November 15, 2011, to fill out the remaining six weeks of the term of former Board member, Stacey Jassey. On April 20, 2012, Mr Goetz was appointed by the governor to a full term. Mr Goetz is from Red Wing, MN, and has over 41 years of experience as a registered

Continued on page 4



FDA Warned Medical Practices About Counterfeits in US and Risks to Patients

In April 2012, Food and Drug Administration (FDA) sent letters to medical practices in several states requesting that they stop administering drugs purchased from any foreign or unlicensed source. FDA's letters were sent in response to the discovery that the medical practices purchased medications from foreign or unlicensed suppliers that sold illegal prescription medications. FDA has advised that these medical practices are putting patients at risk of exposure to medications that may be counterfeit, contaminated, improperly stored and transported, ineffective, and dangerous.

In an FDA statement, the agency urges the health care community "to examine their purchasing practices to ensure that they buy directly from the manufacturer or from licensed wholesale drug distributors in the United States." Further, FDA reminds health care providers, pharmacies, and wholesalers/distributors that they are valuable partners in protecting consumers from the threat of unsafe or ineffective products that may be stolen, counterfeit, contaminated, or improperly stored and transported. FDA advises that the receipt of suspicious or unsolicited offers from unknown suppliers should be questioned, and extra caution should be taken when considering such offers.

FDA notes that the "Verify Wholesale Drug Distributor Licenses" FDA Web page, available at www.fda.gov/Drugs/DrugSafety/DrugIntegrityandSupplyChainSecurity/ucm281446.htm, may be used to verify that a wholesale drug distributor is licensed in the state(s) where it is conducting business.

The FDA warning letters were sent following two incidences of counterfeit injectable cancer drugs found in US medical practices, one in February 2012, involving counterfeit Avastin® 400 mg/16 mL, and another in April 2012, involving a counterfeit version of Roche's Altuzan® 400 mg/16 ml (bevacizumab).

More information and a list of the medical practices that were sent warning letters are available on the FDA Web site at www.fda.gov/Drugs/DrugSafety/DrugIntegrityandSupplyChainSecurity/ucm299920.htm.

Rethink the Vial



This column was prepared by the Institute for Safe Medication Practices (ISMP). ISMP is an independent nonprofit agency that analyzes 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 risk reduction strategies that you can put into practice today, subscribe to ISMP Medication Safety Alert!® Community/Ambulatory Care Edition by visiting www.ismp.org. ISMP is a federally certified patient safety organization, providing legal protection and confidentiality for submitted patient safety data and error reports. ISMP is also an FDA MedWatch partner. Call 1-800/FAIL-SAF(E) to report medication errors to the ISMP Medication Errors Reporting Program or report online at www.ismp.org. ISMP address: 200 Lakeside Dr, Suite 200, Horsham, PA 19044. Phone: 215/947-7797. E-mail: ismpinfo@ismp.org.

Recently, ISMP has been receiving many reports from consumers who report the pharmacy "shorted them" on a variety of opioid pre-

scriptions. They report that when they call the pharmacy to complain about the missing number of tablets or capsules the pharmacy staff insists the proper quantity was dispensed. ISMP also receives reports from pharmacists reporting this same situation. The concern is that pharmacy personnel may be diverting the medication, the patient may be seeking more medication than what was prescribed, or some of the medication may be taken by someone else in the patient's home.

In the US, we dispense almost all oral solid drugs as loose tablets or capsules in a plastic vial that is labeled for the patient. This manner of dispensing makes diversion of a few tablets or capsules relatively easy. However, in many other countries, unit-dose and unit-of-use packaging is widely used.

It seems to reason that if unit-of-use, manufacturer-sealed containers or individual unit-dose packages of medications were used in the US for these drugs, diversion and/or speculation of diversion could be reduced. Manufacturers could produce unit-dose or unit-of-use packages, in numbered strips for ease of inventory and dispensing. Patients could be asked to sign for and agree to the amount dispensed at the point-of-sale. The numbered packaging would also help patients at home know if they had taken their medication or possibly alert them to diversion within their home. Of course, prescribers would need to prescribe quantities available in patient compliance packs or in multiples of that packaging, and insurance companies would have to pay for this specialized packaging.

Unit-of-use packs would provide other safety benefits. For example, patients would be able to verify the drug name on the label for each dose, which would add a redundancy in checking the pharmacy label to what was actually dispensed. Also, the manufacturer could print and attach the patient information sheet and/or medication guide to the package the patient receives, eliminating extra work in the pharmacy to print and supply these mandated education sheets to the patient.

It is evident that further steps must be taken to reduce and minimize abuse of prescription drugs. It is critical that education be provided to patients, caregivers, and health care providers to increase awareness about the dangers of prescription drug abuse and about ways to appropriately prescribe, dispense, store, and dispose of prescription medications. Development and deployment of consumer-friendly and environmentally responsible prescription drug disposal programs may also help to limit diversion (as well as reduce the risk of accidental ingestion) of drugs by family members and friends. FDA must continue its efforts to require new concepts for risk evaluation and mitigation strategies and provider education for opioid drugs. For more information on understanding prescription drug abuse, and to request Parents' Guide to Understanding Prescription Drug Abuse brochures for distribution to your patients, visit www.SafeguardMyMeds.org.

Counterfeit Vicodin ES Sold Via Rogue Internet Drug Outlet, Abbott Reports

In March 2012, Abbott warned consumers and health care providers about counterfeit Vicodin® ES purchased via the Internet. Abbott reports that the counterfeit product drug and package do not match that of Abbott's FDA-approved Vicodin ES (hydrocodone bitartrate and acetaminophen). Descriptions and images of the counterfeit product and authentic Vicodin ES are shown in a consumer alert posted on the Abbott Web site at www.abbott.com/vicodin-consumer-alert.htm. Abbott advises that anyone who has the counterfeit ver-



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

sion should stop taking the product. Further, consumers who suspect a product to be counterfeit or have questions about the legitimacy of Vicodin ES are encouraged to make a report to FDA Office of Criminal Investigations (OCI) by calling 800/551-3989 or by completing the online form on the OCI Web site at www.accessdata.fda.gov/scripts/email/oc/oci/contact.cfm.

PSM LEADER's Guide Offers Tips for Protecting Patients from Counterfeits

The Partnership for Safe Medicines (PSM) released a guide to assist health care providers in protecting patients from counterfeit drugs and recognizing the signs that may indicate use of counterfeits. Three versions of the *LEADER's Guide* – including one for nurses, one for doctors, and another specific to pharmacists – are available for download from the PSM Web site at www.safemedicines.org/resources-for-healthcare-professionals.html. Each guide provides tips specific to these health care provider roles and includes guidance for safe sourcing of medications, evaluating suspect medications, educating patients about counterfeit drugs and the risks of ordering drugs online, and reporting suspected counterfeit drugs.

FDA Urges Providers to Help Prevent Children's Accidental Exposure to Fentanyl Patches

FDA issued a safety alert reminding patients, caregivers, and health care providers to appropriately store, use, and dispose of fentanyl patches to prevent children's accidental exposure to the medication, which is potentially life-threatening. FDA recently evaluated a series of 26 cases of pediatric accidental exposures to fentanyl patches reported over the past 15 years, and determined that 10 of the cases resulted in death, and 12 in hospitalization. In addition, 16 of the 26 cases occurred in children two years old or younger.

FDA warns that young children may be at risk for accidental exposure when fentanyl patches are discarded in trash receptacles, or when children find lost or improperly stored patches. Young children can be harmed when they place the patches in their mouths or stick the patches to their skin. In addition, young children are at risk of exposure when being held by someone wearing a partially detached patch that can then transfer to the child. Exposure of young children to a fentanyl patch can lead to serious adverse events and even death, due to the amount of fentanyl present in the patches. FDA stresses that harm can even occur with used patches because they may still contain a considerable amount of fentanyl.

To prevent accidental exposure, FDA advises that patients securely store needed fentanyl patches out of children's reach and sight. When applying a patch, FDA also recommends that patients consider covering the fentanyl patch with an adhesive film to make sure the patch does not come off. Finally, FDA recommends checking throughout the day to make sure that the patch is still in place.

Further, FDA advises that used or unneeded patches are properly disposed. FDA recommends that the adhesive side of the patch should be folded together and then the patch should be flushed down the toilet. FDA notes that the agency "recognizes that there are environmental concerns about flushing medicines down the toilet. However, FDA believes that the risk associated with accidental exposure to this strong narcotic medicine outweighs any potential risk associated with disposal by flushing. When the patches are no longer needed, disposing by flushing completely eliminates the risk of harm to people in the home."

FDA urges health care providers to educate patients and their caregivers about the appropriate use and disposal of fentanyl patches. FDA's consumer Web page provides detailed information for patients and caregivers and is available at www.fda.gov/ForConsumers/ConsumerUpdates/ucm300803.htm. Providers, patients, and caregivers are also encouraged to review the fentanyl patch product label for instructions. The FDA safety alert is available at www.fda.gov/Drugs/DrugSafety/ucm300747.htm. Additional consumer information about safe medication use and storage, and the importance of proper disposal of unneeded medications, is available on the AWARE_xE[®] Web site at www.awarerx.org/informedSiteMap.php.

Providers Asked to Advise Patients of Acetaminophen Safe Use Steps

With a world of conditions and hundreds of medicines, the Acetaminophen Awareness Coalition asks pharmacists and other health care providers to educate patients and caregivers about the proper use of medications containing acetaminophen. As the most common drug ingredient in America, acetaminophen can be found in over 600 medicines, including many prescription and over-the-counter medicines. The coalition notes that when used as directed, acetaminophen is safe and effective. The coalition asks providers to advise patients that there is a daily dosage limit for acetaminophen and that taking more than directed is an overdose and can lead to liver damage.

The coalition calls on health care providers to participate in the Know Your Dose campaign, by reminding all patients and caregivers to (1) always read and follow the labels on their medicines; (2) know if a medicine contains acetaminophen; and (3) never take or administer two medicines that contain acetaminophen at the same time. Additional medication safety tips for consumers and more information about the Know Your Dose campaign are available on the "OTC Medication Use" page of the AWARE_xE Web site at www.awarerx.org/OTCMedUse.php. The AWARE_xE consumer protection program and the National Association of Boards of Pharmacy[®] (NABP[®]) are part of the Acetaminophen Awareness Coalition.



Pharmacists & Technicians:
Don't Miss Out on Valuable CPE Credit.
Set Up Your NABP e-Profile and Register for CPE Monitor Today!

CPE Monitor™ integration is underway. Soon all Accreditation Council for Pharmacy Education (ACPE)-accredited providers will require you to submit your NABP e-Profile ID, assigned when you set up your NABP e-Profile, along with your date of birth (MMDD), in order to obtain continuing pharmacy education (CPE) credit for any ACPE-accredited activity. Many have already begun to do so.

Visit www.MyCPEmonitor.net to set up your e-Profile and register for CPE Monitor and avoid possible delays in your CPE reporting.

CPE Monitor is a national collaborative service from NABP, ACPE, and ACPE providers that will allow licensees to track their completed CPE credit electronically.

pharmacist, having worked in various retail pharmacies and in various states. He is currently a pharmacist at Red Wing Corner Drug – a Walgreen’s pharmacy. Prior to the Walgreen buyout, in 2010, he was a pharmacist and manager for 29 years at Corner Drug of Red Wing, then an independent store. He is a native of western North Dakota and earned his bachelor of science degree in pharmacy from North Dakota State University in Fargo, ND, in 1969.

Pharmacist 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 just a couple of months left during which pharmacists can complete and report their CE for the period from October 1, 2010 to September 30, 2012. During previous reporting cycles, pharmacists were asked to download a Certificate of Completion from the Board’s Web site and then sign, date, and return it to the Board’s office. This cycle, pharmacists have the option of online certification of the completion of their required CE hours.

Pharmacists can access the main page of the Board’s secure online services system at <https://www.hlb.state.mn.us/mnbop/glsuiteweb/homeframe.aspx>. Once on that page, clicking the “Licensee/Registrant Services” link in the upper left-hand corner will display the Licensee/Registrant Services Menu. Pharmacists who already have a password can click on the “Login” link to log in to the system. Pharmacists without a password should click on “Create New Login.” Once logged into the system, pharmacists should click “Continuing Education review and certification” to certify the completion of their CE. The Board strongly encourages pharmacists to certify completion of their CE online, but for those pharmacists who do not want to do so, a Certificate of Completion can be downloaded from www.phcybrd.state.mn.us/forms/cecet12.pdf. That form can be filled out manually and mailed to the Board’s office.

Pharmacy Technician Training Requirement

Effective **January 1, 2014**, the Board will not renew the registration of a pharmacy technician who was **initially** registered after **January 1, 2013**, or who was initially registered prior to that date but did not maintain continuous registration, unless the individual has completed a pharmacy technician training program. There are several types of training that will be acceptable, one of which is an employer-based program that includes a minimum of 240 hours in a one-year period of both theoretical and practical instruction. An employer that uses an internal training program must develop and regularly update a technician training manual that must be available for Board inspection. The following standards for employer-based training programs were adopted by the Board at the June 20, 2012 meeting:

I. General considerations

- a. The content areas, listed in Section II, are required for all employer-based technician training programs.
- b. Minnesota Rules 6800.3850 contains the provision that “(n)otwithstanding the fact that a technician has completed a training program as specified in item B, it is the responsibility of the pharmacist-in-charge of a pharmacy to ensure that a technician receives adequate training in the tasks performed by technicians working at that pharmacy.” Consequently, pharmacies may have to include additional content in their technician training program. For example, a pharmacy that utilizes technicians to assist in sterile compounding must include training that covers what technicians need to know about

United States Pharmacopeia (USP) Chapter 797 standards. Similarly, a pharmacy that utilizes technicians to assist in nonsterile compounding must include training that covers what technicians need to know about USP Chapter 795 standards. Other examples include, but are not limited to, the use of automated drug distribution systems and unit-dose packaging or prepackaging of drugs.

- c. These are the minimum standards that must be met in order for a technician training program to be considered Board approved. However, pharmacies may develop training programs that include additional content areas.

II. Minimum content areas required for all employer-based pharmacy technician training programs

- a. Legal and ethical content
 - i. Differences between the permissible duties, activities and roles of pharmacists, pharmacy technicians, pharmacy interns, and unregistered supportive personnel. Duties and activities that may not be performed by a pharmacy technician.
 - ii. Requirements for a valid prescription drug order.
 - iii. Requirements for a valid controlled substance prescription drug order.
 - iv. Pharmacy technician registration and CE requirements.
 - v. Activities that constitute unprofessional conduct or unethical behavior, including diversion of drugs.
 - vi. Patient privacy. (May be completed as separate training.)
- b. Pharmacy and medical terminology, abbreviations, and symbols: sufficient to accurately complete data entry of prescription drug orders.
- c. Basic pharmaceutical calculations necessary for the preparation and dispensing of drug products.
- d. Basic information about commonly available drug dosage forms and routes of administration.
- e. Trade and generic names and the common indications for medications frequently dispensed by the pharmacy.
- f. Error prevention, reporting, and follow-up. (May be completed as separate training).
- g. Dispensing processes:
 - i. Data entry
 - ii. Retrieval of medication
 - iii. Filling of containers/packaging of medications
 - iv. Affixing labels
 - v. Pharmacist certification requirement
- h. Basic knowledge of proper and safe handling, storage, and disposal of drugs.