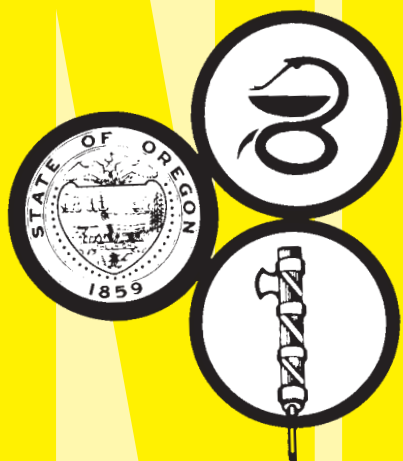


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# Oregon State Board of Pharmacy

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## **No. 454: No License Fee Increase**

The February 2009 *Newsletter* carried an article titled, *No. 448: License Fee Increases Proposed for 2009-2011 Budget*. For the 2009-2011 biennium, the Oregon State Board of Pharmacy proposed a budget that included a fee increase for several of its license categories, including pharmacies, pharmacists, and pharmacy technicians. The Board is a state agency under Governor Ted Kulongoski's administration, and its budget must be approved by the governor and the legislature. However, the Board does not receive any state general funds for its operations. The agency's operating revenue is derived completely from the licensing and registration fees it collects.

It turns out that, as is often the case, the budget proposed for 2009-2011 by the Board was not approved by the legislature. The budget for the Board that was ultimately approved appears slightly different (smaller). It does not include the proposed fee increase or the revenue that would have been raised by the proposed fee increase.

While this may be relatively good news for those who stood to pay a higher license fee this year, it does present a challenge for the Board. Board members and staff have worked many hours together over the past year to review priorities, rearrange expenditure line items, and generally tighten the agency's belt in an attempt to make ends meet without needing to eliminate full-time equivalents. Although management staff have been put under salary freezes or pay cuts and have been required to take unpaid furlough days for the last few months of the 2007-2009 biennium, and a number of other operational cost saving measures have been employed, the full impact of the agency's legislatively adopted budget on staffing and operations for 2009-2011 has not yet been determined. State and public employee representatives continue to negotiate the final contract settlements and all indications point to the continuation of budget constraints, belt tightening, and furlough days for the next two years.

Complicating the overall budget picture for the upcoming biennium, is the list of bills that have passed through the current legislature, which will have a direct impact on the Board's workload. A number of these bills require the Board to engage in rulemaking, research, and reorganization of internal structure and staffing. It is very likely that a fee increase will need to be considered for the 2011-2013 biennium.

## **No. 455: Recent Cases Show Trend**

Cases numbered 09-0049 and 09-0219, presented during the Board's June 2009 meeting, demonstrate a recurring, but easily

preventable, dispensing error. A patient who arrived at the drive-through window was given a lorazepam prescription that had been filled and labeled for another patient. How could this happen?

The patient for whom the prescription was labeled and the patient who received the prescription had "sound alike," although not identical, names. When the certified pharmacy technician (CPT) read aloud the name on the container, the patient in the car nodded. When the CPT read the patient's address, the patient in the car nodded. So the technician gave the prescription to the patient. Should be good enough, right? Not in this case because the patient received the wrong drug, somebody else's drug.

How can this remarkably common error be prevented? The first rule to remember is, do not take shortcuts, even for the drive-up/walk-up window. Open the bag and review the prescription container(s) with the patient. Ask "open-ended" questions of the patient, and confirm.

Ask the patient to say and spell his or her name. Ask the patient to state his or her address, date of birth, or other identifying information. Show the patient the prescription vial and confirm the information. Take responsibility to make sure the patient always gets the right medication in the right dose with the right information.

The Board is committed to eliminating prescribing and dispensing errors and ensuring patient safety through its evaluation, education, and enforcement activities. Also, the Board expects all pharmacists, interns, and technicians to adhere to accepted professional standards for safe and accurate medication dispensing. To this end, the Board is driven by its mission statement, "... to promote, preserve and protect the public health, safety and welfare by ensuring high standards in the practice of pharmacy and by regulating the quality, manufacture, sale and distribution of drugs."

## **No. 456: Pharmacists May Take Breaks**

The question of whether or not pharmacists are allowed to take breaks during the workday for meals and other necessities has been one of much discussion over the years. An article detailing the Board's position on the issue and clarifying the existing regulatory requirements was published in the November 2001 *Newsletter*.

In a community pharmacy, as in a hospital pharmacy, under current rules when only one pharmacist is on duty it is permissible for the pharmacist to leave the prescription area for meal or restroom breaks provided that no prescription leaves the prescription area that

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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.

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## **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.

has not previously been verified and approved by the pharmacist for release to a customer, and provided that the pharmacist remains in the building. It is not necessary to close the pharmacy or remove the non-pharmacist staff as long as the above conditions are met. If the pharmacist chooses to leave the building, the prescription area must be closed and secured with no unlicensed staff left in the pharmacy. It is advised that pharmacies which, at times, have only one pharmacist on duty have training in place that educates the technicians on exactly what they can and cannot do in the absence of the pharmacist.

It is for the pharmacist to decide, using his or her best professional judgment, whether to return to the pharmacy during a break or wait until the end of the break to return and answer a question or release a prescription that had not been verified and could not be released by the technician. This is viewed by the Board as an employer/employee/customer relations issue. It is the Board's expectation that the customer (patient) is instructed on when the pharmacist will be available.

### **No. 457: Duty of Pharmacy Staff to Report Unsafe Conditions**

*By Kevin DeClercq, PharmD Candidate, Pacific University and Joseph Ball, RPh, Chief Investigator, Oregon State Board of Pharmacy*

The February 2009 Board of Pharmacy Newsletter carried *Item No. 450: Duty to Report*, in which the pharmacist's duty to report suspected violations of pharmacy laws or rules was reviewed. Similarly, the duty to report conditions that, in the pharmacist's judgment, are considered to be potentially unsafe is reviewed in this article.

Community pharmacies are busier than ever, and every pharmacy experiences heavy workload days during which staffing is low, customer traffic accumulates, and waiting lines increase. Days occur in which the community or institutional pharmacy receives more interruptions and phone calls than usual, medication orders pile up, and the work does not flow smoothly. We have all been there. It is inevitable for every pharmacy to experience this from time-to-time and we learn to adapt. A serious problem exists when this becomes the norm rather than the exception, when the "bad days" seem to be more like "regular days" or seem to outnumber the "good days."

Ensuring patient safety is a professional responsibility of every pharmacist, as well as every pharmacy as a licensed drug outlet, and failure to do so may be considered unprofessional conduct by

the Board. This expectation includes providing appropriate levels of appropriately trained staff and a work environment that promotes patient services and quality health care. The Board expects licensees to be proactive and take steps to prevent errors from occurring. Items to consider when evaluating your practice include the following:

- ◆ understaffing leading to delays in patient service;
- ◆ mistakes and near misses;
- ◆ frequent backups in filling prescriptions;
- ◆ constantly losing prescription paperwork;
- ◆ inadequate employee training; and
- ◆ any environment or practice that causes employees to question the safety of themselves or patients.

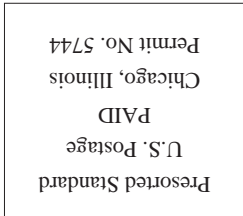
It is not the Board's intention to impose rules that infer or restrict the amount of work a pharmacist may perform in a shift or a day. Because each pharmacist feels competent at his or her own pace, the Board believes that it is best left to the individual to use his or her professional judgment to determine what is safe and appropriate. The Board also believes that setting limits on numbers of prescriptions or number of hours will not be beneficial.

The Board's intention is to see that each pharmacy operates in a manner that best serves the patient and ensures the highest possible level of safety. In addition, the Board encourages pharmacists to be vigilant about potentially unsafe conditions and take any necessary steps to prevent potential problems.

Under ORS 689.455, it is the duty of every pharmacist and technician to report to the Board if they feel they are being asked to work under conditions that are leading to unsafe or potentially unsafe patient care.

The *Oregon State Board of Pharmacy News* is published by the Oregon State 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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