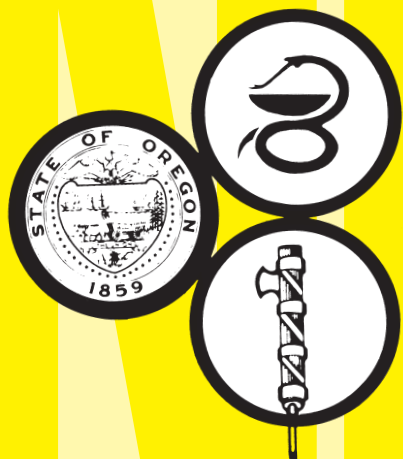


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# Oregon State Board of Pharmacy

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## **No. 393: Stop Sending Pseudoephedrine Logs to State Police**

On March 24, 2006, Lieutenant Michael Dingeman of the Oregon State Police (OSP) issued an announcement acknowledging and thanking pharmacists for their efforts in sending pseudoephedrine (PSE) transaction logs. He stated that the logs have been successfully used to gather information leading to several investigations and that it is no longer necessary for pharmacists to continue sending the logs. Following is Lieutenant Dingeman's letter.

Oregon Pharmacies,

The [OSP] Drug Enforcement Section forwarded a letter dated December 15, 2005[,] to Oregon [p]harmacies requesting they forward [PSE] sales transaction logs for review and analysis. This decision was made after we obtained and reviewed several copies of PSE logs that culminated in successful investigations. The information contained within the logs was analyzed for indicators of PSE diversion related to the manufacture of methamphetamine [meth].

From these logs, we have identified a number of suspicious transactions that are currently under investigation. During many of our conversations with pharmacies, several have expressed an interest in hearing about the results of some of the investigations. We intend to report back to you with the results of some of these investigations in the future as they are completed and we are able to release the information.

We want to extend our sincere thanks to all the pharmacies for your assistance, cooperation[,] and patience in providing us with the logs. We understand that maintaining the logs and sending them to us has been time consuming and a burden.

Effective upon receipt of this letter, the [OSP] Drug Enforcement Section is requesting all pharmacies to discontinue forwarding PSE sales transaction logs. The volume of logs we have currently received will be sufficient for review and analysis to determine PSE diversion investigations. The [OSP] may still make requests from specific pharmacies if additional PSE sales transaction logs will provide additional information related to on-going diversion investigations. Some local law enforcement agencies or drug task forces will continue to examine PSE sales transaction logs in person at their discretion.

Again, thank you for your help and cooperation in this endeavor. Please feel free to contact the [OSP] Drug Enforce-

ment Section at 503/378-3720 with any suspicious purchases that you notice, or contact your local law enforcement agency or drug task force.

Sincerely,  
Michael Dingeman, Lieutenant

## **No. 394: PSE Transaction Logs Lead to Arrests**

On March 30, 2006, a press release by the OSP stated that information provided by local pharmacists led to the arrest of four men in Cottage Grove, OR, and a suspected drug house located within 1,000 feet from a preschool was shut down. State police investigators were joined by federal Drug Enforcement Administration agents and Cottage Grove police officers in serving a search warrant at the home where they found meth, PSE, all the chemicals used to make meth, meth making paraphernalia, and directions on how to cook the drug. Pharmacists alerted investigators after noticing two individuals purchasing large amounts of non-prescription medications containing PSE. Information from pharmacists' reports reviewed by police showed products were purchased by two of the arrested individuals from at least 13 different pharmacies in the Eugene, OR, area and led police to the men's identities. The press release said the partnership with pharmacists was key to the investigation.

## **No. 395: Inspectors Are Back on the Road**

For the first time in recent history, the Oregon State Board of Pharmacy's goal of inspecting all Oregon pharmacies annually has been reached. Though all of the inspectors are making on-site appearances, Inspector Mike Beck has been on the road performing the majority of inspections. Most pharmacies are reporting this as a positive experience and express support for the idea of annual on-site inspections. Most pharmacists view the inspection as a time to ask questions and consult with the inspector, and they see the value in this interaction with the Board of Pharmacy staff. Likewise, the Board views these interactions as being very valuable and continues to place a priority on continuing the regular on site inspection schedule.

Now that the Board has been able to recommit resources to the road, the inspectors will be more available to provide pharmacy law updates and other continuing education (CE) opportunities. The Board has always felt these functions were important and has tried to make compliance staff available. We are asking pharmacists to help make arrangements for local CE presentations in their area. Pharmacists are encouraged to contact Compliance Director Gary

*Continued on page 4*



## **FDA Cautions Consumers About Filling US Prescriptions Abroad**

Food and Drug Administration (FDA) issued a warning to health care professionals and consumers that filling their prescriptions abroad may have adverse health consequences due to the confusion with drug brand names that could inadvertently lead consumers to take the wrong medication for their condition. In an investigation, FDA has found that many foreign medications, although marketed under the same or similar-sounding brand names as those in the United States, contain different active ingredients than in the US. Taking a different active ingredient could potentially harm the user.

FDA found 105 US brand names that have foreign counterparts that look or sound so similar that consumers who fill such prescriptions abroad may receive a drug with the wrong active ingredient. For example, in the United Kingdom, Amyben<sup>®</sup>, a brand name for a drug product containing amiodarone, used to treat abnormal heart rhythms, could be mistaken for Ambien<sup>®</sup>, a US brand name for a sedative. Using Amyben instead of Ambien could have a serious adverse outcome. For more information on this topic visit [www.fda.gov/oc/opacom/reports/confusingnames.html](http://www.fda.gov/oc/opacom/reports/confusingnames.html).

## **Safety Can Not be Sacrificed For Speed**



*This column was prepared by the Institute for Safe Medication Practices (ISMP). ISMP is an independent nonprofit agency that works closely with United States Pharmacopeia (USP) and FDA in analyzing 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, then publishes its recommendations. If you would like to report a problem confidentially to these organizations, go to the ISMP Web site ([www.ismp.org](http://www.ismp.org)) for links with USP, ISMP, and FDA. Or call 1-800/23-ERROR to report directly to the USP-ISMP Medication Errors Reporting Program. ISMP address: 1800 Byberry Rd, Huntingdon Valley, PA 19006. Phone: 215/947-7797. E-mail: [ismpinfo@ismp.org](mailto:ismpinfo@ismp.org).*

**Problem:** Typically, pharmacies have developed well-established methods for monitoring the accuracy of the dispensing process. But today, pharmacy work is increasingly stressful and these checks and balances can easily be strained beyond capacity. With an increasing number of prescriptions and a shortage of qualified pharmacists, conditions are ripe for potentially unsafe working conditions – long hours without breaks; multitasking between answering phones, overseeing other pharmacy staff, dispensing prescriptions, and counseling patients; and ever-increasing time spent attending to insurance issues. Inevitably, these conditions can increase the chance for dispensing errors.

One pharmacy knows this all too well after a five-year-old boy died as a result of an order entry and medication compounding error that was not caught by the usual verification process. In this case, imipramine was dispensed in a concentration five times greater than prescribed. Imipramine is a tricyclic antidepressant used to treat adults, but it is also used to treat childhood enuresis.

An extemporaneous solution was to be prepared at this pharmacy that specialized in compounded prescriptions since a liquid formulation was not commercially available. A pharmacy technician incorrectly entered the concentration of the prescribed solution into the computer as **50 mg/mL** instead of **50 mg/5 mL**, along with the prescribed directions to give 2 tsp at bedtime. He then proceeded to prepare the solution using the incorrect concentration on the label rather than the concentration indicated on the prescription. When the compound was completed, the technician placed it in a holding area to await a pharmacist's verification. At this time, one of the two pharmacists on duty was at lunch and the high workload of the pharmacy made it difficult for the pharmacist to check the prescription right away. When the child's mother returned to pick up the prescription, the cash register clerk retrieved the prescription from the holding area without telling a pharmacist, and gave it to the mother, unaware that it had not yet been checked. At bedtime, the mother administered 2 tsp of the drug (500 mg instead of the intended 100 mg) to the child. When she went to wake him the next morning, the child was dead. An autopsy confirmed imipramine poisoning.

There are many factors that contributed to this error including inaccurate order entry and issues related to high workload. However, a critical breakdown in safety processes occurred when the cash register clerk took the prescription from the pharmacy holding area (to prevent the mother from waiting any longer for the prescription), thereby circumventing the usual pharmacist verification process.

While this error underscores a growing problem in health care, the problem was clearly evident to this pharmacy owner – even a year before the error occurred. When interviewed for an article that appeared in a national publication, he vented his frustrations about the scant attention paid in our society to pharmacist workload difficulties faced in today's health care environment. On the day of the interview, 49 prescriptions were in the process of being prepared and about a dozen patients were standing in line or wandering around the store waiting for prescriptions. Yet this was a slow day. The owner also said that, while managed care had reduced profits considerably over the past several years, prescription volume had increased 50% (at the time of the error, the pharmacy was dispensing about 10,000 prescriptions per month versus 7,000 per month during the prior year, without an increase in staff) and medication regimens and drug interactions were more complex. To overcome these barriers, the owner added private consultation areas for patient counseling; installed a \$175,000 robot that accurately dispenses the 200 most common drugs; and diversified sales to offset full-time pharmacists' salaries. But these efforts could not have prevented this tragic fatal error that circumvented the normal safety processes.

**Safe Practice Recommendations:** The environment and demands placed on health professionals significantly affect their ability to provide safe health care services. While technology such as robots can help, overstressed professionals cannot consistently perform at the maximum level of safety. Therefore, it is important that the public and health care leadership understand this problem so they can be more open to tradeoffs, such as working



with one patient at a time and incurring longer turnaround times, which are necessary to enhance patient safety. With a shortage of qualified professionals, we need to demand more rapid adoption of computerized prescribing to reduce time spent with prescription transcription. We should identify the biggest distractions that occur in our workplaces and eliminate or reduce the source by batching common interruptions and reorganizing work areas. Staff members need to be properly trained to understand safety procedures that are in place and know the limits of their specific duties. Fail-safe processes to ensure an independent double check before dispensing medications and performing other critical processes are a must. The pharmacy where this error occurred now requires two pharmacists to check every prescription. Unfortunately, this level of vigilance is typical after a patient has been harmed from an error. In other pharmacies, especially where there is only one pharmacist on duty, technicians may be involved in the double-check process.

A few other strategies can be used to prevent similar errors:

- ◆ Have one person perform order entry and a different person prepare the prescription, if possible, to add an independent validation of the order entry process.
- ◆ Do not prepare prescriptions using only the computer-generated label, as order entry may have been incorrect.
- ◆ Ensure that the original prescription, computer-generated label, prepared product, and manufacturer's product(s) remain together throughout the preparation process.
- ◆ Verify dispensing accuracy by comparing the original prescription with the labeled patient product and the manufacturer's product(s) used.

## **NIH Develops Community Drug Alert Bulletin**

The National Institute on Drug Abuse, as part of the National Institutes of Health (NIH), has developed a new Community Drug Alert Bulletin that addresses the latest scientific research on the non-medical use of prescription drugs of abuse and addiction.

This bulletin is geared toward parents, teachers, counselors, school nurses, and health professionals who are associated with those at risk from prescription drug abuse for non-medical purposes. It summarizes the growing problem in the US and the trend of non-medical use of prescription drugs. For more information on this bulletin visit [www.nida.nih.gov/PrescripAlert/index.html](http://www.nida.nih.gov/PrescripAlert/index.html).

## **Implementation of the Anabolic Steroid Control Act of 2004**

According to the December 16, 2005 *Federal Register*, effective January 20, 2005, the Anabolic Steroid Control Act of 2004 amended the Controlled Substances Act (CSA) and replaced the existing definition of "anabolic steroid" with a new definition. This new definition changed the basis for all future administrative scheduling actions relating to the control of the anabolic steroids as Schedule III controlled substances (CS) by eliminating the requirement to prove muscle growth. Also, the Act lists 59 substances as being anabolic steroids; these substances and their salts, esters, and ethers are Schedule III CS. The Act also revised the language of the CSA requiring exclusion of certain over-the-counter products from regulation as CS.

According to the House Report, the purpose of the Act is "to prevent the abuse of steroids by professional athletes. It will also address the widespread use of steroids and steroid precursors by college, high school, and even middle school students."

The changes to the definition include the following:

- ◆ Correction of the listing of steroid names resulting from the passage of the Anabolic Steroid Control Act of 1990.
- ◆ Replacement of the list of 23 steroids with a list of 59 steroids, including both intrinsically active steroids as well as steroid metabolic precursors.
- ◆ Automatic scheduling of the salts, esters, and ethers of Schedule III anabolic steroids without the need to prove that these salts, esters, or ethers promote muscle growth.
- ◆ Removal of the automatic scheduling of isomers of steroids listed as Schedule III anabolic steroids.
- ◆ Addition of dehydroepiandrosterone to the list of excluded substances.

## **FDA Unveils New Package Insert Format**

On January 18, 2006, FDA unveiled a major revision to the format of prescription drug information, commonly called the package insert, which will give health care professionals clear and concise prescribing information. This new format was developed in order to manage the risks of medication use and reduce medical errors; the new package insert will provide the most up-to-date information in an easy-to-read format. This new format will also make prescription information more accessible for use with electronic prescribing tools and other electronic information resources.

Revised for the first time in more than 25 years, the new format requires that the prescription information for new and recently approved products meet specific graphical requirements and includes the reorganization of critical information so physicians can find the information they need quickly. Some of the more important changes include:

- ◆ A new section called *Highlights* to provide immediate access to the most important prescribing information about benefits and risks.
- ◆ A table of contents for easy reference to detailed safety and efficacy information.
- ◆ The date of initial product approval, making it easier to determine how long a product has been on the market.
- ◆ A toll-free number and Internet reporting information for suspected adverse events to encourage more widespread reporting of suspected side effects.

This new format will be integrated into FDA's other e-Health initiatives and standards-settings through a variety of ongoing initiatives at FDA. For more information please visit [www.fda.gov/cder/regulatory/physLabel/default.htm](http://www.fda.gov/cder/regulatory/physLabel/default.htm).

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Miner at the Board office to coordinate the availability of an inspector for a local pharmacy group meeting. The best way to contact the compliance director, or any other Board staff, is by e-mail either directly or through the Board's Web site at [www.pharmacy.state.or.us](http://www.pharmacy.state.or.us) if you do not know the e-mail address. From the home page, click on "Agency Staff."

### **No. 396: New Pharmacy Technician License Application Form**

The Board's official application form for pharmacy technician licensure is being updated. The new form will include necessary information that was not included in the previous version of the form, and it is expected to be available in May 2006. When the new form appears on the Web site, the previous version will no longer be considered valid. Pharmacies that have a supply of application forms that are being provided to technician applicants should dispose of any of the old forms and make sure that only new forms are provided. This will save time and the cost of postage and paper for every time an application has to be returned.

The new form may be found on the Board's Web site and downloaded for use. If the Board receives an application on the outdated form, it will return the application to the sender and include a copy of the new form with instructions. You will always find the most current version of the application forms on our Web site.

### **No. 397: Pseudoephedrine Rule Effective July 1, 2006**

Throughout the past year, Oregon pharmacists and other retailers have endured a superfluity of press coverage regarding the new rules and legislation, both at the state and federal levels, regulating and restricting the sale of ephedrine, PSE, and phenylpropanolamine (PPA). Indeed, at times, it seemed difficult to remember what regulations actually applied and when and to whom they applied. Governor Ted Kulongoski, in response to recommendations from his "Meth" Task Force, asked the Board of Pharmacy to adopt emergency rules restricting the sale of the three meth precursor substances in October 2004, and later permanent rules providing additional restrictions in May 2005. Then, in August 2005, the governor signed legislation that required the Board of Pharmacy to adopt new permanent rules listing PSE, ephedrine, and PPA as Schedule III controlled substances (CS). After much consultation with the legislature, the Attorney General's office and, an advisory committee, the Board adopted its final rules on

April 5, 2006. This rule making action should simplify what has been a fairly complicated regulatory roadmap.

The rules will become effective on July 1, 2006. On that date, all products with any amount of ephedrine, PSE, or PPA become Schedule III CS in Oregon. On that date, the 9-gram sales limits that existed for these products under Oregon law no longer apply when they are dispensed pursuant to a prescription. As with other Schedule III CS these prescriptions may be refilled as authorized for up to six months or five refills, whichever occurs first. In addition, after July 1, 2006, these must be included in the Oregon pharmacy's annual inventory of CS. The good news is there will no longer be a requirement to manually record and maintain a sales transaction log.

### **No. 398: CE Clarification-Requirements, Fifty Minute Hour and PSAM**

Confusion has been expressed regarding the Board's CE requirements since the CE rule was updated last year. The Board requires pharmacists to complete 15 contact hours of CE credit or 1.5 continuing education units (CEUs) per year to be eligible for license renewal. To meet this requirement one must obtain at least 11 hours in the subject of therapeutics and at least one hour in pharmacy law. One contact hour of CE credit is 50 minutes. One contact hour of CE credit equals 0.1 CEUs. The Board regrets any confusion that may have occurred following this rule change

The Board has also indicated that it will approve up to four hours of CE credit for taking the National Association of Boards of Pharmacy's (NABP®) Pharmacist Self-Assessment Mechanism™ (PSAM®). PSAM is available through the NABP Web site at [www.nabp.net](http://www.nabp.net) and should take about three hours to complete. As with other CE programs you must maintain documentation of completion and the number of hours taken to complete the examination. The Board does not need to see your results, but if you are audited for CE with your annual renewal, you must provide documentation of completion.

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