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Iowa Board of Pharmacy

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Reminder to All Pharmacy Technicians

Pharmacy technicians must be certified beginning July 1, 2010, and must maintain **both** national certification and their pharmacy technician registration with the Iowa Board of Pharmacy. All currently registered pharmacy technicians who have not provided the Board with documentation that they have attained national certification should have received a new registration certificate identifying the technician as a "technician trainee" with a registration expiration date of June 30, 2010. Once a technician trainee attains certification, the individual must complete an application for registration as a certified technician and submit that application, fee, and supporting documents to the Board. Certified pharmacy technicians will receive a registration certificate that identifies the technician as a "certified" technician.

Iowa Prescription Monitoring Program Update

As reported in the last issue of this *Newsletter*, the Iowa Prescription Monitoring Program (PMP) is fully operational. Pharmacists may utilize "alerts" within the PMP program to notify other pharmacists and prescribing practitioners when a patient is identified for using multiple prescribers and multiple pharmacies to obtain controlled substances. Alerts may also be used when a patient is identified for presenting forged or altered prescriptions.

Requests that are submitted to the PMP program should identify the patient by **last name**, **first name**, and **date of birth**. Using those three criteria, and **only** those three criteria, usually provides an automatically processed report that is viewable within seconds of submitting the request.

When submitting prescription data to the PMP program, which includes prescriptions issued by physician assistants (PA), pharmacists are reminded to submit the Drug Enforcement Administration (DEA) number of the PA and **not** the DEA number of the PA's supervising physician.

The Board encourages Iowa pharmacists and prescribers to register for program access if they have not already done so. To register, please go to *https://pmp.iowa.gov/IAPMPWebCenter/* and click on the following line: "Not a User? Register to become a User." Questions or concerns should be directed to program administrators Terry Witkowski or Debbie Jorgenson at 515/281-5944 or via e-mail at terry.witkowski@iowa.gov or debbie.jorgenson@iowa.gov.

Board Action Spurs Record-Setting Federal Prosecution

In September 2003, the Iowa Board of Pharmacy took emergency disciplinary action against the Union Family Pharmacy in Dubuque, IA, and two pharmacists – Jack E. Huzl and Douglas W. Bouchey. This case later became a six-year criminal prosecution, which led to the conviction of 26 people in United States District Court – including 19 doctors – and the forfeiture of more than $7 million in assets. "This federal prosecution resulted in the most defendants ever convicted in an Internet pharmacy case in the United States," said US Attorney Matt Dummermuth on June 10, 2009, noting that the forfeiture was the largest ever in the northern district of Iowa. Federal authorities found evidence that Union Family Pharmacy had illegally dispensed more than a million prescription pain, diet, and psychiatric medications over a six-month period for two Florida-based Internet companies, Pharmacon International Corporation and Medical Web Services. Federal prosecutors said the two companies recruited doctors from around the country to review orders placed by customers online. The prescriptions were filled without any medical examination or any contact between physicians and patients, prosecutors said. Between 2002 and 2004, the companies together issued about 500,000 prescriptions for roughly 31 million dosages, authorities said.

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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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Along with the doctors, those convicted in Iowa included corporate officers, physician recruiters, and a pharmacist. Twelve other doctors either entered into agreements to avoid prosecution or were prosecuted in other states.

In Memory Of . . .

Debra C. "Debi" Ringgenberg. Debi Ringgenberg passed away on June 2, 2009, at the age of 55. A 1977 graduate of the University of Iowa College of Pharmacy, Debi worked extensively in retail pharmacy in both Nebraska and Iowa and as a staff pharmacist at Mercy Medical Center in Sioux City. She worked for the Iowa Board of Pharmacy as an inspector, investigator, and compliance officer from November 18, 2002 to March 27, 2007. During that time she covered the northwest corner of the state. She was instrumental in handling Internet drug investigations and in helping the Board develop rules for sterile compounding. In April 2007, Debi became the executive director of the Missouri Board of Pharmacy, a position she held until the summer of 2008. Debi had an indomitable spirit. Her passions included skiing and tennis. The Board extends its sincerest sympathy to Debi's children, Jeff and Jennifer.

Janet A. "Jan" Horrigan. Jan Horrigan passed away on March 30, 2009, at the age of 73. Jan worked for the Iowa Board of Pharmacy for 25 years and served as the personal secretary to three executive directors. She was also responsible for processing new pharmacist license applications and for administering the intern program. She retired at the end of 1998. Jan had a great sense of humor and was loved by all. The Board extends its sincerest sympathy to Jan's loving companion, Ed Bartine; her children – John, Judy, and Teri; and her six grandchildren and one great-grandchild.

With the passing of Debi and Jan, we have lost two dear friends and colleagues. Their record of involvement in the pharmacy profession and their respective communities is a legacy of distinguished service and accomplishment. Their contributions to the Iowa Board of Pharmacy will long be remembered

Board Meeting Calendar

The following meeting dates have been set for future Board meetings:

- September 22-23, 2009
- November 17-18, 2009

Dates are subject to change. All meetings will be held at the Board office in Des Moines, IA. Please visit the Board's Web site at *www.state.ia.us/ibpe* or call 515/281-5944 to confirm meeting dates.

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