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Congratulations to Board Appointee

The South Carolina Department of Labor, Licensing, and Regulation – Board of Pharmacy would like to congratulate Mr J. Addison Livingston, RPh, of Swansea, SC, on his recent appointment to the Board by Governor Mark Sanford. His six-year term expires on June 30, 2015. Mr Livingston represents the second congressional district and replaces Mr David C. Hook, Jr, RPh. He will provide valuable expertise in compounding, consultant, and independent community pharmacy practice settings. We welcome Mr Livingston, and we offer our sincere appreciation to Mr Hook for his dedicated service to the citizens of South Carolina and to the profession of pharmacy.

Board Elections

At the June 2009 meeting, the Board of Pharmacy elected Mr Al Toole, RPh, as its new chairman. Mr Toole is the pharmacist representative serving the third congressional district. Mr James Robert "Bobby" Bradham, RPh, of Charleston, SC, representing the first congressional district, was elected as vice chairman. Each will serve a one-year term for the positions to which they were elected.

Remote Order Entry

The Board reaffirms its position on remote order entry. The site where the remote order entry occurs by a licensed pharmacist must be permitted by the South Carolina Board of Pharmacy as a pharmacy or a nonresident pharmacy. If the site is a nonresident pharmacy, the pharmacist-in-charge must be licensed as a pharmacist in the state of South Carolina.

Board Meetings on Web Site

The Board of Pharmacy meetings will be audio and video taped with live feed to the Board's Web site via the new Granicus system. The meeting's link will be available on the Board's Web site for review in the future.

Online Service Change

There is an online service change: When a licensee uses the online service to change their address, it will now be automatically changed in the ReLaes data management system. Before now, a licensee would submit the request and an e-mail would be generated for staff to make the change in the ReLaes system. Selected individuals will now receive an automatic e-mail making them aware a licensee has changed their address.

Board Approves Change in Acceptable ACPE CPE Programs for Pharmacy Techs

Due the lack of availability of continuing pharmacy education (CPE) programs specifically designated for pharmacy technicians, at the June 2009 Board of Pharmacy Meeting, the Board voted to accept Accreditation Council for Pharmacy Education (ACPE) universal programs numbers with the new "topic designator" – "P" **or** "T" for pharmacy technicians. This will be applied to CPE programs earned in 2008 and afterwards.

Promotional Coupons to Transfer Prescriptions

The Board of Pharmacy is concerned with the safety and welfare of the public in South Carolina as it relates to the promotional coupon offers to transfer prescriptions from one pharmacy to another. In an effort to maximize excellent pharmaceutical care, the customer should obtain all of their prescriptions from one pharmacy entity. This allows for the pharmacist to review all of their prescription medications for drug utilization, drug interactions, therapeutic duplication, drug-allergy interactions, as well as appropriate patient counseling on all prescriptions. The use of these promotional coupons raises issues in regard to public safety.

Display of Permits, Licenses, and Registrations

§40-43-83(F) of the South Carolina Pharmacy Practice Act states, *"Permits issued under this section must be displayed in a conspicuous place in the permitted facility for which it was issued in such a manner that will enable an interested person to determine the name of the permittee, permit number, and permit expiration date."*

Regulation 99-15 states that a pharmacist ". . . *shall display his annual renewal certificate in a conspicuous place in the primary pharmacy or other permitted facility . . . in which he is employed, so that the annual renewable certificate is easily and readily observable by the public."*

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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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§40-43-82(3) of the South Carolina Pharmacy Practice Act states, *"A pharmacy technician shall display his or her current registration in a conspicuous place in the primary pharmacy . . . so that the current registration is easily and readily observable by the public."*

The Board has reaffirmed its position that permits, renewal certificates for pharmacists, and renewal certificates for all pharmacy technicians must be displayed where the public can **see and read** all information on the permit or renewal certificates.

Diversion and Abuse of Pharmaceutical Controlled Substances

On June 24, 2009, Group Supervisor Cheri Crowley from Drug Enforcement Administration (DEA) met with the Board to discuss several issues regarding the diversion and abuse of pharmaceutical controlled substances. A few of the areas discussed with Mrs Crowley were the following:

- Pharmaceutical controlled substance abuse ranks second only to marijuana as the most prevalent category of drug abuse according to the 2007 National Survey on Drug Use and Health. This study was previously called the National Household Survey of Drug Abuse. The latest report was published in September 2008.
- According to the study, 6.9 million persons used prescription controlled substances for a non-medical reason and the majority (5.2 million) were users of pain relievers.
- According to Mrs Crowley, no one can deny the problems of pharmaceutical controlled substance abuse, and we must all work together to make a difference for the public health and safety of the citizens of South Carolina.
- Liability may rest with each pharmacist who fills a prescription for a non-medical condition; just because a prescription for controlled substances is written by a physician does not make it a legitimate prescription.
- Mrs Crowley also explained that notifying the Board, the South Carolina Bureau of Drug Control, and the Columbia, SC DEA Diversion Group of all potential violations of the state and federal laws and regulations governing controlled substances is critical. Each group should be notified individually so that the shared information can then be used jointly to make all of us a strong team to stop the diversion at the retail level, especially.
- Mrs Crowley emphasized taking stronger and swifter actions against pharmacists and technicians who violate the controlled substance laws, especially those that steal from pharmacies. These individuals deserve more than a slap on the wrist when they have stolen controlled substances from the pharmacies that have trusted them to protect the public's health and safety.
- Mrs Crowley also acknowledged the South Carolina Prescription Monitoring Program as an extremely valuable tool in stopping pharmaceutical controlled substance diversion. She cautioned that each licensee that enters information into the computer system must take the time to make sure the information is accurate. Mrs Crowley gave an example of a physician who is currently under restriction by the DEA and Department of Health and Environmental Control who was thought to have begun writing prescriptions he was not authorized to prescribe. However, an on-site check at the pharmacy revealed that his DEA number had been misused instead of the physician's DEA number who had actually written/authorized the prescription.
- Mrs Crowley encouraged each of us to contact her office in Columbia, SC, at 803/253-3441 to report any concerns or violations regarding controlled substances. Anyone at the DEA office is always available to answer questions and to work with all of us to make a difference in South Carolina in the prevention of drug diversion and abuse.

The *South Carolina Board of Pharmacy News* is published by the South Carolina 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.

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