January 2005

Kansas State Board of Pharmacy

Landon State Office Bldg
900 Jackson, Room 560
Topeka, KS 66612
www.accesskansas.org/pharmacy

Published to promote voluntary compliance of pharmacy and drug law.

Training of Pharmacy Technicians

K.A.R. 68-5-15 requires that the pharmacist-in-charge (PIC) ensure that the pharmacy technician training manual has been kept up-to-date for completeness. The Kansas State Board of Pharmacy inspectors will accept either a signed and dated statement that the manual has been reviewed annually or an annually signed and dated list of functions that each technician has been trained to perform. You will also need to have separate documentation that your pharmacy technicians have been trained within 180 days of their employment at your practice. All technicians should now be registered with the Board of Pharmacy.

State Pharmacy Board Orders/ Disciplinary Matters

Diane Adamson, RPh; Topeka – was disciplined by the Board for violation of K.A.R. 68-7-12b(b) for failing to file an incident report. Ms Adamson was assessed a fine of $500 and placed on a one-year probationary period.

Jarrell Bridges, RPh; Dodge City – was disciplined by the Board for violation of K.A.R. 68-7-12b(b) for failing to file an incident report. Mr Bridges was assessed a fine of $500 and was required to attend six hours of additional continuing education (CE) regarding error prevention.

Michael Bellesine, RPh; El Dorado – was disciplined by the Board for incorrectly filling a prescription for NovoLog® with NovoLog 70/30 in violation of K.S.A. 65-1627(a)(6). He was also disciplined for failure to file an incident report in violation of K.A.R. 68-7-12b(b). Mr Bellesine was assessed a fine of $500 for each violation. Mr Bellesine was also placed on one-year probation and required to obtain six hours of additional CE regarding error prevention.

Dandurand Drug Company; Wichita – was disciplined by the Board for violation of K.A.R. 68-7-12b(b) for failures to file incident reports. The Respondent was fined $1,000 and required to provide the Board with a written copy of procedures providing a system to identify the pharmacists that file each prescription and provide for a system to verify that the correct prescription is dispensed.

Lesley Harris, RPh; Holton – was disciplined by the Board for a violation of K.A.R. 68-7-12b(b) for failure to file an incident report regarding a counting error. Ms Harris was assessed a fine in the amount of $500.

Roger Fort, RPh; Paola – was disciplined by the Board for a violation of K.S.A. 65-1637(a) for increasing the quantity from four to 10 Lovenox® syringes without authorization from the physician. Mr Fort was assessed a fine in the amount of $500.

Ricky K. Stone, RPh; Wichita – was disciplined by the Board for a violation of K.S.A. 65-1637(a) for filling a prescription for metoclopramide 10 mg tablets with Lanoxin® 0.25 mg. Mr Stone was assessed a fine in the amount of $1,000. He was also placed on probation for one year and required to forward a copy of all personal incident reports to the Board's executive secretary/director. Mr Stone shall also complete five additional hours of CE regarding error prevention.

Alan Conrady, RPh; Independence – The Board entered into a Stipulation with Mr Conrady whereby he would remain in an agreement with the Committee on Impaired Practice Program for additional time, until September 22, 2009, and comply with program requirements.

Lorie Brinkman, RPh; Coffeyville – The Board entered an Order compelling the Respondent to submit to a mental or physical examination pursuant to K.S.A. 65-1627 (b).

Travis Scott, RPh; Oak Grove, MO – The Board reinstated Mr Scott's license on the condition that he remain in an agreement with the Committee on Impaired Practice Program until August 21, 2008, and comply with other specific terms and conditions.

George Saghbene, RPh; Wichita – was disciplined by the Board for a violation K.S.A. 65-1637(a) for filling a

Continued on page 4

New Over-the-Counter Product Labeling

On March 24, 2004, Food and Drug Administration (FDA) passed final rulings requiring content labeling for over-the counter (OTC) medications that contain levels of calcium, magnesium, sodium, or potassium that might be harmful to persons with certain underlying medical conditions. The final rule was effective April 23, 2004, with compliance expected by September 24, 2005. The labeling changes for oral OTC products were deemed necessary as persons with certain medical conditions such as heart disease, hypertension, kidney disease, kidney stones, or other medical conditions could worsen their condition upon consumption of these products. For example, OTC use of medications containing potassium may cause hyperkalemia in persons with compromised renal function. Under the new rules, oral OTC medications must state the exact amount of a particular ingredient in each dose if they contain:

- 5 mg or more of sodium in a single dose,
- 20 mg or more of calcium in a single dose,
- 8 mg or more of magnesium in a single dose, or
- 5 mg or more of potassium in a single dose.

The rules also require warnings to alert consumers on sodium-, calcium-, magnesium-, or potassium-restricted diets to consult their physician before using oral products that contain maximum daily doses of:

- more than 140 mg sodium,
- more than 3.2 grams calcium,
- more than 600 mg magnesium, or
- more than 975 mg potassium.

Currently the new label requirements do not include mouth rinses, fluoride toothpastes, or mouth washes. Detailed information on the rulings can be found in the Federal Register at www.fda.gov/OHRMS/DOCKETS/98fr/04-6479.htm and www.fda.gov/OHRMS/DOCKETS/98fr/04-6480.htm.

FDA Requests Antidepressant Manufacturers to Strengthen Warnings

On March 22, 2004, FDA issued a public health advisory that cautions physicians, their patients, and families and caregivers to closely monitor adults and children with depression. Results of antidepressant studies in children since June 2003 appeared to suggest an increased risk of suicidal thoughts and actions in those children taking certain antidepressants. FDA has initiated a review of these reports, but it is not clear whether or not antidepressants contribute to suicidal thinking and behavior.

As a result of the studies, FDA is asking manufacturers to change the labels of 10 drugs to include stronger cautions and warnings to monitor patients for worsening depression and the emergence of suicidal ideation. The drugs affected include bupropion (Wellbutrin®), citalopram (Celexa™), escitalopram (Lexapro™), fluvoxamine (Luvox® – not FDA approved for treatment of depression in the US), fluoxetine (Prozac®), mirtazapine (Remeron®), nefazodone (Serzone®), paroxetine (Paxil®), venlaxafine (Effexor®), and sertraline (Zoloft®). It should be noted that Prozac is the only drug approved for use in children with major depressive disorder. Prozac, Zoloft, and Luvox are approved for pediatric patients with obsessive-compulsive disorder.

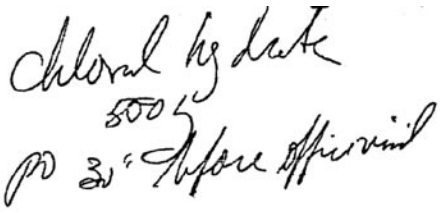
Patients taking these antidepressants should be monitored for behaviors associated with the drugs such as anxiety, agitation, panic attacks, insomnia, irritability, hostility, impulsivity, akathisia, hypomania, and mania. Physicians are urged to closely monitor patients with bipolar disorder as monotherapy with antidepressants is believed to have the potential to induce manic episodes in such patients. A causal relationship has not been established between physical symptoms and suicidal ideation; however, medications may need to be discontinued when the symptoms are severe, abrupt in onset, or were not part of the presenting symptoms. Further information can be found on CDER's Web site: www.fda.gov/cder/drug/antidepressants/default.htm.

Let Past Experience with Chloral Hydrate Syrup Guide its Safe Use

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.

Chloral hydrate can be used safely to sedate pediatric patients for diagnostic procedures such as endoscopic procedures, CT scans, or MRIs. However, in several error reports over the years we have seen the sad stories of fatalities that have occurred after excessive doses of the drug were dispensed in error. Typically, deaths have occurred in cases where the order was not clear or when untrained individuals, both staff and parents, were involved without adequate supervision or the knowledge that they were administering an overdose. In some cases, to save time, chloral hydrate has been prescribed for use at home prior to travel to the practice site. In one instance, a 500 mg/5 mL concentration was dispensed instead of 250 mg/5 mL, which also is available. Unfortunately, the dose was prescribed by volume (teaspoonful), which made detection of the twofold overdose impossible. In another incidence, 120 mL of syrup was incorrectly dispensed instead of the prescribed 12 mL. The label instructed the mother to give her child the entire bottle, which she did. Without trained personnel and emergency equipment present to treat these accidental overdoses, the children in both cases died.

Recently the tragedy happened again. A prescription was written for a 17-month-old child; the pharmacist read the directions as "30 cc before office visit" and instructed the mother to give her child that amount. In truth, the physician wanted the child to receive 500 mg 30 *minutes* before the office visit. The double hash-mark symbol (''), which the physician intended to mean minutes, was misread as cc. Actually, a double hash mark stands for seconds; a single hash mark (') is used for minutes. Neither symbol should be used in medicine, however, because not everyone understands their meaning.



Errors also happen in diagnostic areas where technical support personnel often administer oral conscious sedation even though they are not properly trained. In some cases, an ambiguous physician order such as "give chloral hydrate 5 cc prn sedation" or ". . . prn agitation," rather than a specific milligram amount and maximum dose, has led to events where multiple doses of chloral hydrate were dispensed from the supply available to personnel. By the time the child fell asleep, the amount administered was a massive overdose leading to respiratory arrest.

Please consider reviewing your process for dispensing oral liquids used for conscious sedation in children, whether to a medical facility or to a family member. We suggest that the following precautions, in addition to package insert recommendations, be employed. Advise physicians that the drug should not be prescribed by volume (eg, "5 mL," "one teaspoonful," etc). There are two available concentrations of this drug. Instead, the specific milligram dose should be expressed. The prescription should state that it is for pre-procedure sedation. In hospital situations or when pharmacies dispense to health care facilities, prescriptions are best dispensed for each patient in labeled, unit-dose, oral syringes; providing the product in bulk packages as floor stock is less safe. We believe it is safest for pharmacists to *not* dispense prescriptions for patient use in the home when it is for pre-procedure sedation. Should the caregiver receive such a prescription, he or she should be advised that they are safest for the dose to be administered where the procedure will be performed. Official labeling for Versed® Syrup, another drug used for conscious sedation in children, notes that the syrup is intended for use only in monitored settings, never the home. Also, as noted in the product's boxed warning, only health care professionals trained in conscious sedation procedures and authorized to administer conscious sedation drugs should do so. Careful monitoring by direct visual observation is necessary and age-/size- appropriate resuscitation equipment must be readily available. The American Academy of Pediatrics agrees; the Academy's current "Guidelines for Monitoring and Management of Pediatric Patients During and After Sedation for Diagnostic and Therapeutic Procedures" (*Pediatrics* 2002; 110:836-838) recommend that children should not receive sedative or anxiolytic medications without supervision by skilled medical personnel. These medications should be administered by, or in the presence of, individuals skilled in airway management and cardiopulmonary resuscitation and administered in a health care facility where appropriate monitoring, including continuous pulse oximetry, can be instituted.

One final argument for administering children's sedation on site is to ensure proper timing in case of unpredictable schedule delays.

NABP Releases Updated NAPLEX Blueprint

NABP has released the updated blueprint for the North American Pharmacist Licensure Examination™ (NAPLEX®). The blueprint is available for viewing on NABP's Web site, www.nabp.net, as of September 2004. Examinations based on the updated blueprint will be administered beginning spring 2005.

Changes to the NAPLEX blueprint include the addition of competency statements addressing dietary supplements and pharmacotherapeutic equivalency as well as integration of the skill of communicating with patients and other health care providers in the entire examination blueprint instead of focusing it within a single competency area as with the current NAPLEX. The examination continues to consist of three major areas that are divided into several competency and subcompetency statements.

The updated blueprint and competency statements require a new passing standard. However, the NAPLEX continues to be a computer-adaptive examination that requires a scaled score of 75 or greater to pass. Calculation of the score is the same as in the past: the score is calculated by first determining the candidate's ability level on the NAPLEX and then comparing this to the predetermined minimum acceptable ability level established for the NAPLEX. The new passing standard will go into effect along with the updated blueprint in spring 2005.

For more information about the NAPLEX, contact the Customer Service Department by calling 847/391-4406 or visit the Association's Web site at www.nabp.net.

December 2004 FPGEE Date and Location Announced

On December 4, 2004, NABP will again administer a paper-and-pencil Foreign Pharmacy Graduate Equivalency Examination® (FPGEE®). The examination is being offered at three United States locations: Northlake (Chicago area), IL; New York, NY; and San Mateo, CA. Candidates who have been accepted to sit for the December 4, 2004 administration were mailed their admission tickets in early fall.

To prepare for the December examination, candidates may take the Pre-FPGEE™, a Web-based practice examination for the FPGEE. The practice examination is accessible at www.nabp.net and www.pre-fpgee.com.

For more information on the FPGEE, visit NABP's Web site at www.nabp.net.

Continued from page 1

prescription written for 60 Desoxyn® but dispensing 40 Desoxyn and billing the insurance company for the larger amount. The Respondent failed to notify the physician that the pharmacy could not fill a partial filling within 72 hours. Mr Saghbene was also disciplined for failure to counsel in violation of K.A.R. 68-20-19(a)(1). Mr Saghbene was assessed a fine in the amount of $1,000. He was placed on one-year probation and required to take the PIC test and score 85% or higher.

Steven Roy Bramlet; Seabrook, TX – was disciplined by the Board for violation of K.S.A. 65-1627(a)(12). Mr Bramlet's license was revoked based on a Final Order of revocation out of Texas.

Dispensing of Controlled Substances

On November 16, 2004, the United States Department of Justice published an interim statement of policy entitled *Dispensing of Controlled Substances for the Treatment of Pain* (69 FR 67170). This policy conflicts with information that the Board of Pharmacy previously provided in a *Newsletter*. The misinformation is also located in the Frequently Asked Questions on page xvii of the 2004 *Kansas Pharmacy and Related Laws* book.

In summary, Drug Enforcement Administration (DEA) had published on its Office of Diversion Control Web site a document entitled *Prescription Pain Medication: Frequently Asked Questions and Answers for Health Care Professionals and Law Enforcement Personnel* (August 2004 FAQ). DEA has withdrawn the document because it contained misstatements. One of the erroneous statements was in regard to Schedule II prescription refills. The FAQ stated, "Schedule II prescriptions may not be refilled; however, a physician may prepare multiple prescriptions on the same day with instructions to fill on different dates." The first part of this sentence is correct, as the Controlled Substances Act expressly states: "No prescription for a controlled substance in [S]chedule II may be refilled." 21 U.S.A. 829(a). However, the second part of the sentence is incorrect. For a physician to prepare multiple prescriptions on the same day with instructions to fill on different dates is tantamount to writing a prescription authorizing refills of a Schedule II controlled substance. Likewise, one prescription with the same directive to fill a Schedule II prescription on different dates is not permitted. The Kansas State Board of Pharmacy regrets any confusion caused by the previous information provided. The interim policy is available at www.DEAdiversion.usdoj.gov (look under "What's New").

Intern/Student Transfers Permitted

On December 1, 2004, the Kansas State Board of Pharmacy discussed whether or not an intern or student could transfer prescriptions. The Board determined that interns/students were permitted to transfer prescriptions. The Board will make the appropriate changes in the *Kansas Pharmacy and Related Laws* book to accurately reflect this position.

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