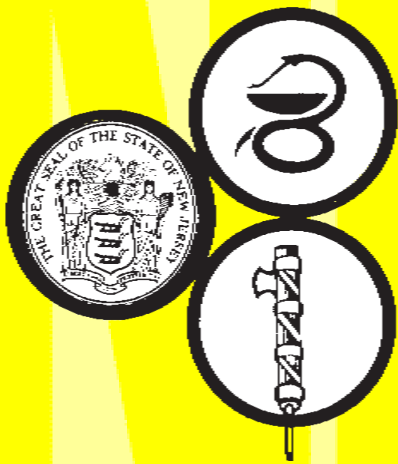
July 2009



New Jersey Board of Pharmacy

PO Box 45013
124 Halsey St, 6th Floor
Newark, NJ 07101
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Published to promote voluntary compliance of pharmacy and drug law.

Adoption of Immunization Regulation

Please note that N.J.A.C. 13:39-4.20, "Procedures for Physician Ordered or Government-Sponsored Immunizations Performed by Pharmacists," was adopted on April 6, 2009. The regulation can be accessed from the New Jersey Board of Pharmacy Web site under the "Laws and Regulations" link, followed by the "Adoptions" link. Additionally, the application to administer immunizations is now available on the Board Web site under the "Applications" link, followed by the link "Pharmacist Application for Initial Approval to Administer Vaccines."

Verbal Prescription Orders from Assisted Living Facilities

The Board recently received an inquiry regarding the authority of nurses in assisted living facilities to telephone pharmacies with verbal prescription orders taken from the prescriber. N.J.A.C. 13:39-7.10 lists the regulations regarding prescriptions transmitted by facsimile, while N.J.A.C. 13:39-7.11 lists the regulations with respect to electronically transmitted prescriptions. Both sets of regulations specify that the authority to transmit a prescription order to the pharmacy is limited to a practitioner authorized to prescribe medications, pursuant to N.J.S.A. 45:14-14, or the prescribing practitioner's authorized agent. During the June 10, 2009 open session, the New Jersey Board of Pharmacy determined that a nurse employed by an assisted living facility cannot be considered an authorized agent of a prescribing practitioner with respect to taking a verbal prescription order and transmitting such prescription order to a pharmacy. Under such circumstances the pharmacist may receive the prescription order only from the prescribing practitioner directly or his or her authorized agent.

Disciplinary Actions

The actions listed below include only those in which the individual's license to practice has been revoked, surrendered, suspended, restricted, or reinstated and do not include any other actions taken by the Board. Information regarding the current status of a pharmacist's license may be obtained either at the Division of Consumer Affairs Web site or by calling the License Verification Line at 973/273-8090.

Suspensions

Sanford Kessler, RPh – Specifically, Respondent from January 1, 2004 until April 12, 2007, distributed Lipitor®, which was not purchased from drug wholesalers, to customers, and submitted claims for payment of prescription medications, that in fact were not dispensed. **Ordered:** Respondent's license to practice pharmacy is hereby surrendered, such surrender to be deemed a revocation of Respondent's license with prejudice. *(Filed on October 8, 2008.)*

Reinstatements

Naleen R. Thakkar, RPh – As of February 6, 2008, Respondent has entered into an order with the Board to reinstate his license to practice pharmacy pending being fingerprinted for a criminal background check, and pay all relevant renewal and reinstatement fees. **Ordered:** Upon completion of requirements, Respondent's license to practice pharmacy shall be reinstated subject to one (1) year period of probation during which he shall not serve as pharmacist-in-charge or preceptor; and until further order of the Board, shall be barred from being a permit holder either directly or indirectly through connection with any person related by blood or marriage. *(Filed on February 13, 2008.)*

Steven Kim, RPh – As of March 12, 2008, Respondent has entered into an order with the Board to reinstate his license to practice pharmacy, pending proof of continuing education credits and pay all reinstatement fees. **Ordered:** Respondent shall not act as a preceptor

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Pharmaceutical Cargo Theft of Copaxone®

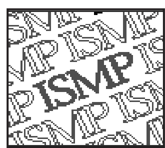
The Food and Drug Administration (FDA) Office of Criminal Investigations (OCI) reported that a shipment of approximately 14 pallets/994 cartons/5,962 packs of Copaxone® (glatiramer acetate) 20 mg, a non-controlled substance, was stolen during the week of April 13-17, 2009. The tractor trailer was recovered 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 74º 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 compounder-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.

Continued from page 1

or pharmacist-in-charge at any pharmacy for three (3) years. Respondent shall present a copy of the order to any future employers if he plans to practice pharmacy. *(Filed on March 12, 2008.)*

Mohammad Ismail, RPh – As of March 12, 2008, Respondent has entered into an order with the Board to reinstate his license to practice pharmacy. **Ordered:** Prior to reinstatement Respondent must pay all applicable fees for renewal and reinstatement. In addition, Respondent must complete continuing education credits and the Multistate Pharmacy Jurisprudence Examination®. Upon satisfying the terms of the order Respondent's license will be reinstated and placed on probation for a minimum of two (2) years from the date of reinstatement. Respondent shall not be a preceptor, pharmacist-in-charge, or a permit holder. *(Filed on March 19, 2008.)*

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New Jersey Board of Pharmacy - State News Editor

Carmen A. Catizone, MS, RPh, DPh - National News Editor & Executive Editor

Larissa Doucette - Communications Manager