



# Nevada State Board of Pharmacy

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Published to promote voluntary compliance of pharmacy and drug law.

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## Inspecting For Safety

Besides having the goal of ensuring compliance with pharmacy rules and regulations by both pharmacists and pharmacies, a recent focus and commitment by Nevada State Board of Pharmacy inspectors is to help a pharmacy identify potential safety issues. After all, the Board's major responsibility is to the public in ensuring safe pharmaceutical care.

As part of the inspection process, Board inspectors have integrated into their inspection forms questions regarding safe pharmacy practices based upon recommendations by the Institute for Safe Medication Practices (ISMP). ISMP has identified factors that may contribute to medication errors and gives recommendations on how to address these factors, including the improvement of an environment that may be questionable. The purpose of questions on the inspection form and questions that the inspector may ask at the time of inspection is to raise awareness and educate practitioners on various risk factors. The Board is confident that when working together, better patient care is the outcome.

## Computer-Generated Prescription Issues

The Board office is constantly fielding questions from both prescribers and pharmacists regarding computer-generated prescriptions in one form or another. Hopefully the following will clarify some of the confusion:

1. Current federal law does **not** permit "electronic signatures" (e-prescribing) of controlled substances of any schedule.

- a. We anticipate that this will change sometime this year as the Drug Enforcement Administration moves forward on e-prescribing.
2. A pharmacist may dispense a Schedule III through V controlled substance only pursuant to a written and **manually** signed prescription presented either directly to the pharmacist or transmitted via fax, or pursuant to an oral order directly to the pharmacist that must be immediately reduced to writing.
3. Schedule II prescriptions must be manually signed by the practitioner and presented at the pharmacy (there are limited exceptions under federal law). They may not be faxed.
4. "Electronically signed" prescriptions are not valid for **any** drug unless via e-prescription (again, controlled substances may not be e-prescribed at this time). Hence, a prescription presented as "electronic signature on file" received either by fax or in person is invalid. The pharmacist may, however, contact the practitioner and take the prescription as an oral order.

## FDA Statement

Effective July 1, 2009, the Food and Drug Administration (FDA) Amendments Act of 2007 mandates that pharmacies must provide the patient, on all new **and** refill prescriptions, with the FDA phone number for reporting adverse events. The statement must include the following: "**Call your practitioner for medical advice about side effects. You may report side effects to the FDA at 1-800-FDA-1088.**"

There are several acceptable methods of giving this information to the patient:

- ◆ In consumer medication information (Patient Package Inserts [PPI])
- ◆ On a separate piece of paper
- ◆ On a sticker attached to the medication container
- ◆ On a preprinted prescription vial cap
- ◆ In an FDA-approved medication guide

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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](http://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](http://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](http://www.ismp.org). ISMP address: 200 Lakeside Dr, Suite 200, Horsham, PA 19044. Phone: 215/947-7797. E-mail: [ismpinfo@ismp.org](mailto: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.<sup>1</sup> 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.<sup>2</sup>

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-



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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](http://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](http://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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The original date of implementation was set for January 1, 2009; however, FDA delayed the rule in October 2008 to the July 2009 date. For further information on the rule, please access [www.mtpharmacist.org/documents/FRO4-9069\\_FDA\\_phone#.pdf](http://www.mtpharmacist.org/documents/FRO4-9069_FDA_phone#.pdf).

## **Pharmaceutical Technician Law CE Requirement**

Pursuant to a request by the Pharmaceutical Technician Advisory Committee, the Board of Pharmacy has passed a regulation requiring pharmaceutical technicians to obtain a minimum of one hour (1 CEU) of law continuing education (CE) prior to licensure renewal. The regulation became effective this April, meaning that the requirement will need to be met prior to the pharmaceutical technician renewal date of October 31, 2010. **It is imperative that you as pharmacists help communicate this new requirement to your technicians.**

The law CE can be obtained by attending a Board of Pharmacy meeting or by attending a Board of Pharmacy law CE presentation along with pharmacists. The Board recognizes the important role that pharmaceutical technicians play in providing quality pharmaceutical care to Nevadans and the need for all health care professionals to keep abreast of ever-changing statutes and regulations. The law CE will also provide a forum for the discussion of the ever-increasing technician diversion issues the Board faces. Auditing of the law CE will be accomplished during your pharmacy's annual inspection so the certificate should be logged in your technician's in-service training hours file. Advise your technicians that they **do not** send law CE documentation to the Board office.

## **Drug Shortages**

Recent Ethex Corporation drug recalls apparently are causing shortages of oxycodone as well as metoprolol extended release. Consequently, oxycodone IR is becoming more difficult to obtain, often prompting patients to call the Board office complaining that the pharmacist will not fill their prescriptions. Board staff assures such patients

that the fault does not lay with the pharmacist, and then recommends that the patient contact the prescriber for an alternative. Please use caution in advising prescribers on switching preparations, giving consideration to equivalent dosages of different drugs as well as their rate of release (ie, switching from an IR to an ER for acute or breakthrough pain may not be effective).

## **October 31 Is Closer Than You Think**

It is that time of year for pharmacists to be thinking about renewing their Nevada license in order to avoid late fees. The deadline is October 31, 2009. If you have moved and **not** already notified the Board office, please do so by visiting <http://bop.nv.gov> and clicking on the "Change Licensee Information" tab. Renewal applications will be printed in August with the address of record at that time. Please expect to receive your form mid-September. Instructions to renew online will be included with the renewal application, should you choose that option.

Remember to obtain one hour of law CE by either attending a Board meeting or some other program approved by the Board. Programs will be posted to the Web site under the "Continuing Education" tab. If nothing is listed, there are not any. Please refrain from sending in any CE certificates when you renew. You will sign (or click online) a statement acknowledging completion of the required CE. Should you be audited, you will receive a letter requesting the appropriate documentation once the renewal cycle is finished.

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