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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 March 17, 2009 and June 10, 2009.

Astrup, Daniel, License #113575. Mr Astrup petitioned the Board for the reinstatement of an unrestricted license. He had been on probation with the Board since 2004 for activities involving the diversion and personal use of controlled substances. The Board granted the petition and issued an Order of Reinstatement.

Hayenga, Timothy J., License #115088. Mr Hayenga admitted to diverting controlled substances from his employer and to the unauthorized personal use of those drugs. The Board suspended his license but stayed the suspension on condition that he enter into a participation agreement with the Health Professionals Services Program, pay a civil penalty in the amount of \$300, and comply with all provisions of any court order that is issued in the event that he is convicted of any criminal offenses relating to the diversion of controlled substances.

Ploszay, Thomas M., License #112617. Mr Ploszay petitioned the Board for the reinstatement of an unrestricted license. He had been on probation with the Board since 2006 for several practice-related deficiencies, which had resulted in a number of dispensing errors. The Board granted the petition and issued an Order of Reinstatement.

Scott, Craig J., License #114393. Mr Scott petitioned the Board for the reinstatement of his license. His license had been suspended by the Board on January 30, 1997, for the diversion and personal use of controlled substances. The Board issued an Order Denying Reinstatement of Pharmacist License that allows Mr Scott to re-petition for reinstatement of his license after completing 800 hours of internship, completing 60 hours of continuing education, passing the Multistate Pharmacy Jurisprudence Examination® (MPJE®) and obtaining a current chemical dependency evaluation.

Snyder, Timothy B., License #112876. Mr Snyder petitioned the Board for reinstatement of his license. His license had

been suspended by the Board on March 5, 2008, after he admitted to the habitual consumption of alcohol in a manner that could cause conduct endangering public health. The Board granted his petition and issued an Order to Reinstate License with Conditions. Mr Snyder must enter into and abide by a participation agreement with the Health Professionals Services Program. He may petition the Board to remove limitations placed on his license no sooner than June 10, 2012.

Thompson, Thomas A., License #110509. Mr Thompson petitioned the Board for approval of his application for relicensure as a pharmacist. He had voluntarily surrendered his license in August 2008 after admitting he participated in the dispensing and distribution of orders for controlled substances that were not legitimate prescriptions in that they were not issued in the usual course of professional practice. The Board granted his petition and issued a Stipulation and Consent Order with the following limitations and conditions. Mr Thompson must pass the MPJE, may not own or have a controlling ownership interest in any pharmacy in Minnesota, may not serve as a pharmacist-in-charge, and may not register or serve as a preceptor. Mr Thompson may not petition for removal of the limitations prior to June 10, 2014.

The following pharmacy technicians voluntarily surrendered their registrations between the dates of March 17, 2009 and June 10, 2009: **Holm, Dianne D., Registration #718154; Nafstad, Claire M., Registration #713320; Pena, Lisa M., Registration #708991; and Saxowsky, Lisa A., Registration #715099.**

Governor Pawlenty Appoints New Board Member

On April 15, 2009, Governor Tim Pawlenty appointed James Koppen to the Minnesota Board of Pharmacy. Mr Koppen, of Pine City, is the director of pharmacy at Pine Medical Center in Sandstone, MN, where he oversees all pharmacy operations and has been involved in upgrading the medication delivery system and launching a medication safety program. He earned his bachelor of science degree in pharmacy from South Dakota State University, in Brookings, SD, and has been a licensed phar-

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Pharmaceutical Cargo Theft of Copaxone®

The Food and Drug Administration (FDA) Office of Criminal Investigations (OCI) reported that a shipment of approximately 14 pallets/994 cartons/5,962 packs of Copaxone® (glatiramer acetate) 20 mg, a non-controlled substance, was stolen during the week of April 13-17, 2009. The tractor trailer was recovered at a rest stop on the New Jersey Turnpike on April 20. Unfortunately the trailer was empty. Corporate security from Teva Pharmaceutical Industries Ltd recalled the remainder of lot #P53159, which has an expiration date of January 2011. If that particular product is found anywhere or offered for sale, it would be the stolen product.

Copaxone is a unique product and is used only to treat patients suffering from multiple sclerosis. If the product is not stored below 74° F and out of the sunlight, it becomes ineffective and may not be safe for use.

Immediately notify the FDA OCI if you are contacted by individuals offering to sell this product, if you have purchased this product, or if you know of anyone that may be involved with the theft and the distribution of this product.

Any information should be provided to Special Agent Gregg Goneconto or Special Agent Nancy Kennedy at OCI Headquarters (800/551-3989), or at www.fda.gov/oci/contact.html.

Failed Check System Leads to Pharmacist's No Contest Plea for Involuntary Manslaughter



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.

A former Ohio pharmacist will plead no contest to involuntary manslaughter of a two-year-old child who died in 2006 as a result of a chemotherapy compounding error.¹ The pharmacy board revoked the pharmacist's license and, after

holding a criminal investigation, a grand jury indicted him on charges of reckless homicide and involuntary manslaughter. The pharmacist faces up to five years in prison.

Prosecutors hold the pharmacist responsible for the toddler's death because he oversaw the preparation of her chemotherapy. A pharmacy technician mistakenly prepared the infusion using too much 23.4% sodium chloride. The infusion was administered to the child, who died three days later.

Though we cannot shed more light on the root causes of the error, our experiences with analyzing other errors strongly suggest that underlying system vulnerabilities played a role. Compounding the solution from scratch is error prone. Communication failures between technicians and pharmacists, IV compounding-related failures, inadequate documentation of the exact products and amounts of additives, and other system issues have contributed to numerous fatal errors. ISMP has also received reports of compounding errors and subsequent failed double-checks due to adverse performance-shaping factors such as poor lighting, clutter, noise, and interruptions. In fact, in this particular case, news reports suggest that the pharmacist felt rushed, causing him to miss any flags that may have signaled an error.²

Without minimizing the loss of life in this case, we continue to be deeply concerned about the criminalization of human errors in health care. Safety experts including ISMP advocate for a fair and just path for individuals involved in adverse events, arguing that punishment simply because the patient was harmed does not serve the public interest. Its potential impact on patient safety is enormous, sending the wrong message to health care professionals about the importance of reporting and analyzing errors. All professionals are fallible human beings destined to make mistakes and drift away from safe behaviors as perceptions of risk fade when trying to do more in resource-strapped professions. When warranted, licensing boards can protect patients from reckless or incompetent actions of health care practitioners by limiting or revoking licenses.

While the law clearly allows for the criminal indictment of health care professionals who make harmful errors, the greater good is served by focusing on system issues that allow tragedies like this to happen. Focusing on the easy target, the pharmacist, makes us wonder whether any regulatory or accreditation agency is ensuring that all hospitals learn from this event and adjust their systems to prevent the same type of error. If not, the death of this little girl is a heartbreaking commentary on health care's inability to truly learn from mistakes so that they are not destined to repeat.

References

1. McCarty J. *Eric Cropp, ex-pharmacist in case in which Emily Jerry died, is ready to plead no contest.* Cleve-



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2. McCoy K, Brady E. *Rx for Errors: Drug error killed their little girl*. USA Today. February 25, 2008. Available at: www.usatoday.com/money/industries/health/2008-02-24-emily_N.htm.

NABP Wins ASAE's 2009 Associations Advance America Award of Excellence

In recognition of its efforts for educating patients on the potential dangers of buying medications online and empowering patients to make informed choices through its Internet Drug Outlet Identification program, the National Association of Boards of Pharmacy® (NABP®) recently received the 2009 Associations Advance America (AAA) Award from the American Society of Association Executives (ASAE) and the Center for Association Leadership in Washington, DC.

Launched in May 2008, the Internet Drug Outlet Identification program reviews and monitors Web sites selling prescription medications and distinguishes those sites that do and do not meet state and federal laws and/or NABP patient safety and pharmacy practice standards. Internet drug outlets that appear to be operating in conflict with program criteria, such as dispensing drugs that are unapproved and potentially counterfeit, frequently without a valid prescription, pose a significant risk to the public health. Such findings underscore the importance of this project and other efforts to contain the Web-based distribution of prescription drugs within the appropriate legal and regulatory framework.

"NABP is honored to have been selected for this prestigious award for our efforts to bring about positive change," says NABP President Gary A. Schnabel, RN, RPh. "This program represents a strong demonstration of our commitment to the NABP mission of assisting the state boards of pharmacy in protecting the public health."

NABP is one of only 21 organizations nationally to receive an award of excellence in the first round of ASAE's 2009 AAA Award program, an award that recognizes associations that propel America forward with innovative projects in education, skills training, standards setting, business and social innovation, knowledge creation, citizenship, and community service.

Consumer Directed Questions and Answers about FDA's Initiative Against Contaminated Weight-Loss Products

FDA has developed questions and answers to help consumers, health care practitioners, and the general public understand FDA's actions regarding weight-loss products contaminated with various prescription drugs and chemicals.

Many of these products are marketed as dietary supplements. Unfortunately, FDA cannot test and identify all weight-loss products on the market that have potentially harmful contaminants in order to ensure their safety. FDA laboratory tests have revealed the presence of sibutramine, fenproporex, fluoxetine, bumetanide, furosemide, phenytoin, rimonabant, cetilistat, and phenolphthalein in weight-loss products being sold over-the-counter. Enforcement actions and consumer advisories for unapproved products only cover a small fraction of the potentially hazardous weight-loss products marketed to consumers on the Internet and at some retail establishments.

Pharmacists can advise patients to help protect themselves from harm by consulting with their health care professional before taking dietary supplements to treat obesity or other diseases. Patients should be advised of the following signs of health fraud:

- ◆ Promises of an "easy" fix for problems like excess weight, hair loss, or impotency
- ◆ Claims such as "scientific breakthrough," "miraculous cure," "secret ingredient," and "ancient remedy"
- ◆ Impressive-sounding terms, such as "hunger stimulation point" and "thermogenesis" for a weight-loss product
- ◆ Claims that the product is safe because it is "natural"
- ◆ Undocumented case histories or personal testimonials by consumers or doctors claiming amazing results
- ◆ Promises of no-risk, money-back guarantees

More information is available on the FDA Web site at www.fda.gov/Drugs/ResourcesForYou/Consumers/QuestionsAnswers/ucm136187.htm.

Jury Trial Set for Doctor Charged with Bringing Misbranded Foreign Cancer Drugs into US

A jury trial to hear the case of *USA v. Vinod Chandrashekm Patwardhan, MD* was set to begin on April 21, 2009, in the US District Court for the Central District of California. Patwardhan, an Upland, CA doctor who specialized in treating cancer patients, was arrested in August 2008 by federal authorities after being charged with introducing foreign misbranded drugs into interstate commerce. These drugs reportedly were sometimes diluted when they were administered to his patients, according to a news release issued by Thomas P. O'Brien, US attorney for the Central District of California, on the day of the arrest. The charge of delivering misbranded drugs into interstate commerce with the intent to defraud or mislead carries a penalty of up to three years in federal prison.

macist for over 39 years, with experience in both community and hospital pharmacy. Mr Koppen was appointed to a four-year term as a pharmacist member and replaced Mr Thomas Dickson on the Board. The Board and staff wish to take this opportunity to acknowledge the many contributions made by Mr Dickson during his eight years of service on the Board.

Pharmacist Intern to Preceptor Ratio

It has come to the attention of the Board that some pharmacies are employing what appears to be an excessive number of interns. In one case, 16 interns were listed as being employed at a pharmacy that had only four registered pharmacist preceptors on staff. Minnesota Rules 6800.5100, subp. 8 states the following:

Supervision. Except as provided in subpart 9, "supervision," as used in connection with parts 6800.5100 to 6800.5600, means that in the pharmacy where the intern is being trained, a registered pharmacist designated as preceptor or another registered pharmacist shall be in continuous personal contact with and actually giving instructions to the intern during all professional activities of the entire period of the intern's internship.

Minnesota Rules 6800.5400, subp. 4 states the following:

Maximum trainees. No more than one intern shall be trained by a preceptor at one time.

Taken together, these parts imply that there is a 1:1 intern to preceptor ratio. (Meaning that a preceptor cannot be assigned more than one intern at a time.) However, some individuals have interpreted these rules to mean that a preceptor may have multiple interns assigned to him or her, but that a pharmacist can only supervise one intern at a time when the intern is working in a traditional dispensing or compounding setting.

At its June 10 meeting, the Board adopted an interpretation of these rules that clarifies that there is a 1:1 intern to preceptor ratio and that a preceptor may not have more than one assigned intern at any one time without requesting a variance from the Board. Since the Board is in the process of adopting a rule change that would modify the ratio to 2:1, the Board directed staff to automatically approve variance requests that ask for permission to use a 2:1 ratio.

Note that approval of a variance that allows two interns to be assigned to a preceptor does not mean that the two interns can be on duty at the same time, performing compounding and dispensing functions, while being supervised by only one pharmacist. Each intern performing compounding and dispensing tasks must be supervised by a separate licensed pharmacist. If only one licensed pharmacist is on duty, two interns can be supervised at the same time provided that one of the interns is performing only those duties that a pharmacy technician is allowed to perform. That intern may not certify prescriptions, receive new verbal prescription orders, or counsel patients. That intern also counts in the technician to pharmacist ratio.

Pharmacists and pharmacy owners are reminded that a "graduate intern" is not allowed to do anything more than

any other intern is allowed to do. They must have an assigned preceptor, they must work under the supervision of a licensed pharmacist, and they should not be used as if they were substitutes for pharmacists.

Syringe Access Initiative to Prevent HIV and HCV Transmission

The Minnesota Department of Health is requesting the assistance of Minnesota community pharmacies in updating the directory of participating pharmacies with the Minnesota Pharmacy Syringe Access Initiative (SAI).

As you may recall, HIV prevention legislation, enacted in 1997 by the Minnesota Legislature regarding pharmacy access to limited quantities of syringes and needles, has been effective since July 1, 1998. According to the legislation, pharmacies may voluntarily participate in this initiative to sell, without a prescription, unused hypodermic needles and syringes in quantities of 10 or fewer. Participating pharmacies, however, are required to certify to the Department of Health that they will participate in an activity that supports effective disposal of used syringes. Types of activities in which pharmacies may choose to participate to support syringe disposal range from distribution of education materials (including referral to Web sites) about proper personal disposal of syringes to collection of used syringes from customers.

Over 400 pharmacies have been participating with SAI for more than 10 years, resulting in successfully reducing the transmission of HIV and the hepatitis C virus (HCV) among injecting drug users (IDU) in Minnesota. The initiative also provides IDUs with information on HIV prevention, health care resources, drug treatment facilities, and the safe disposal of used syringes.

Since SAI began in 1998, a substantial number of new pharmacies have opened in Minnesota, and the Department of Health would like to update and expand the directory to include any new pharmacies that wish to participate with the SAI. In an early July mailing, you will be requested to complete a form that will allow your pharmacy staff to sell 10 or fewer syringes without a prescription. Your participation will contribute to maintaining Minnesota's success in preventing the transmission of HIV and HCV.

If you have any questions please e-mail Gary Novotny, program manager, at gary.novotny@state.mn.us; phone him at 651/201-4029; or visit the program Web site at www.health.state.mn.us/divs/idepc/diseases/hiv/hivother.html.

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