August 2007

Ohio State Board of Pharmacy

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Published to promote voluntary compliance of pharmacy and drug law.

New Members Appointed to the Board of Pharmacy

On July 5, 2007, Governor Ted Strickland announced the appointment of two new members to the Ohio State Board of Pharmacy. Jerome J. Wiesenhahn, RPh, of Mason, OH, and Richard Kolezynski, RPh, of Strongsville, OH, were appointed to replace Suzanne Eastman, RPh, and Robert Giacalone, RPh, who had completed their second terms as Board members on June 30. Congratulations to our two new members on their appointments and thanks to Sue and Bob for their eight years each of service to the people of Ohio.

Pharmacist License Renewal Time is at Hand

Pharmacist renewal forms were mailed out late in July to all pharmacists licensed with the Board who are eligible for renewal. If you do not receive your renewal form by the middle of August, you need to check with the Board office to find out what you need to do to renew your license. If your license is not renewed before September 15, you may not continue to practice as a pharmacist in Ohio until you do get it renewed.

We apologize that the renewal forms went out later than usual. We thought that we would be able to have online renewal available this year, but it became obvious in late June that online renewal was not going to happen this year. Therefore, we had to obtain the printed materials to send out instead, which caused the delay. Please note that you will still need to renew your license by September 15, 2007, if you plan to continue practicing pharmacy in Ohio.

Recent Legislation Affecting Pharmacy Practice

The Ohio General Assembly has passed, and the governor has signed, some bills that will have an impact on the practice of pharmacy in Ohio. In addition, the General Assembly is also considering other bills that you may wish to review and comment on, since they also could greatly affect the way you practice.

Senate Bill (SB) 58 – Pharmacists – Signed by the Governor; Effective Date August 30, 2007

SB 58, introduced by Senator Kevin Coughlin, modifies the list of immunizations that pharmacists may administer to patients under a protocol with a physician. Currently, pharmacists are authorized by law to administer immunizations for influenza, pneumonia, tetanus, hepatitis A, and hepatitis B to patients at least 18 years of age. This bill changes the law by adding meningitis, diphtheria, and pertussis to the list of immunizations that pharmacists may administer. In addition, it lowers the age limit for pharmacist administration of influenza vaccine to 14 years of age with parental or guardian consent for those patients between the ages of 14 and 17 years old. The bill also allows pharmacists to administer epinephrine and diphenhydramine injections to patients in an emergency situation. Finally, the bill provides authorization for properly trained pharmacy interns to administer influenza immunizations to adults under the pharmacist's direct supervision.

Please note: while the law has an effective date of August 30, 2007, the Board of Pharmacy still has to promulgate rules to implement the changes. By the time this *Newsletter* arrives, the rules should be posted on the Board's Web site. Click on the "What's New" box to locate the notice for the public hearing and all of the Board's proposed new and changed rules. The public hearing will be held on September 10, 2007, during the Board's September meeting. We hope to have the rules in effect on or before November 1, 2007, so interns can participate in this year's influenza immunization program.

Senate Bill 33 – Acupuncture – Signed by the Governor; Effective Date August 22, 2007

SB 33, introduced by Senator J. Kirk Schuring, deals primarily with acupuncture, which is certainly not a part of the practice of pharmacy. However, it also contained language relating to the Drug Repository Program that may be of interest to those nursing home pharmacies who have not yet started to participate. After discussions with several pharmacies who were not contributing returned drugs to the repository programs in their area, language was put in this bill that added increased liability protection for people who donate drugs to the program. If your pharmacy was not participating due to liability concerns, please review this change to the law and reconsider. It seems such a waste to destroy drugs that could be used for people who really need them but cannot afford them.

House Bill (HB) 99 – Epilepsy Treatment – Introduced – In Hearings

HB 99, introduced by Representative Michelle G. Schneider, and its companion bill SB 114, introduced by Senator Coughlin, have both been introduced but are still in the hearing process. These bills, as introduced, would require a pharmacist to obtain written authorization from the prescriber and the patient or caregiver before a generically equivalent drug used for epilepsy was dispensed. In other words, the pharmacist would be required to dispense the same manufacturer's product that the patient was stabilized on unless the pharmacist first received written permission to change to a different manufacturer's product. One would think that the current law regarding the substitution of generically equivalent products

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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*.

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(§4729.38 ORC) would be enough since the prescriber has the ability to write "DAW" (dispense as written) along with the brand name or the generic name and the manufacturer. In addition, the patient has the right to refuse substitution. In either case, the insurance company does not have the legal right to mandate substitution. The patient may have to pay, but many patients with epilepsy would rather pay than switch manufacturers and potentially end up with seizures. Unfortunately, this bill relies totally on the pharmacist to ascertain the current product (if not already known) and then to receive permission before a change could be made. Interested parties should review the bill in its current form on the state of Ohio's Web site. Hearings will probably continue in the fall.

HB 149 – Optometry– Introduced – In Hearings

HB 149, introduced by Representative David Daniels, contains changes to the laws regarding the practice of optometry. Of interest to pharmacists is that this bill will remove the written formulary of drugs that optometrists may prescribe. Instead, they will be limited to prescribing those drugs that are within an optometrist's scope of practice. This is similar to the current situation with dentists and podiatrists, both of whom are limited practitioners. Pharmacists have always made good judgments when filling prescriptions written by dentists and podiatrists, so there should be no problems with pharmacists using the same good judgment with optometrists' prescriptions. Of more importance, however, is that this bill would add Schedule III narcotic drugs to those drugs that optometrists would be able to prescribe. Currently, optometrists do not have the ability to prescribe controlled substances and, therefore, do not have Drug Enforcement Administration numbers. If this bill passes, that will change.

HB 253 – Nurses – Introduced – In Hearings

HB 253, introduced by Representative W. Scott Oelslager, would add Schedule II controlled substances to the drugs that may be prescribed by an advanced practice nurse (APN) with prescribing privileges. Currently, the only Schedule II substances that APNs may prescribe are opiates for a terminal patient that have been previously prescribed by the patient's physician. The current law limits the quantity to a 24-hour supply. If this bill passes, APNs would be able to prescribe any Schedule II drug as long as the drug was approved for APN prescribing by the Ohio Board of Nursing's Committee on Prescriptive Governance (CPG). This would also be subject to any quantity or time limits that the CPG saw fit to impose, if it chose to do so.

Physician Assistant Prescribing

At the current time, it appears that physician assistant (PA) prescribing will begin some time this fall. The State Medical Board of Ohio is in the process of finalizing the rules needed to implement the process. Once the rules are finished and the Medical Board sets the implementation date, the process of licensing PAs to prescribe will begin. Until that time, PAs may not prescribe drugs. Information on licensing of PAs should be available on the Medical Board's Web site at *www.med.ohio.gov* once the process begins.

If you have any questions about PA prescribing, you may call the Medical Board (614/466-3934) or, if you wish, the Board of Pharmacy (614/466-4143). Overall, we hope the process goes as smoothly as the APN prescribing did.

Disciplinary Actions

Anyone with a question regarding the license status of a particular prescriber, nurse, pharmacist, pharmacy intern, or dangerous drug distributor in Ohio should contact the appropriate licensing board. The Web sites listed below may include disciplinary actions for their respective licensees.

State Dental Board – 614/466-2580, *www.dental.ohio.gov*
State Medical Board – 614/466-3934, *www.med.ohio.gov*
State Nursing Board – 614/466-3947, *www.nursing.ohio.gov*
State Optometry Board – 614/466-5115, *www.optometry.ohio.gov*
State Pharmacy Board – 614/466-4143, *www.pharmacy.ohio.gov*
State Veterinary Medical Board – 614/644-5281, *www.ovmlb.ohio.gov*
Drug Enforcement Administration – 800/230-6844; *www.deadiversion.usdoj.gov*

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