



Minnesota Board of Pharmacy

Published to promote compliance of pharmacy and drug law

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Disciplinary Activity

The Minnesota Board of Pharmacy took the following disciplinary actions concerning **pharmacists** between the dates of March 18, 2010 and May 12, 2010.

Ahlquist, Susan S. License #112631. Ms Ahlquist petitioned the Board for reinstatement of an unrestricted license. The Board had placed conditions and limitations on her license in May of 2004 after she admitted to consuming alcohol in a manner that could cause conduct endangering the public health. The Board granted Ms Ahlquist's petition and issued an order of unconditional license at its May 12, 2010 meeting.

DeBernardi, Michael J. License #112554. Mr DeBernardi failed to appear at a scheduled meeting of the Board's Complaint Review Panel to discuss allegations that he had consumed alcohol in a manner that could cause conduct endangering the public health. He further failed to respond to a notice of and order for prehearing conference and hearing. Consequently, at its May 12, 2010 meeting, the Board adopted a findings of fact, conclusions, and final order that suspends Mr DeBernardi's license for an indefinite period of time.

Growette, Jessica A. License #115628. Ms Growette petitioned the Board for reinstatement of an unrestricted license. The Board had placed conditions and limitations on her license in December of 2007 after she admitted to the theft of controlled substances from her employer and the unauthorized personal use of those drugs. The Board granted Ms Growette's petition and issued an order of unconditional license at its May 12, 2010 meeting.

Lundstad, Lance J. License #119193. Mr Lundstad petitioned the Board for an amendment to his 2007 stipulation and consent order that would allow him to work alone in a pharmacy. The Board had placed conditions and limitations on his license in 2007 due to the fact that his Wisconsin license was under restriction in

that state due to the diversion of controlled substances. The Board granted Mr Lundstad's petition and issued an amended order at its May 12, 2010 meeting.

Sanders, Robin. License #113801. Mr Sanders admitted that he diverted controlled substances from his employer. He also agreed that the Board could consider a number of facts to be true for the purpose of settling his case, including that a large quantity of controlled substances went missing from the pharmacy at which he was pharmacist-in-charge. Consequently, at its May 12, 2010 meeting, the Board issued a stipulation and consent order that accepted the voluntary surrender of Mr Sanders' license. Mr Sanders will not be eligible to petition for reinstatement of his license for a minimum of three years.

The Board considers the following **technicians** to have voluntarily surrendered their registrations between the dates of March 18, 2010 and June 22, 2010: **Bruns, Heidi G.**, Registration #719108; **Holly, Shannon L.**, Registration #720227, and **Madigan, Dawn**, Registration #714896. The Board revoked the registration of the following technician after receiving a notice of license revocation from the Minnesota Department of Revenue indicating that she owes \$500 or more in delinquent taxes, penalties, or interest, or has not filed a return: **Jokinen, Joan M.**, Registration #717210.

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 just a couple of months left during which pharmacists can complete and report their continuing education for the period from October 1, 2008 to September 30, 2010. Upon completion of at least the required 30 hours of continuing education, a Certificate of Completion should be signed, dated, and returned to the Board of Pharmacy office. The Certificate of Completion can be found at www.pharmacy.state.mn.us/forms/cecert10.pdf.



FDA Updates 'Medicines in My Home' Patient Education Resources

Food and Drug Administration (FDA) has updated the Medicines in My Home (MIMH) section of the agency's Web site with new resources and materials for patients. MIMH resources teach patients from adolescence through adulthood how to choose over-the-counter (OTC) medicines and how to use them safely. An interactive video teaches users how to understand the drug facts label and make sound medicine decisions. Downloadable documents provide information on caffeine use, choosing appropriate OTC medications, and other related topics. The MIMH Web page can be accessed at www.fda.gov/Drugs/Resources/ForYou/Consumers/BuyingUsingMedicineSafely/UnderstandingOver-the-CounterMedicines/ucm092139.htm.

DEA Releases e-Prescription for Controlled Substances Interim Final Rule

The Drug Enforcement Administration (DEA) Interim Final Rule on electronic prescriptions for controlled substances was published in the *Federal Register* on March 31, 2010, and was scheduled to go into effect June 1, 2010, subject to Congressional review. The regulations would allow prescribers the option to write prescriptions for controlled substances electronically, and allow pharmacies to receive, dispense, and archive these electronic prescriptions. The regulations are an addition to existing rules, and include stipulations to ensure that a closed system of controls on controlled substances dispensing is maintained. The regulations have the potential to reduce prescription forgery and reduce the number of prescription errors, and should also reduce paperwork and help integrate prescription records into other medical records.

Confirmation Bias



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 a 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.

Although pharmaceutical companies and regulatory agencies have been working on design changes to improve the situation, ISMP still associates many medication errors with confusion over "look-alike" or "sound-alike" product names. Since patients receive the wrong drug, these sometimes result in serious harm. A common cause of name mix-ups is what human factors experts call "confirmation bias." Confirmation bias refers to a type of selective thinking whereby individuals select what is familiar to them or what they expect to see, rather than what is actually there.

Many errors often occur when pharmacists or technicians, due to familiarity with certain products, see the name of the product they think it is rather than what it actually is. For instance, if a pharmacist reads a poorly written drug name, he or she is most likely to see a name that is most familiar to him or her, overlooking any disconfirming evidence. Another example of this is if a pharmacy technician chooses a medication container based on a mental picture of the item, whether it is a characteristic of the drug label, the shape, size, or color of the container, or the location of the item on a shelf.

Although various compilations of look-alike name pairs are available for posting (see www.ismp.org/Tools/confuseddrugnames.pdf for ISMP's List of Confused Drug names, which has recently been updated), these lists have only limited usefulness since it is impossible for practitioners to memorize them in order to know when to check on questionable prescriptions. Also, when confirmation bias occurs, there is never a reason for the practitioner to question the order to begin with.

In many cases, hospital or pharmacy computer systems can be used to reduce the risk of confirmation bias and resulting name mix-ups. Many systems have a "formulary note" field that can be easily adapted to display important information prominently on the computer screen. Similar to a road sign warning about a dangerous intersection ahead, this feature can be used to alert the person inputting the medication when a look-alike or sound-alike danger is present. For example, when *Norvasc*® is entered into the computer, a formulary note screen appears, alerting the pharmacist that *Norvasc* often looks like *Navane*® when handwritten. The pharmacist will then take the necessary steps to confirm the prescription if necessary.

In addition, physically separating drugs with look-alike labels and packaging helps to reduce this confirmation bias as does implementing bar-coding technology for the verification process of drug selection. Employing a simple system that compares computer-generated National Drug Codes (NDC) on prescription labels and NDC codes on manufacturers' containers to verify that the appropriate drug has been selected and dispensed also helps reduce confirmation bias.

It is human nature for people to associate items by certain characteristics. It is very important for the health care community and regulators to recognize the role that confirmation bias may play in medication errors and to work together to address associated problems.

FDA-TRACK Provides Public Access to Agency's Performance Data

The new FDA-TRACK will provide access to updated information about FDA programs, projects, and core responsibilities. The system is part of the FDA transparency initiative and its objectives are represented in the TRACK name which stands for transparency, results, accountability, credibility, and knowledge-sharing. This agency-wide system will track performance measurement data reported from over 100 FDA program offices. Common measures, key center director measures, program measures, and key projects are the measurement areas currently in use, and more information about these areas is available in the FDA-TRACK announcement available at www.fda.gov/AboutFDA/WhatWeDo/track/default.htm. FDA-TRACK will continue to be updated and the latest information can be found on the following Web pages: Cross-Agency FDA-TRACK Program Areas available at www.fda.gov/AboutFDA/WhatWeDo/track/ucm206441.htm, Center FDA-TRACK Program Areas available at www.fda.gov/AboutFDA/WhatWeDo/track/ucm206441.htm.



AboutFDA/WhatWeDo/track/ucm195008.htm, and Dashboards available at *www.fda.gov/AboutFDA/WhatWeDo/track/ucm195011.htm*. Public feedback on FDA-Track and its measures can be submitted by e-mail to FDATRACK@fda.hhs.gov.

Survey Suggests Majority of Patients Seek Pharmacist Advice About OTC Medications

When selecting OTC medications, 82% of pharmacy customers base their decision on a pharmacist's recommendation, according to a survey of over 1,000 pharmacists conducted by the American Pharmacists Association (APhA). Survey results also indicate which products, among 76 categories presented to pharmacists, are most often recommended. The survey results are published in the Pharmacy Today Over-the-Counter Supplement available at *www.imirus.com/tmp/2536/2501/1001/pm2536.pdf*. An APhA news release, available at *www.pharmacist.com/AM/Template.cfm?Section=News_Releases2&Template=/CM/ContentDisplay.cfm&ContentID=23117*, indicates that 90% of patients seek help identifying the most appropriate product and 80% seek counsel regarding using an OTC product with their prescription medications.

California PMP Data Shows Frequency of Doctor Shopping

Early data collected from California's prescription monitoring program (PMP), the Controlled Substances Utilization Review and Evaluation System (CURES), correlates the frequency of patient "doctor shopping," or obtaining multiple prescriptions from various providers, with the number of prescriptions patients receive for additional controlled substances, as reported in *Medical News Today*. The research analysis, presented at the American Academy of Pain Medicine 26th Annual Meeting, showed that patients prescribed a single additional class of a controlled substance, such as benzodiazepines, had a two-fold likelihood of doctor shopping for multiple opioid prescriptions. A 13-fold increase in doctor shopping was seen when more than one additional drug class was involved. Researchers at the University of California, Davis, conducted the analysis using de-identified CURES data, and also found that patients involved in doctor shopping were involved in more than one episode about 50% of the time.

Highest Dose of Zocor Increases Risk of Muscle Injury, FDA Warns

FDA has informed health care practitioners that there is an increased risk of muscle injury in patients taking the highest approved dose of the cholesterol-lowering medication, Zocor[®] (simvastatin) 80 mg. This information is based on review of data from a large clinical trial and other sources, and FDA is currently reviewing additional data to better understand the relationship between high-dose simvastatin use and muscle injury. More information is included in an FDA Drug Safety Communication at *www.fda.gov/Drugs/DrugSafety/PostmarketDrugSafetyInformationforPatientsandProviders/ucm204882.htm*.

New OxyContin Formulation to Help Prevent Abuse of the Drug

FDA has approved a new formulation of the controlled-release drug OxyContin[®] which is designed to decrease the likelihood that this medication will be misused or abused, and result in overdose. FDA explains that the new formulation adds in new tamper-resistant features aimed at

preserving the controlled release of the active ingredient, oxycodone. The old formulation allowed tampering with the tablet, via cutting, chewing, breaking, or dissolving, which resulted in dangerously high levels of oxycodone being released at once. In accordance with FDA requirements, Purdue Pharma L.P. will conduct a post-marketing study to determine the impact of the new formulation, and the manufacturers will follow a Risk Evaluation and Mitigation Strategy (REMS) for this product. The REMS will include the issuance of a Medication Guide to all patients who use the product. More information is provided on the FDA OxyContin Question and Answer Web page at *www.fda.gov/Drugs/DrugSafety/PostmarketDrugSafetyInformationforPatientsandProviders/ucm207196.htm*.

Use of e-Prescribing Grows Dramatically

The number of electronic prescriptions increased 181% from 2008 to 2009, according to the 2009 National Progress Report on E-Prescribing, published by Surescripts, operator of the largest e-prescription network that connects prescribers' e-prescribing software to pharmacies. Over 190 million e-prescriptions were routed in 2009, compared with 68 million in 2008, and 29 million in 2007. Correlating with those increases, 156,000 prescribers were using e-prescriptions by the end of 2009 compared with 74,000 at the end of 2008, a 109% increase. The report also indicates that 85% of community pharmacies in the United States are connected and able to receive e-prescriptions from prescribers.

Study Shows e-Prescribing Reduces Prescriber Errors

Prescribers using e-prescribing were seven times less likely to make errors than those writing their prescriptions by hand, according to a new study published in the *Journal of General Internal Medicine*. The study, conducted by researchers at Weill Cornell Medical College, focused on 12 community practices and compared the prescriptions of 15 providers using e-prescribing and 15 providers writing prescriptions by hand. The researchers found that two in five handwritten prescriptions contained errors such as incomplete directions, prescribing a medication but omitting the quantity, and prescribing incorrect dosages. Further, comparing handwritten prescriptions and e-prescriptions one year from the start of the study, researchers found that errors dropped from 42.5% to 6.6% for the providers using e-prescriptions. Errors associated with the handwritten prescriptions in the study increased from 37.3% to 38.4% a Weill Cornell Medical College press release providing more information about the study is available at http://weill.cornell.edu/news/releases/wcmc/wcmc_2010/02_26_10.shtml.

Counterfeit Drug Investigation Leads to Two Arrests

Two individuals have been arrested and face charges related to illegally importing counterfeit weight-loss medication. FDA issued a series of alerts, from 2008 to 2010, about tainted weight-loss pills and counterfeit drugs, and an undercover investigation identified one of the defendants as the alleged trafficker of these tainted and counterfeit drugs. This investigation was a joint effort by FDA Office of Criminal Investigations, US Immigration and Customs Enforcement, and US Postal Inspection Service. More information about the investigation and arrests is available in a US Attorney's Office Press Release at *www.fda.gov/ICECI/CriminalInvestigations/ucm206314.htm*.

2010 Legislation Affecting the Practice of Pharmacy

As seems to be the case every year, a large number of bills related to the profession of pharmacy or to pharmaceutical manufacturers were introduced this past session. Most of the bills died in committee and were never enacted into law. Descriptions of some of the provisions that were enacted into law follow.

Pharmaceutical Waste

The Minnesota Safe Drug Disposal Act, as originally drafted, would have required pharmaceutical manufacturers to establish product stewardship programs to promote the disposal of unwanted prescription drugs in a manner other than sewerage (or even just throwing them in the trash). That portion of the bill was removed, as was a prohibition on the sewerage of drugs by long-term care facilities. The final version that was enacted into law clarifies that law enforcement agencies, hazardous waste haulers, and facilities regulated by the Minnesota Pollution Control Agency can possess pharmaceuticals for the purpose of disposing of them. It also formally allows members of the public to transfer non-controlled legend drugs to these entities. Pharmacists are reminded that they cannot accept pharmaceuticals from patients or long-term care facilities, for the purpose of disposing of them, unless all applicable state and federal laws and rules are followed. This applies to both scheduled and non-scheduled drugs – although the restrictions are greater for scheduled drugs.

A separate law was enacted that requires the Board of Pharmacy to “study prescription drug waste reduction techniques and technologies applicable to long-term care facilities, veterans nursing homes, and correctional facilities.” In conducting the study the Board is to evaluate the extent to which new prescription drug waste reduction techniques and technologies can reduce the amount of prescription drugs that enter the waste stream and also reduce state prescription drug costs. The techniques and technologies studied must include, at a minimum, daily or weekly medication exchanges and automated distribution devices. The Board must provide an estimate of the cost of adopting these and other techniques and technologies, and an estimate of waste reduction and state prescription drug savings that would result from adoption. The study must also evaluate methods of encouraging the adoption of effective drug waste reduction techniques and technologies. The Board must present recommendations on the adoption of new prescription drug waste reduction techniques and technologies to the Legislature by December 15, 2011.

Substitution of Drugs Used for the Treatment of Epilepsy

The following language was added to the section of law that lists the Board’s powers and duties (Minnesota Statutes §151.06):

If the United States Food and Drug Administration (FDA) determines that the substitution of drugs used for the treatment of epilepsy or seizures poses a health risk to patients, the board shall adopt rules in accordance with accompanying FDA interchangeability standards regarding the use of substitution for these drugs. If the board adopts a rule regarding the substitution of drugs used for the treatment of epilepsy or seizures that conflicts with the substitution requirements of section 151.21, subdivision 3, the rule shall supersede the conflicting statute. If the rule proposed by the board would increase state costs for state public health care programs, the board shall report to the chairs and ranking minority members of the senate Health and Human Services Budget Division and the house of representatives Health Care and Human Services Finance Division the proposed rule and the increased cost associated with the proposed rule before the board may adopt the rule.

It is the Board’s understanding that Congress has directed FDA to study this issue. If FDA issues a determination as described above, the Board will engage in the formal rule-making process in order to comply with the law.

In Memoriam: Former Board Member Joseph F. Zastera, Jr

Joseph F. Zastera, Jr, died on June 10, 2010, in Two Harbors, MN. Mr Zastera received his degree in pharmacy from the University of Nebraska in 1949. He moved to Two Harbors in 1956, where he practiced pharmacy for many years. Mr Zastera was appointed to the Board of Pharmacy in 1980 by Governor Rudy Perpich. He was reappointed twice and served as vice president and president. The National Association of Boards of Pharmacy® recognized his outstanding contributions by naming him the recipient of the Distinguished Service Award in 1995. The Board recognizes and honors Mr Zastera’s many contributions to the public and to the profession and offers its condolences to his family and friends.

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