December 2004

Kentucky Board of Pharmacy

NEWS

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Published to promote voluntary compliance of pharmacy and drug law.

New Executive Director

On October 1, 2004, Michael A. Burleson, RPh, assumed the position of executive director of the Kentucky Board of Pharmacy, which was vacated by the resignation of Michael A. Moné. Mr Burleson is a 1974 graduate of the University of Kentucky College of Pharmacy.

Prior to assuming his position with the Board, Mr Burleson was pharmacy manager with Walgreens. He was also a pharmacy owner for 19 years in Henderson, KY, and has worked in various retail and hospital settings.

Mr Burleson is involved in the University of Kentucky Alumni Association, having served as president of the National Alumni Association in 1994-1995. He is also a past-president of the University of Kentucky College of Pharmacy Alumni Association and has served on various committees within the College.

He has also been involved with the Kentucky Pharmacists Association as a committee member and served two terms on the association's Board of Directors. Mr Burleson served as secretary/treasurer for the Tri-County Pharmacists Association for many years.

New Board Member Appointed

Governor Ernie Fletcher appointed Peter Joseph Orzali, Jr, RPh, of Cold Springs, KY, to serve a four-year term on the Board expiring January 1, 2009. Mr Orzali is a 1977 graduate of the University of Cincinnati College of Pharmacy and is currently employed by Catholic Healthcare Partners as director of pharmacy for Mercy Health Partners of Cincinnati, OH.

Governor Fletcher reappointed Patricia H. Thornbury, RPh, of Lexington, KY, to serve on the Board until January 1, 2009. Mrs Thornbury has been a practicing pharmacist for 44 years in Kentucky and Virginia. She is a 1961 graduate of the University of Kentucky College of Pharmacy.

2005 Pharmacist License Renewal

Applications for renewal of 2005 pharmacist licenses will be mailed out to all Kentucky-licensed pharmacists in early January. Return the completed and signed application with an $80 check made payable to the Kentucky State Treasurer by February 28, 2005. Before mailing your application back to the Board, please take a few minutes to review the completed application. Incomplete or unsigned applications, or applications submitted without a fee, will be returned. Pharmacists seeking to serve as preceptors must include an additional $10 with their renewal.

Continuing Education Reminder

The end of the year is here, and successful completion of the continuing education (CE) requirements is critical to this process. Pharmacists should have proof of fifteen (15) hours of general pharmacy CE completed and certified by December 31, 2004, at their primary place of practice available for review by the pharmacy and drug inspectors. All courses and/or providers shall be Kentucky Board of Pharmacy or Accreditation Council for Pharmacy Education approved. Courses that have pending approval should not automatically be accepted as proof of completion.

If you attend a live CE program, the completion date and the credit date for the program is the day that you were in attendance. If you participated in a home study program, these programs are not considered complete until you are awarded a certificate of completion from the provider with a dated certifying signature. Credit for the home study program is awarded on the date specified on the certificate, not the date you completed the CE and submitted it for grading.

2005 Board Meeting/Examination Dates

The Kentucky Board of Pharmacy set the following meeting dates for 2005. All meetings, except examinations, are held at the Board office and begin at 9 AM. However, one meeting is planned at the University of Kentucky campus. Case Review Committee meetings regarding disciplinary actions are held the day before Board meetings at 1 PM. Pharmacists and the public are invited to attend. Should you wish to have a matter considered by the Board, kindly provide ten (10) copies of the information to the Board office not less than fourteen (14) days before the meeting date.

January 5	Board Meeting
January 22	Board Examination
March 9	Board Meeting at the University of Kentucky
April 13	Board Meeting
June 8	Board Meeting
July 6	Board Meeting
July 9-10	Board Examination
September 14	Board Meeting
October 5	Board Meeting
December 14	Board Meeting

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.

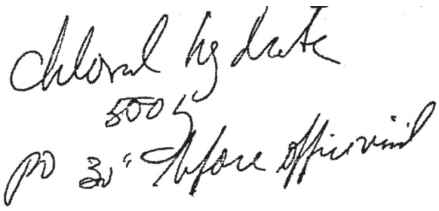
Patients taking these antidepressants should be monitored for behaviors associated with the drugs such as anxiety, agitation, panic attacks, insomnia, irritability, hostility, impulsivity, akathisia, hypomania, and mania. Physicians are urged to closely monitor patients with bipolar disorder as monotherapy 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.

Comments of a Board of Pharmacy Student Intern

Submitted by Shanna Jackson, PharmD Candidate

As a fourth-year pharmacy student on rotations, I had the opportunity to spend the month of September at the Kentucky Board of Pharmacy. The rotation proved to be a refreshing foray into an area of pharmacy that not many students have the chance to observe.

My activities during the month consistently provided a learning experience. Almost daily I participated in inspections of pharmacies, which proved to be more educational than I could have predicted! Inspections gave me a good opportunity to see pharmacy law put to work. I was able to brush up on my own knowledge of the law, and in some instances observe very good examples of what not to do when out in practice! On several occasions I was able to assist in investigations of complaints against pharmacies. I gained an appreciation for how time consuming the job of an inspector can be, as much of an investigation consists of gathering the appropriate information. Of course, participating in inspections and investigations was educational in other ways. I found it extremely interesting simply to be able to go into so many different pharmacies and see how they operate. Each one was different from the other, and it was worthwhile to see the various layouts, technology systems, and workflows being utilized. Some of the types of pharmacies inspected I was not familiar with, such as nuclear pharmacy. Also, many of the daily destinations were in parts of Kentucky I had never visited. I have to say, being able to travel to new areas of the state, even briefly, was one of the best parts of the month.

Not all of my monthly activities consisted of inspections and investigations. Interspersed throughout were several more unique learning experiences. I had the opportunity to spend time with the Cabinet for Health Services, Drug Enforcement Branch, which introduced me to the workings of KASPER (Kentucky All Schedule Prescription Electronic Reporting). I also attended a Medicaid Pharmacy and Therapeutics Committee meeting with Mike Mayes, executive director of the Kentucky Pharmacists Association, which made for an interesting glimpse into part of our state government. During days spent at the Board office, I was able to review the law, learn about the Impaired Pharmacists Committee, and generally enjoy observing the day-to-day activities.

I genuinely enjoyed my month at the Board. In a year of rotations that often places students in community and hospital pharmacy sites, the Board rotation is one of the few that allows students to truly see a different area of pharmacy practice. I feel as though I gained a better working knowledge of the law, as well as the duties and responsibilities of the Board of Pharmacy. I believe I can take this knowledge and apply it to the rest of my rotations and my pharmacy practice in the future. For this, I am appreciative of the opportunity I had to work with and learn from the inspectors and staff at the Board of Pharmacy.

USP 797 Update

Submitted by Philip C. Losch, Pharmacy and Drug Inspector

Recently, the Board was asked for its opinion as to the interpretation of "preparation of sterile compounds for immediate use outside the confines of the controlled environment." In the introduction of Chapter 797 of the United States Pharmacopeia (USP) a specific statement is made: "The content of this Chapter applies to healthcare institutions, pharmacies, physician practices and other facilities in which compounded sterile products are prepared, stored and dispensed." The issue explored was the intent of the wording ". . . prepared, stored and dispensed." It was suggested that if a product is prepared for immediate use and is not "stored," then the mandates of USP 797 do **not** apply. Only if the product is prepared and stored prior to dispensing does the full weight of USP 797 apply.

The Board is in agreement with the above statement. Additionally, it was reported that the Joint Commission on Accreditation of Healthcare Organizations, in a teleconference program hosted by the Institute for Safe Medication Practices, has stated that "In discussions with USP, it appears that these guidelines were never meant to apply to situations where someone immediately prepares a drug and administers it to a patient."

The *Kentucky Board of Pharmacy News* is published by the Kentucky 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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