August 2007

Arkansas State Board of Pharmacy

Published to promote voluntary compliance of pharmacy and drug law.

101 E Capitol, Suite 218, Little Rock, AR 72201
Tel: 501/682-0190 Fax: 501/682-0195

Staffing Updates

After serving the Arkansas State Board of Pharmacy as the chief fiscal officer (CFO) for the past five years, **Margaret Lincourt** decided to retire July 1, 2007. Although her title was that of CFO, the Board and staff recognize that her work and impact on the Board of Pharmacy has far outreached her title or job description. We wish her well in her retirement.

Robin Morrissey has joined the Board staff as our new CFO. Robin has worked for the state for over 20 years, most recently as an accounting supervisor at the Employee Benefits Division.

Board Inspector **James Myatt** left the Board of Pharmacy to work for the Arkansas Department of Health, Pharmacy Services after serving the Board for the past seven years.

Clyde C. Frazier has joined the Arkansas State Board of Pharmacy as a Board inspector. We are excited to have Clyde on our team and are already learning from his expertise from his experience working for Pharmacy Services/Drug Control in the Department of Health.

Web Site Changes

The Board of Pharmacy is continuing to push our technology and licensing software to help make our office more user-friendly for the public and for licensees. If you visit our Web site you will see on the front page that there are two new links that may be very useful for your practice. The first link is entitled "License Verification," and it allows you to verify the licensure status of a business or individual. This can serve as a useful tool to verify if a technician, pharmacist, wholesaler, or other person or entity has a current permit with the Board of Pharmacy. However, this does not excuse a business from displaying the current permits for the business and staff. When checking a facility, this tool can display the list of employees registered to work at the facility. Conversely, when checking the status of a pharmacist or technician you can see the list of pharmacies in which the individual is registered to work.

The second link is for "License Maintenance and Online Renewals." When you enter this page you may choose either individuals or facilities to update the file for your permit. For individuals you must type in the license number and the last four digits of your social security number. Please remember that this is the license number as printed on your permit so it would appear as something such as PD05555 for pharmacists or PT88888 for technicians. For individuals, you can update your preferred mailing address, your physical address, and your place of employment. Updating this information through our Web site will serve as your official notification to the Board for changes in employment or address. The Board encourages you to check your address for accuracy as this is the address where your renewals will be mailed each biennium.

For facilities, you must type in the permit number, such as AR20202, HP12345, or WD03030, and then the facility identification number, which is sent out along with the business permit renewal notices each biennium. When checking your facility through the license maintenance you can check the list of employees for the facility and update changes in employment for the Board of Pharmacy.

Regulation Changes from the June Board Meeting

The Arkansas State Board of Pharmacy approved changes to the following regulations at the June 2007 Board Meeting.

Regulation 1 – General Operations

The proposed changes to Regulation 1 update language regarding technician permit fees related to the restricted charitable clinic pharmacy technician's permit that may be issued pursuant to Board Regulation 04-03-0004 (f).

Regulation 2 – Pharmacists

The changes to Regulation 2 clarify the Board of Pharmacy's ability to approve colleges of pharmacy for internship training and also amend language to allow dean(s) from colleges of pharmacy within Arkansas to participate in the Arkansas Tripartite Committee on Continuing Pharmacy Education.

Regulation 4 – Pharmacy

The changes to Regulation 4 clarify the guidelines for the re-use of medications in nursing homes or correctional facilities and also add language to allow for and regulate off-site order entry in retail pharmacies located in Arkansas. Changes also update the expiration date for the pilot program permits for donated prescription medications and allow for a limited-use technician permit for these facilities.

Regulation 9 – Pharmaceutical Care/Patient Counseling

The changes to Regulation 9 clarify the ability of licensed interns to administer immunizations under the direct supervision of a pharmacist certified to give immunizations.

The updated regulations may be viewed in their entirety in the Pharmacy Lawbook section of our Web site at *www.arkansas.gov/asbp.*

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® (cefpodoxime) 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*.

Complaints Against Internet Brokers

The Arkansas State Board of Pharmacy has received hundreds of faxes, calls, and complaints regarding Internet brokers faxing business solicitations in Arkansas for individuals to obtain prescription medications either without a prescription or based upon an online questionnaire. Offending parties include MyPharma.com, MyFirstPharma.com, MyPharma1.net, MyPharmaNow.com, MyPharmaUSA.com, MyPharmaUSA.biz and possibly other similar domain names or identical Web sites. These Web sites are not pharmacies but function as brokers to bring buyers and sellers together via the Internet. Numerous attempts have been made to contact these Web sites as well as search changing addresses to verify a physical location for these businesses. The locations differ and the addresses include at least two cities in the Republic of the Philippines. In some instances, the fax header on these faxes would indicate a 501 (Arkansas) prefix, when in fact the phone number had been purchased by an Internet hosting site in New Jersey. The Arkansas State Board of Pharmacy is working in coordination with Drug Enforcement Administration (DEA) to subpoena records from the hosting site to identify the upstream source of the faxes and drug supply. Providing medication without a valid patient-physician relationship and functioning as an Internet broker without verifying compliance with this valid relationship both violate Act 128 of 2007.

Requirement to Report Immunizations – Department of Health Message

Act 432 of 1995 requires all providers who give vaccines to persons 22 years of age and younger to provide this information to the Department of Health. The Immunization section will provide you with the training needed to access the Web based Immunization Registry. For more information please call the Immunization section at 501/661-2720.

Continuing Education

Pharmacist renewals will be sent out at the end of the year for Arkansas licensed pharmacists. As with years past, part of the renewal process will be for pharmacists to report their continuing education (CE) for the last two years. This will be included for online renewals as well as paper renewals. Specific instructions will be included in your renewal packet that will be sent to your mailing address of record. Once again, the best way to renew your license will be through the Internet as this allows our staff to turn around your renewal much faster. Additionally, this is the only way to use a credit card when renewing your permit. As a reminder, the CE requirements for Arkansas include a total of 30 hours of CE credit with 12 of the hours being live drug therapy or patient-care oriented. Specific questions regarding CE should be directed to Board staff. Only CE attained during the 2006-2007 biennium will count towards this requirement. Please remember that Board regulations require pharmacists to retain certificates of participation for CE for a period of four years. Pharmacists may be required to show proof of CE as part of the Board's random CE audit.

Tramadol Placed in Schedule IV July 31

Please note that all prescription products containing the active ingredient tramadol became Schedule IV controlled substances per Act 558 of 2007, sponsored by Representative Tommy Dickinson, and Act 585, sponsored by Senator Percy Malone, effective July 31, 2007. To quote the DEA Pharmacist's Manual, "When a drug not previously controlled is scheduled, the drug must be inventoried as of the effective date of scheduling." This is also addressed in the Code of Federal Regulations 21 CFR §1304.11 Inventory Requirements.

Arkansas Pharmacy Support Group Help Line
870/636-0923

The *Arkansas State Board of Pharmacy News* is published by the Arkansas 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.

John Kirtley, PharmD - State News Editor

Carmen A. Catizone, MS, RPh, DPh - National News Editor & Executive Editor

Larissa Doucette - Editorial Manager

National Association of Boards of Pharmacy Foundation, Inc
1600 Feehanville Drive
Mount Prospect, IL 60056

ARKANSAS STATE BOARD OF PHARMACY

Presorted Standard
U.S. Postage
PAID
Chicago, Illinois
Permit No. 5744