



Oklahoma State Board of Pharmacy

Published to promote voluntary compliance of pharmacy and drug law.

4545 N Lincoln Blvd, Suite 112
Oklahoma City, OK 73105-3488

Have You Mailed Your Renewal?

The Oklahoma State Board of Pharmacy mails renewal applications 60 days in advance of expiration. If you do not receive a renewal, it is your responsibility to obtain one (see www.pharmacy.ok.gov under "Download Forms").

Please allow a **minimum of 10-15 business days** from the date of receipt for your application to be processed. Renewals are processed in the order they are received and special consideration will not be given to anyone. Please do not call the Board office before the 15-day period has passed.

Change of Address or Employment?

All pharmacists, technicians, and interns must notify the Board in writing within 10 days of a change of address or employment.

From the Inspector's Desk

- ◆ **Over-the-Counter (OTC) Pseudoephedrine Invoices:** OTC pseudoephedrine invoices should be filed with other Schedule III, IV, and V invoices. Some pharmacies keep OTC pseudoephedrine invoices in a file with no other invoices and this would be acceptable also.
- ◆ **OTC Pseudoephedrine Sales:** Pseudoephedrine must be sold by a pharmacist or a pharmacy technician. The purchaser must present a valid state ID or valid state driver's license.
- ◆ **ID requirements for Schedule II through Schedule V versus OTC Pseudoephedrine:**

Schedule II-Schedule V	OTC Pseudoephedrine
Valid State-issued ID	Valid State-issued ID
Valid State-issued Driver's License	Valid State-issued Driver's License
Valid Passport	--
Valid Military-issued ID	--

- ◆ **Schedule II through Schedule V prescriptions:** Inspectors wish to remind pharmacists that they may make the following **additions** (not alterations) to controlled dangerous substances prescriptions: *the patient's age, address, the practitioner's Drug Enforcement Administration (DEA) number, and the generic drug name, if used.* If an error is made in filling out the prescription, a new prescription must be written. **After confirming with the practitioner** a pharmacist may **add** the *quantity, strength,*

indicate whether tablet or capsule form, indicate whether it is compounded, and directions (Sig). Documentation of contacting the prescribing practitioner must be noted on the back of the prescription.

◆ Waiver References:

- **Oklahoma Bureau of Narcotics:** OAC 475:20-1-5(g) No registrant shall knowingly employ as an agent or employee any person who will have access to controlled dangerous substances if such person has been convicted of a misdemeanor or felony relating to any controlled dangerous substances as defined by the Uniform Controlled Dangerous Substances Act in this state, any other state, or the United States, or any person convicted of any felony of this state, any other state, or the United States, unless, after full review of the circumstances, the Director waives this requirement in writing with respect to each such person on a case-by-case basis.
- **DEA:** 21 CFR 1301.76(a) The registrant shall not employ, as an agent or employee who has access to controlled substances, any person who has been convicted of a felony offense relating to controlled substances or who, at any time, had an application for registration with the DEA denied, had a DEA registration revoked or has surrendered a DEA registration for cause. For purposes of this subsection, the term "for cause" means a surrender in lieu of, or as a consequence of, any federal or state administrative, civil or criminal action resulting from an investigation of the individual's handling of controlled substances.

Ryan Haight Online Pharmacy Consumer Protection Act

New DEA regulations implementing the Ryan Haight Online Pharmacy Consumer Protection Act (www.govtech.com/gt/419355) went into effect on April 13, 2009. The act counters the growing sale of federally scheduled prescription drugs over the Internet without a valid prescription by (1) providing new disclosure standards for Internet pharmacies; (2) barring Internet sites from selling or dispensing prescription drugs to consumers **who are provided a prescription solely on the basis of an online questionnaire;** and (3) allowing state attorneys general to go to federal court to shut down rogue sites. The bill is geared to counter domestic Internet pharmacies that sell drugs without a valid prescription.

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.

Continued from page 1

The act requires that a physician have at least one face-to-face evaluation with the patient prior to writing the patient a prescription for a controlled substance. The act amends the Federal Food, Drug, and Cosmetic Act to address this problem in three steps.

First, it requires Internet pharmacy Web sites to display information identifying the business, pharmacist, and physician associated with the Web site.

Second, the bill bars **the selling or dispensing of a prescription drug** via the Internet when the Web site has referred the customer to a doctor who then writes a prescription without ever seeing the patient.

Third, the bill provides states with new enforcement authority modeled on the Federal Telemarketing Sales Rule that will allow a state attorney general to shut down a rogue site across the country, rather than only bar sales to consumers in his or her state.

Prescriptions not resulting from a valid patient-physician relationship have always been considered invalid, but the act sets out additional specific language to be used to help determine if a controlled substance prescription is valid. Pharmacists-in-charge should review store policy to ensure compliance. For example, a patient presenting a prescription for a controlled substance written by a physician located a significant distance from the patient's home **should alert a pharmacist to exercise due diligence in determining the prescription presented for filling is a valid prescription resulting from a valid physician-patient relationship.**

Board Committees Formed

Committees on remote order entry, collaborative drug therapy, and long-term care emergency boxes have been established to promulgate rules that will be submitted to the Board for consideration later this year. Gail Schmidt, DPh, chairs the Remote Order Entry for Hospitals committee, Dr Tom Davis chairs the Collaborative Drug Therapy committee, and Gary Porter, DPh, chairs the Emergency Boxes in Long-Term Care Facilities committee. Committee membership is open. Pharmacists that have an interest in serving may contact the Board for committee meeting times. Committees generally meet once monthly until completion of the recommended rule. The recommended rule language is then submitted to the Board for consideration. A public hearing will be held on the rule, and the Board may make changes in the rule language. Once approved by the Board, the new rule may be submitted to the legislature and governor for consideration. If approved by the legislature and governor, the rule becomes effective 10 days after publication in *The Oklahoma Register* or at a time set by the Board. Bills regarding non-emergency rules may only be submitted to the legislature and governor during the legislative session that is held from February through May of each year.

Disciplinary Actions – April 15, 2009

(For more information you may view hearing minutes at www.pharmacy.ok.gov)

Emily Lott, Tech #10856 – Case 908: Application denied.

Pamela D. Adams, Tech #12410 – Case 913: Revoked.

Lacey Stephens, Tech #8924 – Case 919: Revoked.

Trista Sandin, Tech #6217 – Case 917: Revoked.

Crystal Jones, Tech #10654 – Case 918: Revoked.

Gary Crawford, DPh #9127 and CVS/Pharmacy No. 05959, #1-4972 – Case 920: Combined fine of \$1,100 and pharmacist must attend 2009 Law Seminar.

Hugh Edward Work, DPh #13115 – Case 923: Revoked.

Impaired Pharmacist #10460 – Case 829: Probation granted.

Calendar Notes

The Board will meet August 19 at the Board office. The Board will be closed Monday, September 7 in observance of Labor Day. Future Board dates will be available at www.pharmacy.ok.gov and will be noted in the October *Newsletter*.

New and Revised Rules

Please be advised that the Oklahoma State Board of Pharmacy 2009 new and revised rules will be effective July 1, 2009. To view these rules, visit the Board's Web site at www.pharmacy.ok.gov and click on "Rules."

Special Notice About the Newsletter

The *Oklahoma State Board of Pharmacy Newsletter* is an official method of notification to pharmacies, pharmacists, pharmacy interns, and pharmacy technicians registered by the Board. Please read them carefully. We encourage you to keep them for future reference.

Oklahoma Pharmacists Helping Pharmacists

If you or a pharmacist you care about is suffering from chemical dependency, there is a solution. Oklahoma Pharmacists Helping Pharmacists (OPHP) is readily available for help. Pharmacists in Oklahoma, Texas, and Louisiana may call the OPHP Help-Line at 1-800/260-7574 ext. 5773. All calls are confidential.

Let Us Hear From You

The Board welcomes your comments and questions. You may mail them to the Oklahoma State Board of Pharmacy, 4545 N Lincoln Blvd, Ste 112, Oklahoma City, OK 73105, fax us at 405/521-3758, or e-mail us at pharmacy@pharmacy.ok.gov. Visit our Web site at www.pharmacy.ok.gov.

This publication is issued by the Oklahoma State Board of Pharmacy as authorized by Title 59 O.S. 353.7. Copies have not been printed but are available through the agency Web site. Two printout copies have been deposited with the Publications Clearinghouse of the Oklahoma Department of Libraries. [74 O.S. 2001 § 3105(B)]

Page 4 – July 2009

The *Oklahoma State Board of Pharmacy News* is published by the Oklahoma State Board of Pharmacy and the National Association of Boards of Pharmacy Foundation, Inc, to promote voluntary compliance of pharmacy and drug law. The opinions and views expressed in this publication do not necessarily reflect the official views, opinions, or policies of the Foundation or the Board unless expressly so stated.

John A. Foust, DPh - State News Editor

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

Larissa Doucette - Communications Manager
