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Montana Board of Pharmacy

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New Pharmacy Board Member

The Montana Board of Pharmacy is pleased to announce the appointment of Mike Bertagnolli, RPh, as a pharmacist member of the Board by Governor Brian Schweitzer. Mr Bertagnolli replaces Mark Meredith, RPh, who is retiring from the Board. Mr Bertagnolli's term runs from July 1, 2009, to July 1, 2014.

Mr Bertagnolli is manager of pharmacy services at Deaconess Hospital, Bozeman, a position he has held since 2005. Prior to this he has held staff and management pharmacy positions in Bozeman, Billings, and Miles City. From 2001 to 2005 he was district pharmacy manager for Albertsons.

Mr Bertagnolli says he has been "hooked on pharmacy" since he got a job in the local drug store in Three Forks while in high school. He is a 1991 graduate of the University of Montana School of Pharmacy and also earned a master of business administration degree from Regis University, Denver, CO. He has served on the Montana Pharmacist Association Board of Directors, and served as president in 2001-2002.

Mr Bertagnolli and his wife, Connie, have five children. They enjoy anything that has to do with University of Montana sports, camping, skiing, golfing, and time with their children.

Montana Board of Pharmacy to Increase in Size

On April 16, 2009, Governor Schweitzer signed legislative senate bill 275. The legislation amends section 2-15-1733 (2) MCA to read as follows:

The board consists of seven members appointed by the governor with the consent of the senate. Four members must be licensed pharmacists, one member must be a registered pharmacy technician, and two members must be from the general public.

The legislation takes effect October 1, 2009.

If you are a pharmacist and are interested in an appointment to and service on the Board of Pharmacy, an application form may be found on the Board's Web site at www.mt.gov/dli/bsd/license/bsd_boards/pha_board/board_page.asp.

Change of Pharmacist-in-Charge

Whenever there is a change of pharmacist-in-charge of a pharmacy, the departing pharmacist must notify the Board of Pharmacy of the termination of their services. The pharmacy must designate a new pharmacist-in-charge within 72 hours. Please call the Board office if you have any questions. The form to designate a new pharmacist-in-charge is available on the Web site.

The applicable portion of the Administrative Rules of Montana (ARM) is reprinted below for your reference.

24.174.805 Change of Pharmacist-in-Charge

- (1) When the pharmacist-in-charge of a pharmacy leaves the employment of such pharmacy, the pharmacist will be held responsible for the proper notification to the board of such termination of services.
- (2) Within 72 hours of termination of services of the pharmacist-in-charge, a new pharmacist-in-charge must be designated and an affidavit filed with the board.

The license will then be updated to indicate the name of the new pharmacist-in-charge.

Compliance Corner

Hi and best wishes to all,

First, I would like to let you all know that the new Web site is up and running for the Board of Pharmacy, and that while all the same information is still available to you, the format has changed, and you may have to play a little with the site to familiarize yourself with it. I encourage all of you to go to the site often so that when you need to find information, forms, or contacts you will not only be comfortable doing so, but you will find value in the site. It is there and maintained for all in pharmacy to use as a resource for individual practitioners and your practice sites.

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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 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.

Secondly, I want to remind all pharmacists, technicians, and technicians in-training that pursuant to, ARM 24.174.403, all licensees shall notify the Board in writing within ten (10) days of any change in **employment**, and/or change of **business** or **personal** address. Guess what? On our Board Web site there is actually a change of address form available; when you fill the form out and send it to the Board office you have fulfilled your obligation of notice to the Board. This serves not only to let the Board know where you are practicing or living for our records, it ensures that when we need to contact you or send your renewal notice out that you will receive it, as the notice is not mail that can be forwarded. As such, not receiving a renewal notice is not grounds to avoid late fees and/or fines for failure to be renewed on time.

Finally, since we just ended a renewal period (June 30, 2009), it is a good time to make sure that each employee at each facility is current with their state registration in pharmacy. As an additional reminder to certified pharmacy technicians, the state renewal each year with the Board is separate and different from your certification renewal (Pharmacy Technician Certification Board or Exam for the Certification of Pharmacy Technicians) that expires every two years on your anniversary date. Please ensure that you have your continuing education credits done and that you renew on time, as you are not allowed to continue to work as a certified pharmacy technician after your certificate expiration date. I should point out that if you have proof of certificate renewal, the Board will accept that until your new certificate arrives. So, thank you all for your continued efforts to remain compliant in delivering pharmaceutical care to our citizenry; the Board and I really appreciate it. Until next visit, take care.

Bill Sybrant, RPh, Board Inspector

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