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Oregon State Board of Pharmacy

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No. 417: Board Members Reappointed

Two Oregon State Board of Pharmacy members have been reappointed by Governor Ted Kulongoski. It was announced at the June Board meeting that Lee Howard, public member from Redmond, OR, was reappointed for his second four-year term, which will end with the June 2011 Board meeting. Linda Howrey, pharmacist member from Portland, OR, was also reappointed for her second term ending in June of 2011. The names and dates of service for all current Board members can be found on the Board's Web site at www.pharmacy.state.or.us.

No. 418: Confusion Over Pharmacist Versus Technician Duties

An area of confusion over pharmacist and pharmacy technician duties that has recently been brought to the Board's attention is that of reducing an oral prescription to writing. Despite the widespread use of technological advances in pharmacy practice over the past few years, prescriptions still come to the pharmacy over the telephone. It is comforting to note that, unlike prescriptions arriving via the various electronic systems, no controversy exists around the correct method of processing. However, it appears that some confusion does exist. An oral prescription, including oral prescriptions retrieved via voice mail, must be immediately reduced to writing by a pharmacist. This cannot be delegated to a technician or a clerk, although a pharmacy intern may be allowed to perform this function if he or she has been properly trained and is supervised by a pharmacist. A technician is allowed to receive refill authorization over the phone, including voice mail retrieval, but reducing a new prescription to writing does not fall within the technician's allowable duties.

Another area of apparent confusion is the pharmacist's password to access the computer and the pharmacist's drug utilization review (DUR) override code. Recent inspections and investigations have revealed a number of technicians who possess the pharmacist's password or override code. No matter how appropriate, efficient or convenient it may seem for a specific circumstance, a pharmacist should never, under any circumstances, give a password or code to

another pharmacy employee. Each pharmacy should have policies and procedures in place that provide guidance to its employees regarding proper use and maintenance of these important tools.

One area related to pharmacist and technician duties comes to mind within which there should be no confusion. This is the area of violations of pharmacy laws and regulations. If a pharmacist shares his or her password or override code with a technician, both the pharmacist and the technician may be considered in violation. If a pharmacist allows a technician to take or reduce to writing an oral prescription, both the pharmacist and the technician are in violation. Both would be subject to possible disciplinary action by the Board.

This article was prepared at the request of the Board following its June 6 meeting in Portland. Both pharmacists and technicians are responsible for their actions, and both have been disciplined for these offenses. The Board simply wants to illustrate the importance it places on the integrity of new prescriptions, and on security and access codes, as well as to ensure no confusion exists around the potential for disciplinary action for what the Board considers deliberate violations. The Board also wants to remind technicians of the importance of knowing the pharmacy laws and regulations and that they could be subject to disciplinary action for deliberate violations. A memo reinforcing this reminder will be sent to all licensed pharmacy technicians with the next renewal cycle.

No. 419: 50-Year Pharmacists

Once each year, the Board of Pharmacy recognizes and honors a number of pharmacists who have been licensed in the state for 50 years by acknowledging them in the *Newsletter*. The Board is grateful to them for their many years of service and contributions to the profession and to the health and well-being of the citizens of Oregon. These distinguished individuals should be proud of their significant accomplishments, and they deserve the recognition and acknowledgment of the profession. They should be congratulated for their dedication and perseverance.

Continued on page 4



FDA Issues Guidance on Glycerin Testing to Prevent DEG Poisoning

Spurred to action by repeated instances of diethylene glycol (DEG) poisoning, Food and Drug Administration (FDA) recently issued a guidance for industry entitled "Testing of Glycerin for Diethylene Glycol." This guidance provides recommendations on testing that will help pharmaceutical manufacturers, repackers, and other suppliers of glycerin, and pharmacists who engage in drug compounding, to avoid the use of glycerin that is contaminated with DEG and prevent incidents of DEG poisoning.

DEG contamination of glycerin can be detected by using specific analytical test procedures described in the United States Pharmacopeia monograph for glycerin, which quantifies the amount of DEG present at a detection level of 0.1%, as recommended by the interagency Diethylene Glycol Contamination Prevention Workshop of 1997. The guidance is available on the FDA Web site at www.fda.gov/cder/guidance/7654fnl.htm. FDA is accepting electronic comments on the guidance at www.fda.gov/dockets/ecomments.

Improperly Compounded Colchicine Blamed for Recent Deaths

Compounded colchicine that was 10 times as potent as labeled was responsible for two recent deaths in Oregon and Washington, the *Portland Tribune* reported on April 27, 2007. State officials are investigating the drug's role in a third death, also in Oregon. The drug was sent to a Portland, OR, clinic by ApothéCure, Inc, a Dallas, TX-based compounding pharmacy that distributes its drugs throughout the country. The two patients who died had received injections of colchicine as a treatment for back pain. Lab tests revealed that the colchicine administered in the two deaths had a potency of 4 mg/ml, rather than the 0.5 mg/ml stated on labels. According to Gary A. Schnabel, executive director of the Oregon State Board of Pharmacy, ApothéCure, a licensed Texas pharmacy, may be operating as a manufacturer. Both the Oregon Board and the Texas State Board of Pharmacy have opened investigations into the incident. The Texas Board advised ApothéCure to stop making colchicine; the company agreed, the *Portland Tribune* reported. On May 2, FDA announced the recall of all strengths, sizes, and lots of injectable colchicine compounded and sold by ApothéCure within the last year. The FDA MedWatch Safety summary on this issue is available at www.fda.gov/medwatch/safety/2007/safety07.htm#Colchicine.

New Podcasts Provide Emerging Drug Safety Information

FDA recently supplemented its print- and Web-based public health advisories with the launch of an audio broadcast service providing emerging drug safety information. The broadcasts, commonly known as podcasts, can be transmitted to personal computers and personal audio players. The service is part of FDA's ongoing effort to broaden and speed its communications on the safety of marketed medications when unexpected adverse events are reported to FDA. Since FDA launched the service in February 2007, broadcasts have addressed the potential hazards

of local anesthetics used in hair removal; the voluntary market withdrawals of drugs to treat the symptoms of Parkinson's disease and irritable bowel syndrome; and serious adverse events associated with agents that reduce the need for blood transfusions in cancer patients. The broadcasts are available on the FDA Web site at www.fda.gov/cder/drug/podcast/default.htm.

Prevent Tragedies Caused by Syringe Tip Caps



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) 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.

Over the past several years, there have been a number of reports where children have swallowed or choked on hypodermic syringe caps that were overlooked by parents and left on the syringes administering the medication. In 2001, a 5-month-old child asphyxiated when a cap from a Becton Dickinson 3 ml hypodermic syringe ejected into his throat during medication administration. In this case, a pediatrician provided the parents with the hypodermic syringe (without the needle) to administer Vantin® (cefepodoxime) suspension. With the cap intact, the father inserted the syringe into the Vantin, pulled back the plunger, and the medication flowed into the syringe. To him, the cap appeared to be part of the syringe. When he placed the syringe containing the medication into the baby's mouth, the cap flew off and became lodged in his airway. The baby was taken to the hospital where a procedure was performed to remove the cap; however, he did not survive.

Despite these reports, the mother of a 9-month-old child recently notified the Institute for Safe Medication Practices about a near fatal experience involving her child. Her community pharmacist gave her a parenteral syringe (without the needle) to help her accurately measure and administer an oral rehydration liquid for her daughter. Unfortunately, the pharmacist's good intention resulted in patient harm. The mother was unaware that the syringe tip held a small, translucent cap; however, despite this, she was able to withdraw the oral liquid. Then as she administered the liquid, the cap on the end of the syringe ejected and became lodged in the child's throat, causing airway obstruction. Fortunately, the child recovered.

Although parenteral syringes are not designed for oral administration, health care practitioners may provide them to patients or caregivers to measure oral liquids without realizing how dangerous this practice may be. Some syringe



manufacturers place the small, translucent caps on parenteral syringes packaged without needles as a protective cover. However, practitioners may not realize the cap is there or may not inform patients or caregivers of the need for its removal prior to use. The danger arises due to the fact that the cap does not provide a good seal. Subsequently, medications can be drawn into many of these syringes without removing the caps. If not removed before administration, the force of pushing the plunger can eject the cap and cause it to lodge in a child's trachea.

Safe practice recommendations: Consider the following strategies to help protect your patients from tragedies caused by syringe tip caps.

- ◆ **Increase awareness.** Share this and previous errors with staff to illustrate why parenteral syringes should never be used for oral liquid medications. Show staff a video from FDA and ISMP highlighting this issue (access the video link at: www.accessdata.fda.gov/scripts/cdrh/cfdocs/psn/transcript.cfm?show=3#6).
- ◆ **Product availability.** Ensure that oral syringes (without caps) or other appropriate measuring devices are readily available for distribution or purchase at your practice site. Verify that the dosage can be accurately measured using the oral syringe. It may be necessary to keep a few different sizes on hand to ensure proper measurement of smaller doses.
- ◆ **Limit access.** If parenteral syringes must be stocked for use with injectable products, purchase syringes that are not packaged with the translucent caps to minimize the likelihood of this error.
- ◆ **Warning labels.** Add warning labels that state, "not for use with oral liquids" to boxes or storage bins containing parenteral syringes.
- ◆ **Educate patients and caregivers.** Provide education to patients and caregivers regarding proper use of an oral syringe (or other measuring device). Demonstrate how to measure and administer the dose and inform them about how to clean the device, if it is to be reused. Several years ago, Becton Dickinson voluntarily elected to package parenteral syringes without the small caps in response to this serious issue. However, since some manufacturers still include a cap on parenteral syringes, the danger of asphyxiation with the cap is still present. We have again contacted FDA to alert them about this problem. They have stated that they will be following up with each syringe manufacturer with the goal to get the syringe caps removed. At the very minimum, we believe that the packaging of parenteral syringes should be required to clearly state, "not for oral use" or "not for use with oral liquids."

New FDA Web Page Warns Against Buying Isotretinoin Online

FDA has launched a special Web page to warn consumers about the dangers of buying isotretinoin online. Improperly used, isotretinoin can cause severe side effects, including birth defects and serious mental health problems. The Web page, www.fda.gov/buyonline/accutane, is positioned as a search result on Internet search engines when consumers initiate an online search for the drug under any one of its four names (isotretinoin is sold under the brand name of Accutane® and in generic versions called

Amnesteem™, Claravis™, and Sotret®). The Web page warns that the drug "should only be taken under the close supervision" of a physician and a pharmacist, and provides links to related information, including ways to check that drugs purchased online come from legitimate pharmacies.

To reduce risks, FDA and the manufacturers of isotretinoin have implemented a strict distribution program called iPLEDGE to ensure that women using isotretinoin do not become pregnant, and that women who are pregnant do not use isotretinoin. Isotretinoin is available only at pharmacies that are registered for this distribution program. Additionally, the distribution program is designed to prevent the sale of isotretinoin over the Internet. Dispensing must comply with the agency's risk management requirements.

Tampering Results in Misbranding of Ziagen as Combivir

GlaxoSmithKline and FDA warned health care professionals of an apparent third-party tampering that resulted in the misbranding of Ziagen® as Combivir® and employed counterfeit labels for Combivir tablets. Two 60-count misbranded bottles of Combivir tablets contained 300 mg tablets of Ziagen.

The counterfeit labels identified are Lot No. 6ZP9760 with expiration dates of April 2010 and April 2009. The incident appears to be isolated and limited in scope to one pharmacy in California.

Pharmacists are advised to immediately examine the contents of each bottle of Combivir in their pharmacies to confirm that the bottles contain the correct medication. If a bottle contains anything other than Combivir tablets, pharmacists are advised to notify the manufacturer.

The letter from GlaxoSmithKline and FDA, containing photos of actual Combivir and Ziagen tablets, is posted on the FDA Web site at www.fda.gov/medwatch/safety/2007/Ziagen_Dear_RPh_03-29-2007.pdf.

FDA Issues Halt on Manufacture, Distribution of Unapproved Suppository Drugs

FDA notified health care professionals and consumers that companies must stop manufacturing and distributing unapproved suppository drug products containing trimethobenzamide hydrochloride.

These products, used to treat nausea and vomiting in adults and children, have been marketed under various names, including Tigan®, Tebamide™, T-Gen, Trimazide, and Trimethobenz. Drugs containing trimethobenzamide in suppository form lack evidence of effectiveness. This action does not affect oral capsules and injectable products containing trimethobenzamide that have been approved by FDA.

FDA urges consumers currently using trimethobenzamide suppositories or who have questions or concerns to contact their health care professionals. Alternative products approved to effectively treat nausea and vomiting are available in a variety of forms.

The MedWatch safety summary and a link to the full press release are available at www.fda.gov/medwatch/safety/2007/safety07.htm#trimethobenzamide.

Continued from page 1

Following is a list of Oregon's 50-year pharmacists for 2005 and 2006. This information is from the Board's electronic database system, which has been upgraded over the past several years. If you see errors or know of any persons missing from this list please contact the Board.

Bill E. Kuluris, Orange, CA (January 28, 1955)
Jean M. Rennebohm, Salem, OR (March 11, 1955)
Harrison F. Bowman, Beaverton, OR (March 11, 1955)
Wilfred H. Park, McMinnville, OR (March 11, 1955)
John P. Slayton, Portland, OR (August 30, 1955)
Joseph W. Sayre, Ashland, OR (December 14, 1955)
Robert Parsons, Boise, ID (December 14, 1955)
Mitchell P. Daletas, Eugene, OR (December 14, 1955)
Kenneth D. Boshears, North Bend, OR (November 15, 1956)
Max Larson, Medford, OR (November 15, 1956)
Benjamin W. Watkins, Hillsboro, OR (November 15, 1956)

No. 420: Disciplinary Actions Reviewed on Oregon Board of Pharmacy Web site

Several past issues of the *Newsletter* have included a summary of disciplinary actions taken by the Board over a certain period of time. Individual and company names have not been included in these reports, but the violations and the penalties were included. Beginning with the April 2007 Board meeting, reports of disciplinary actions are being posted on the Board's Web site. Names will continue to be deleted from the reports as the Board believes this is not part of a punitive action, but is an educational opportunity to allow pharmacists, technicians, and consumers to learn from the recent cases. Only information (excluding individual and company names) that is currently subject to public disclosure will be included in the reports. These reports can be viewed on the Board's Web site at www.pharmacy.state.or.us/Pharmacy/Board_Actions.shtml.

No. 421: Proper Use of Titles

The Board's compliance staff has run across several examples of improper use of the titles *PharmD* and *RPh*. This is just a reminder that the title *PharmD* is a title that describes

the academic degree (doctor of pharmacy) achieved by the student and bestowed by the school or college of pharmacy following graduation from a pharmacy professional program. The title *RPh* is a title that describes the professional license bestowed by a government regulatory agency on a candidate who has completed all the requirements that are prerequisite to licensure. Prerequisites for licensure as a pharmacist, and the ability to display the title *RPh*, include graduation from a school or college of pharmacy approved by the Board, successful completion of the North American Pharmacist Licensure Examination™ and Multistate Pharmacy Jurisprudence Examination® licensure examinations with passing scores, and submission of a completed application provided by the Board.

To elaborate, a person may hold the doctor of pharmacy degree and still not be licensed by the state as a registered pharmacist. This person could use the title *PharmD*, could perform a variety of research and other activities, but could not independently practice pharmacy, or use the titles pharmacist or *RPh*. Once the individual has completed the prerequisites and becomes licensed with the Oregon State Board of Pharmacy, he or she then may use the title pharmacist or *RPh* in addition to *PharmD*.

To further elaborate, a person may have completed all the courses required for the *PharmD* without, or without yet, having the degree actually conferred. This person could not use the title. The degree must be conferred before the *PharmD* title applies, and the license must be obtained before the *RPh* title applies.

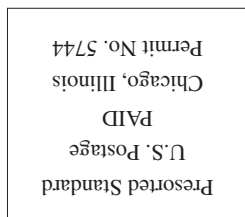
Page 4 – August 2007

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