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Kentucky Board of Pharmacy

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Drug Manufacturer and Wholesale Distributor Renewal Deadline September 30, 2009

Drug manufacturer and wholesale distributor permits/licenses expire on September 30, 2009. A drug manufacturer or wholesale distributor may renew and pay the fee online. Renewal applications will not be mailed out; however, a renewal form may be printed from the Kentucky Board of Pharmacy's Web site at *www.pharmacy.ky.gov*. If you have any questions concerning the renewal process please contact the Board office. A drug manufacturer or wholesale distributor application with only a United States Post Office Box address will **not** be accepted and will be returned. All incomplete applications will be returned. Remember, the deadline is September 30, 2009.

HIV/AIDS Continuing Education 2010

The June 2002 Kentucky Board of Pharmacy *Newsletter* stated that the Board will require that every Kentucky licensed pharmacist shall successfully complete a continuing education program of not less than one contact hour or 0.1 continuing education unit (CEU) regarding HIV/AIDS that complies with KRS 214.610(1). The continuing education program shall be approved by the Cabinet for Health and Family Services HIV/AIDS Branch or be conducted by a provider approved by the Accreditation Council for Pharmacy Education. **Therefore, a Kentucky licensed pharmacist must successfully complete a one-hour (0.1 CEU) HIV/AIDS program during the calendar year January 1-December 31, 2010.**

Board Meeting and Retreat 2009

The Courtyard Cincinnati Covington, located at 500 West 3rd Street, Covington, KY 41011, will be the site of the Friday, November 13, 2009 Board meeting and the site of the Kentucky Board of Pharmacy Retreat to be held on Saturday, November 14, 2009. The Board meeting will begin at 9 AM on Friday and the Board Retreat will be from 8 AM until 5 PM on Saturday, November 14 (the meeting may carry over into Sunday morning if more time is needed).

The Board requests any individual or organization to submit topics to be discussed at the Board Retreat. Please submit any suggestion(s) to the Board office either by mail, fax, or e-mail. The Board will set the agenda at a later date. If you have any questions, please contact the Board office.

A Lower Drinking Age

Submitted by Brian Fingerson, RPh, Chair of the Pharmacist Recovery Network

Most alcoholics start drinking during their teen years, but the disease can also strike those who begin using alcohol at a younger age – and experts say the problem often goes unnoticed.

The underage-drinking rate in the United States has remained steady in recent years, but some research indicates that youths are starting to drink at a younger age. One study, from the Partnership for a Drug-Free America, concluded that about 10% of nine-year-olds had consumed more than a sip of alcohol. Research from the National Institute on Alcohol Abuse and Alcoholism indicates that children who begin drinking before age 15 are four times more likely to have drinking problems than those who start drinking at age 21 or later.

"A third of kids ages 12 to 17 had their first drink before 13," said Susan Foster, director of policy research for the National Center on Addiction and Substance Abuse at Columbia University. "That's about 6.4 million kids; many more than there have been historically. Very young drinkers are a huge concern."

Young drinkers often get started with alcohol use by getting drinks from friends or family liquor cabinets. Polls have shown that youths ages 13 and up say it is easy to get alcohol from adults – and sometimes their own parents, who may themselves have drinking problems. The thinking of some parents is that it's OK for them to "teach" their children how to handle drinking by letting their children drink in the home.

"The traditional thinking is that risk factors for alcohol abuse show up in adolescence," said Robert A. Zucker, PhD, director of the Addiction Research Center at the University of Michigan. "But, actually, they can show up earlier – in children 9 or younger, even in preschoolers."

There is a great deal of information available on how consumption of mind or mood-altering substances can change the way the brain develops in people even on into their early to mid-twenties. The longer one delays drinking or drugging, the better.

If you or someone you know exhibits signs and symptoms of substance abuse problems with alcohol or other drugs, you may confidentially contact Brian Fingerson, RPh, at 502/749-8385 or at kyprn@insightbb.com.

CLIA Waiver Information

In 1998, Congress passed a public law regulating clinical laboratory procedures. This law applies to labs, physician offices, and pharmacies that perform testing of materials derived from the human body for purposes of diagnosis, prevention, treatment, or health assessment. Pharmacies performing lab testing must adhere to strict Occupational Safety and Health Administration guidelines regarding bloodborne pathogen exposure including:

1. appropriate handling and disposal of bloodborne and otherwise potentially infectious material;

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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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2. training of all persons likely to perform tests; and
3. written plan defining what to do in event of an exposure.

To obtain information and a Clinical Laboratory Improvement Amendment (CLIA) Application for Certification Form, CMS-116, visit the following Web site: *www.cms.hhs.gov/CLIA/06_How_to_Apply_for_a_CLIA_Certificate_International_Laboratories.asp*.

You may also contact the Cabinet for Health, Office of Inspector, at 275 E Main Street 5EA, Frankfort, KY 40621, or by phone at 502/564-7963 (for pharmacies A-J, the contact person is Connie Barker, ext 3280; for pharmacies K-Z, the contact person is Jason Bishop, ext 3298).

Authorized Generics and Substitution Laws

Submitted by John Slone, PharmD Candidate, University of Kentucky College of Pharmacy

In recent years, drug manufacturers have been introducing a class of products to the market known as "authorized generics"; these products represent previously "brand name" medications from the original brand manufacturer that have been repackaged and sold under a generic label. These products are often released to coincide with the release of the first abbreviated new drug application-labeled generic product. These authorized generics have recently been the subject of confusion among pharmacists with regard to Kentucky's generic substitution laws and the requirement that substituted drugs must be published as therapeutically equivalent.

Part of the confusion lies in the fact that distributors or computer systems have no uniform method for indicating that a product is an authorized generic version of a brand name medication; sometimes the products are labeled as "AB rated" by the distributor or computer system, even though no such entry will exist when a pharmacist searches the Food and Drug Administration's (FDA) "Orange Book" by active ingredient. However, in the preface to the current edition of the "Orange Book," FDA has the following statement: "Any drug product in the List repackaged and/or distributed by other than the application holder is considered to be therapeutically equivalent to the application holder's drug product even if the application holder's drug product is single source or coded as non-equivalent (e.g., BN). Also, distributors or repackagers of an application holder's drug product are considered to have the same code as the application holder." (29th edition, page vii.) Essentially, this means that regardless of what code a drug product is given, authorized generics may still be substituted for that manufacturer's original product, despite any rating on the manufacturer's original drug product. Example: if a patient is started on a drug in which the product is controlled-release and generic equivalent products would normally be rated "B," you may still consider an authorized generic to be therapeutically equivalent and substitutable.

So what does this mean to a pharmacist in Kentucky? In general, this means authorized generics are therapeutically equivalent by FDA standards, but there is no easy way to search for such products in the "Orange Book," as the search tool does not include these types of products. However, as FDA considers authorized generics to be repackaged versions of new drug application-approved drugs, the package for the drug product must still indicate the original manufacturers' name. This name should match the company listed in the "Orange Book" as the manufacturer of the reference listed drug. To find the manufacturer, one may visit the electronic "Orange Book" at *www.accessdata.fda.gov/scripts/cder/ob/default.cfm* and search by proprietary name or active ingredient; in the search results, look for the line where the **RLD** field is labeled "Yes."

Please note that even though FDA publishes a list of authorized generic products (*www.fda.gov/AboutFDA/CentersOffices/CDER/ucm126391.htm*), it is only updated quarterly and companies only report authorized generics marketed on a yearly basis. If you have questions regarding an authorized generic, you should contact FDA or the Board of Pharmacy.

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