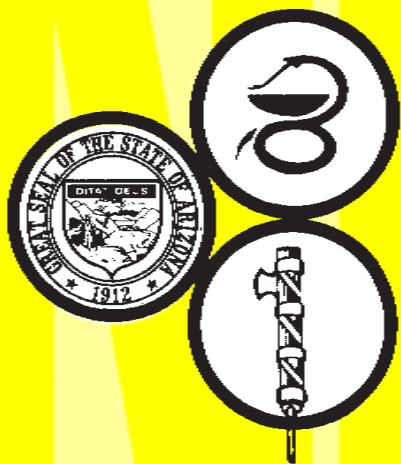


July 2009



Arizona State Board of Pharmacy

1700 W Washington St, Room 250, Phoenix, AZ 85007
Web site: www.azpharmacy.gov
E-mail: chunter@azpharmacy.gov

Published to promote voluntary compliance of pharmacy and drug law.

Update on Board Members and Staff

On March 17, 2009, Governor Jan Brewer reappointed pharmacist member Tom Van Hassel to the Arizona State Board of Pharmacy. Tom has been the director of pharmacy at Yuma Regional Medical Center for many years and is a national expert on pharmacy automation. He previously served the citizens of Arizona by filling an unexpected vacancy on the Board and served four years of the normal five-year term. Board staff has relied on Tom for advice on questions regarding sterile compounding and United States Pharmacopeia General Chapter 797 requirements, and the staff looks forward to continuing to receive his advice in these matters. Congratulations, Tom.

On June 30, 2009, Compliance Officer M. Larry Dick retired from the Board after six years of service. Larry's background before employment with the Board included a stint in academia at the University of Arizona, his alma mater. He also managed an infusion pharmacy for several years before joining the Board staff. Best wishes to Larry and his family in his retirement.

Controlled Substance Prescription Monitoring Program

Controlled Substance Prescription Monitoring Program (CSPMP) Director Dean Wright reports that the program began collecting data from resident and nonresident pharmacies in October 2008. An analysis of the data collected through the end of May 2009 shows that the database contains over 9.8 million controlled substance prescription records. The analysis also shows that there were 977 authorized users, including 190 pharmacists. The CSPMP database is an electronic tool developed to provide pharmacists and prescribers with information about the use of controlled substances by patients. Pharmacists are encouraged to utilize the database whenever providing pharmaceutical care. Pharmacist access to the database is conferred after a pharmacist completes and submits both a Prescriber/Dispenser Database Access Request Form and a Privacy Statement Form. To obtain the forms, go to the Board's Web site at www.azpharmacy.gov, then navigate to the PMP Rx Monitoring tab (which is the tab on the far right of the horizontal navigation tabs) and choose the CSPMP Information link. Once you are on the CSPMP Information page, choose the Access to the Controlled Substances Database link, then choose the Pharmacist link, and follow the instructions for completing the Prescriber/Dispenser Database Access Request Form and the Privacy Statement Form. If you have any questions or difficulty with the forms, contact CSPMP Director Dean Wright at dwright@azpharmacy.gov.

Disciplinary Actions

Notice: Before making a prescription-dispensing or other decision pursuant to information in this issue, you are encouraged to verify the current condition of a license with the appropriate licensing agency (Board).

Disciplinary Actions – Board of Pharmacy (actions since the April 2009 Newsletter)

Pharmacy Technicians

- Adams, Joshua (T006970)** – Revoked. Effective May 8, 2009.
 - Funk, Kimberly (T016987)** – Revoked. Effective May 8, 2009.
 - Golden, Jeffrey (T010493)** – Revoked. Effective May 8, 2009.
 - Marki-Shaw, Rebecca (T00424)** – Respondent suspended until further notice; upon termination of suspension, respondent will be placed on probation. Sign five-year Pharmacists Assisting Pharmacists of Arizona (PAPA) contract. 400 hours of community service. Effective May 8, 2009.
 - Martinez, Christina (T006261)** – Revoked. Effective May 8, 2009.
 - McElroy, Candace (T010534)** – Revoked. Effective March 19, 2009.
 - McKinney, Jeffrey (T008347)** – One-year probation, Treating Assessment Screening Center (TASC) program. Effective May 7, 2009.
 - Mollindo, Candy (T003248)** – Revoked. Effective May 8, 2009.
 - Neuman, Robert (T014468)** – Revoked. Effective May 8, 2009.
 - Perkins, Nicole (T006770)** – Revoked. Effective May 8, 2009.
 - Robinson, Destiny (T007103)** – License censured. Effective May 21, 2009.
 - Uriarte, Oyuki (T012763)** – \$250 fine to be paid within six months. Effective March 19, 2009.
 - Williams, Angelina (T013239)** – Revoked. Effective May 8, 2009.
- #### Interns
- Brown Jr, James (I008924)** – Complete 1,500 intern hours, five-year PAPA contract, and take/pass all exams before being issued an Arizona pharmacist license. Effective March 19, 2009.
- #### Pharmacists
- Alnoah, Fahad (S015734)** – 120-day probation, \$2,000 fine, and retake the North American Pharmacist Licensure Examination®. Effective March 19, 2009.

Continued on page 4



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-



land Plain Dealer. April 19, 2009. Available at: www.cleveland.com/news/plaindealer/index.ssf?/base/cuyahoga/1240129922221300.xml&coll=2.

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.

Armes, Marla (S008738) – \$1,000 fine and eight hours of continuing education (CE) within 90 days. Effective May 7, 2009.

Bird, Christel (S011521) – \$1,000 fine and eight hours of CE. Effective May 7, 2009.

Branson, Thomas (S004208) – Probation terminated. Effective March 19, 2009.

Chen, Joseph (S007891) – Probation terminated. Effective May 15, 2009.

Daram, Rakesh (S016559) – Eight hours of CE due within 60 days. Effective May 7, 2009.

Hendershot, Darrell (S013180) – \$1,000 fine and four hours of CE due within 90 days. Effective May 7, 2009.

Hunter, Lisa (S013072) – Request for reinstatement of surrendered license denied. Effective March 18, 2009.

Lau, Ivan (S014019) – Three-month suspension stayed. One-year probation and \$13,000 fine to be paid within 90 days. Effective May 11, 2009.

Lyman, Terri (S012568) – \$1,000 fine and eight hours of CE. Effective May 7, 2009.

Makai, Gerwyn (S016844) – Six months suspension, followed by four-and-a-half year probation, five-year PAPA contract, 400 hours community service. Effective March 19, 2009.

Markunas, Chris (S014220) – Retake and pass Multistate Pharmacy Jurisprudence Examination® (MPJE®) within 90 days. Effective March 19, 2009.

McKee, Mark (S012049) – Suspended from October 11, 2008 to May 7, 2009. On May 7, 2009, the Board imposed his probation; cannot be preceptor or pharmacist-in-charge (PIC) and 400 hours community service. Effective May 7, 2009.

Peterson, James (S009155) – Probation imposed; subject to the following terms: respondent shall obtain psychiatrist for treatment and submit reports on treatment four times a year; respondent cannot be preceptor or PIC. Effective May 1, 2009.

Thomas, Andrew (S006928) – Request for reinstatement of expired license approved. Must complete 400 interns hours and retake/pass MPJE prior to reopening of license. Effective March 18, 2009.

Walder, Howard (S006112) – Six months probation, \$1,000 fine and eight hours of CE. Effective March 19, 2009.

Disciplinary Actions – Other Boards

Arizona Osteopathic Medical Board (Doctors of Osteopathy)

LeBlanc, Erol (DO 3452) – Respondent placed on probation for two-and-one-half years with set terms and conditions. Effective March 14, 2009.

Arizona Board of Medicine (Allopathic Medical Doctors and Physician Assistants)

Agarwal, Sudhir P. (MD 17587) – License reactivation and probation for five years with set terms and conditions. Effective June 4, 2009.

Bast, Richie P. (MD 14854) – License revoked. Effective 35 days after June 3, 2009, unless respondent petitions for rehearing or review.

Bolick, David (MD 33101) – License surrendered to the Board. Effective April 2, 2009.

Celniker, Benny (MD 3729) – Non-disciplinary – Physician's practice is limited in that he shall not practice medicine in the state of Arizona and is prohibited from prescribing any form of treatment including prescription medications until physician applies to the Board and receives permission to do so. Effective May 27, 2009.

Grams, Mark L. (MD 11869) – Revocation stayed with set terms and conditions. Respondent's practice is restricted in that he shall not practice clinical medicine or any medicine involving direct patient care, and is prohibited from prescribing any form of treatment including prescription medications, until respondent applies to the Board and receives the Board's approval to return to practice. Effective June 4, 2009.

Guo, Weixing (MD 32100) – *Interim Consent Agreement for Practice Restriction* – Before respondent may practice medicine in Arizona, he must obtain a psychosexual evaluation from a Board-approved facility and request that the results of that evaluation be submitted directly to the Board. Respondent shall also notify the executive director at least 30 days prior to practicing medicine in Arizona. Effective April 15, 2009.

Hoversten, Richard (MD 29872) – License surrendered to the Board. Effective June 4, 2009.

Lewis, Richard J. (MD 35079) – *Interim Consent Agreement for Practice Restriction* – Respondent shall not practice clinical medicine or any medicine involving direct patient care, and is prohibited from prescribing any form of treatment including prescription medications, until respondent applies to the Board and receives permission to do so. Effective June 9, 2009.

Mahl, Michael (MD 12868) – License reactivation, letter of reprimand, and probation for five years with set terms and conditions. Effective June 9, 2009.

McRae, Bart (MD 20471) – *Interim consent agreement* – Non-disciplinary – Physician's practice is limited in that he shall not practice medicine in the state of Arizona and is prohibited from prescribing any form of treatment including prescription medications until physician applies to the Board and receives permission to do so. Effective March 19, 2009.

Randhawa, Gurcharan S. (MD 22036) – Non-disciplinary – Respondent's practice is limited in that he shall not practice clinical medicine or any medicine involving direct patient care and is prohibited from prescribing any form of treatment including prescription medications until applying for and receiving Board approval to do so. Effective March 25, 2009.

Simon, Tamara M. (MD 38229) – License surrendered to the Board. Effective June 4, 2009.

Taitague, Gerald J. (MD 26182) – Decree of censure, probation for 10 years with set terms and conditions, and practice restrictions. Respondent shall not prescribe, administer, or dispense any controlled substances. Effective June 4, 2009.

Trentalange, Mark J. (MD 29601) – Decree of censure, probation for five years with set terms and conditions, and practice restrictions. Respondent shall not practice anesthesiology and is prohibited from prescribing, handling, administering, or storing intravenous narcotics. Effective June 4, 2009.