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Arkansas State Board of Pharmacy

NEWS

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Senate Bill 402 Becomes Act 1461 of 2009

The Arkansas State Board of Pharmacy has been updating Arkansas pharmacists regarding Senate Bill 402 and Arkansas Attorney General Opinions regarding the ability of acupuncturists to administer, dispense, or prescribe legend drugs. Senate Bill 402 that was mentioned in the last *Newsletter* was signed by Governor Mike Beebe and became Act 1461 of 2009 for Arkansas. This new law became effective July 31, 2009, and specifically prohibits acupuncturists from administering, dispensing, or prescribing legend drugs as well as prohibiting acupuncturists from identifying themselves as a doctor or physician. You may view the language of Act 1461 (previously SB 402) via the Internet at the Arkansas General Assembly Web site (*www.arkleg.state.ar.us/*). It is important for pharmacists to note that due to this new law, any prescription or order for prescription-only medications from an acupuncturist is not valid after July 31, 2009, and should not be filled. If any pharmacy or pharmacist continues to receive orders after this date, please report this complaint to the Arkansas State Board of Acupuncture and Related Techniques, which can be found at *www.asbart.org* or by telephoning 501/687-1396 to file a complaint with their Board.

Pharmacist License and Other Permit Renewals

Pharmacist renewals will be sent out for Arkansas licensed pharmacists in a couple of months. This year the Board of Pharmacy will be sending reminder cards to pharmacists to show once again how to link to our Web site and renew their permits. Reminders will be sent to your mailing address on record with the Board office. If you need to change your address on file, you must do so in writing (fax, mail, or e-mail) or by logging into your licensure file through the Board Web site (*www.arkansas.gov/asbp)*. As with years past, part of the renewal process will be for pharmacists to report their continuing education (CE) for the last two years. As a reminder, the CE requirements for the current biennium include a total of 30 hours of CE credit with 12 of the hours being live drug therapy or patient-care oriented. The newly adopted regulation changes for CE requirements will not be used until renewing your permit in 2011. Specific questions regarding CE should be directed to Board staff. Only CE attained during the 2008-2009 biennium will count towards this requirement. Please remember that Board regulations require pharmacists to retain certificates of participation for proof of CE for a period of four years.

Regulation Changes Approved During June 2009 Board Meeting

The following regulation changes were discussed in a public hearing during the June 12, 2009 Board meeting. These changes have all been adopted, and updated regulations have been placed on the Arkansas State Board of Pharmacy Web site (*www.arkansas.gov/asbp*) in the Pharmacy Lawbook section.

Regulation 2 – Pharmacists

Changes to Regulation 2 move back the dates that a pharmacy student may be licensed as an intern with the Arkansas State Board of Pharmacy. This is being done because accreditation standards have added new components for colleges of pharmacy that require a greater number of practice hours in a pharmacy setting for pharmacy students during their first year of school. Due to these changes, a request was made by colleges of pharmacy so that they may better comply with accreditation standards as well as State Board of Pharmacy regulations. Changes to Regulation 2 also update CE requirements for pharmacists in Arkansas to require CE credit that has been accredited by the Accreditation Council for Pharmacy Education (ACPE). This will help to ensure that pharmacists are getting quality CE programming that has been nationally accredited. This regulation change was suggested by the Arkansas Tripartite Committee on Continuing Pharmacy Education as established by statute. This change will not be effective until the 2010-2011 biennium; therefore, pharmacists should be sure to have their appropriate CE for the 2008-2009 biennium as stated in the previous section. The requirements starting **next** biennium will be as follows:

Continue to require a total of 30 hours of CE per biennium:

- 12 hours must be live of any type of CE (Board-approved or ACPE-approved)
- 12 hours must be ACPE-accredited

The requirements listed above are not mutually exclusive. As long as 12 live hours are obtained and 12 hours are ACPE-

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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.

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accredited of the 30-hour total, the criteria will be met by the pharmacist. The committee felt that this change would be easier to track for pharmacists and the Board without reducing the quality of CE that must be obtained.

Regulation 5 – Long-Term Care Facilities

Changes to Regulation 5 update the regulation regarding nursing home pharmacist consultants to match recent statutory changes that no longer require the long-term care facility to obtain a permit in the consultant pharmacist-in-charge's name. Changes also remove designations of oral and injectable drugs for two classes of medications (Schedule II analgesics and hypertensive crisis medications) in the emergency kit list for long-term care facilities. This has been a common request for an exception in the list which has been accepted by both long-term care inspectors and the Board of Pharmacy.

Regulation 7 – Drug Products/Prescriptions

Changes to Regulation 7 clarify how a pharmacist may handle new prescriptions and refill authorizations received via facsimile device in the event that there is not a clear signature on the faxed order or refill authorization. This rule is being changed to reflect currently accepted practice whereas faxed authorizations for refills are often initialed by the prescriber or prescriber's agent to authorize the order. This regulation change will clarify that these faxed authorizations may be treated as verbal orders for verification when needed.

Regulation 10 – Arkansas Pharmacy Support Group

Changes to Regulation 10 update terminology regarding the current way that the Arkansas Pharmacy Support Group functions. Changes also update the amount of funding that the Board of Pharmacy may supply to the Pharmacy Support Group for expenses. These changes will reflect changes made to the Arkansas Pharmacy Practice Act through Act 355 of 2009 as well as to better describe the functions of the Pharmacy Support Group and the recovery process.

Regulation 11 – Criminal Background Checks

Changes to Regulation 11 clarify how the Board of Pharmacy handles issues of criminal history for applicants for registration or licensure. The updates to this regulation will better describe the process by which the Board considers issues that arise from the criminal background check process and make the entire regulation easier to understand by a layperson that may be going through this process.

Technician Applications

Board staff continues to receive pharmacy technician applications that have been filled out on outdated forms that a pharmacy or pharmacist has kept on file to copy each time they want to apply for a technician permit for an employee. Whenever the Board receives an application that is not current, Board staff has no choice other than to return the application along with a current one to be completed correctly for consideration. This process in itself usually delays an application's processing by at least one or two weeks before the Board can get a corrected application. Whenever applying for a technician registration please contact the Board office to request a new technician permit application packet. The quickest way to contact our office and to have a new application sent to you is by e-mailing us at asbp@arkansas.gov and giving us your contact information and how many applications you will need. Since the fees for background checks have been changed by the Federal Bureau of Investigation and state police several times over the last few years, this is the best way to ensure you have a current application and a current criminal background check packet rather than a copy or an expired version.

Arkansas Pharmacy Support Group Help Line
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