June 2006

Kentucky Board of Pharmacy

Published to promote voluntary compliance of pharmacy and drug law.

Spindletop Administration Building
2624 Research Park Dr, Suite 302
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Pharmacy Renewal Deadline June 30, 2006

Pharmacy permits expire June 30, 2006. This year a pharmacy permit for a resident Kentucky pharmacy can be renewed online for the first time. A letter explaining the renewal process was mailed to each pharmacy on April 30, 2006. An out-of-state pharmacy permit renewal must be completed with a paper renewal application. This renewal form may be printed off from the Kentucky Board of Pharmacy Web site at www.pharmacy.ky.gov. If you have any questions concerning the renewal process, please contact the Board office. Please be reminded that if your pharmacy has an address change, is relocating within the current premises of the existing permit, or is changing ownership, you must complete a new pharmacy application. A pharmacy application with only a United States Post Office Box address will **not** be accepted and will be returned. All incomplete applications will be returned. Remember, the deadline is June 30, 2006.

Board Meeting Dates Remaining in 2006

Following are the remaining Board meeting dates for 2006: June 7, 2006; July 12, 2006; September 13, 2006; October 11, 2006; and December 13, 2006. All of the meetings will be held at the Board office beginning at 9 AM at the Spindletop Administration Building, 2624 Research Park Dr, Suite 302, Lexington, KY 40511. As a reminder these dates are available on the Board's Web site. Also, any changes will be posted on the Web site.

DEA Form 106 Reporting of Theft/Loss

As a reminder any significant loss of controlled substances (CS) must be reported to the Drug Enforcement Administration (DEA) on Form 106. A copy of DEA Form 106 can be found on the Board's Web site or a link to file DEA Form 106 online. Also, a copy of DEA Form 106 must be sent to the Cabinet for Health and Family Services' Office of Drug Enforcement (phone: 502/564-7985) and a copy to the Kentucky Board of Pharmacy (phone: 859/246-2820).

Legislation Update 2006

The Pharmacy Technician Registration Bill (Senate Bill [SB] 110 sponsored by Senator Richard L. Roeding) was passed by a Senate committee and went to the Floor of the Senate, passed by consent. After passing the Senate it was sent to the House Health and Welfare Committee and passed out of this committee. However, on the Floor of the House, two unfriendly amendments were added to the Bill. House Floor Amendment 1 would have required pharmacies to pay the registration fee for the pharmacy technicians and House Floor Amendment 2 would have allowed the sale of emergency contraceptives over-the-counter (OTC) upon approval by Food and Drug Administration (FDA). Because of these two floor amendments, SB 110 was left on the House Floor.

SB 65 (sponsored by Senator Gary Tapp) was signed into law by Governor Ernie Fletcher on March 6, 2006. This Bill gives Kentucky advanced registered nurse practitioners (ARNP) authority to prescribe CS. This Bill will go into effect July 12, 2006. ARNPs must first apply for a DEA certificate number and have a separate Collaborative Agreement for Prescriptive Authority for Controlled Substances (CAPA-CS) with a physician before prescribing any CS. This agreement must be a separate written agreement from the Collaborative Agreement for Prescriptive Authority for Non-Controlled Substances (CAPA-NS).

Following are the CS prescribing requirements:

- Schedule II – 72-hour supply with no refills;
- Schedule III – 30-day supply with no refills; and
- Schedule IV-V – 30-day supply with up to six months of refills.

ARNPs certified in psychological and/or mental health may prescribe Schedule II psychostimulants for a 30-day supply if they work in a mental health clinic or hospital, but not in private practice. This rule applies only to psychostimulants and only to ARNPs certified in psych/mental health. If an ARNP works in a psych/mental setting, but is not certified in psych/mental health, they may only prescribe a 72-hour supply.

If you are presented a prescription from an ARNP that is licensed outside the state of Kentucky, you must follow the above as it pertains to dispensing CS by Kentucky ARNPs.

ARNPs still **cannot** dispense non-controlled or controlled substances. They may only dispense non-controlled samples.

Dextromethorphan: Friend or Foe

Submitted by Teresa Nelson Hall, PharmD Candidate

In this age of substance abuse, there are a multitude of compounds being consumed by various populations. No longer are we only concerned about "street drugs" and access to prescription drugs for abuse, but also OTC drugs. In recent years there has been a flurry of media coverage over the use of pseudoephedrine

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FDA Cautions Consumers About Filling US Prescriptions Abroad

Food and Drug Administration (FDA) issued a warning to health care professionals and consumers that filling their prescriptions abroad may have adverse health consequences due to the confusion with drug brand names that could inadvertently lead consumers to take the wrong medication for their condition. In an investigation, FDA has found that many foreign medications, although marketed under the same or similar-sounding brand names as those in the United States, contain different active ingredients than in the US. Taking a different active ingredient could potentially harm the user.

FDA found 105 US brand names that have foreign counterparts that look or sound so similar that consumers who fill such prescriptions abroad may receive a drug with the wrong active ingredient. For example, in the United Kingdom, Amyben®, a brand name for a drug product containing amiodarone, used to treat abnormal heart rhythms, could be mistaken for Ambien®, a US brand name for a sedative. Using Amyben instead of Ambien could have a serious adverse outcome. For more information on this topic visit www.fda.gov/oc/opacom/reports/confusingnames.html.

Safety Can Not be Sacrificed For Speed

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.

Problem: Typically, pharmacies have developed well-established methods for monitoring the accuracy of the dispensing process. But today, pharmacy work is increasingly stressful and these checks and balances can easily be strained beyond capacity. With an increasing number of prescriptions and a shortage of qualified pharmacists, conditions are ripe for potentially unsafe working conditions – long hours without breaks; multitasking between answering phones, overseeing other pharmacy staff, dispensing prescriptions, and counseling patients; and ever-increasing time spent attending to insurance issues. Inevitably, these conditions can increase the chance for dispensing errors.

One pharmacy knows this all too well after a five-year-old boy died as a result of an order entry and medication compounding error that was not caught by the usual verification process. In this case, imipramine was dispensed in a concentration five times greater than prescribed. Imipramine is a tricyclic antidepressant used to treat adults, but it is also used to treat childhood enuresis. An extemporaneous solution was to be prepared at this pharmacy that specialized in compounded prescriptions since a liquid formulation was not commercially available. A pharmacy technician incorrectly entered the concentration of the prescribed solution into the computer as **50 mg/mL** instead of **50 mg/5 mL**, along with the prescribed directions to give 2 tsp at bedtime. He then proceeded to prepare the solution using the incorrect concentration on the label rather than the concentration indicated on the prescription. When the compound was completed, the technician placed it in a holding area to await a pharmacist's verification. At this time, one of the two pharmacists on duty was at lunch and the high workload of the pharmacy made it difficult for the pharmacist to check the prescription right away. When the child's mother returned to pick up the prescription, the cash register clerk retrieved the prescription from the holding area without telling a pharmacist, and gave it to the mother, unaware that it had not yet been checked. At bedtime, the mother administered 2 tsp of the drug (500 mg instead of the intended 100 mg) to the child. When she went to wake him the next morning, the child was dead. An autopsy confirmed imipramine poisoning.

There are many factors that contributed to this error including inaccurate order entry and issues related to high workload. However, a critical breakdown in safety processes occurred when the cash register clerk took the prescription from the pharmacy holding area (to prevent the mother from waiting any longer for the prescription), thereby circumventing the usual pharmacist verification process.

While this error underscores a growing problem in health care, the problem was clearly evident to this pharmacy owner – even a year before the error occurred. When interviewed for an article that appeared in a national publication, he vented his frustrations about the scant attention paid in our society to pharmacist workload difficulties faced in today's health care environment. On the day of the interview, 49 prescriptions were in the process of being prepared and about a dozen patients were standing in line or wandering around the store waiting for prescriptions. Yet this was a slow day. The owner also said that, while managed care had reduced profits considerably over the past several years, prescription volume had increased 50% (at the time of the error, the pharmacy was dispensing about 10,000 prescriptions per month versus 7,000 per month during the prior year, without an increase in staff) and medication regimens and drug interactions were more complex. To overcome these barriers, the owner added private consultation areas for patient counseling; installed a $175,000 robot that accurately dispenses the 200 most common drugs; and diversified sales to offset full-time pharmacists' salaries. But these efforts could not have prevented this tragic fatal error that circumvented the normal safety processes.

Safe Practice Recommendations: The environment and demands placed on health professionals significantly affect their ability to provide safe health care services. While technology such as robots can help, overstressed professionals cannot consistently perform at the maximum level of safety. Therefore, it is important that the public and health care leadership understand this problem so they can be more open to tradeoffs, such as working

with one patient at a time and incurring longer turnaround times, which are necessary to enhance patient safety. With a shortage of qualified professionals, we need to demand more rapid adoption of computerized prescribing to reduce time spent with prescription transcription. We should identify the biggest distractions that occur in our workplaces and eliminate or reduce the source by batching common interruptions and reorganizing work areas. Staff members need to be properly trained to understand safety procedures that are in place and know the limits of their specific duties. Fail-safe processes to ensure an independent double check before dispensing medications and performing other critical processes are a must. The pharmacy where this error occurred now requires two pharmacists to check every prescription. Unfortunately, this level of vigilance is typical after a patient has been harmed from an error. In other pharmacies, especially where there is only one pharmacist on duty, technicians may be involved in the double-check process.

A few other strategies can be used to prevent similar errors:

- Have one person perform order entry and a different person prepare the prescription, if possible, to add an independent validation of the order entry process.
- Do not prepare prescriptions using only the computer-generated label, as order entry may have been incorrect.
- Ensure that the original prescription, computer-generated label, prepared product, and manufacturer's product(s) remain together throughout the preparation process.
- Verify dispensing accuracy by comparing the original prescription with the labeled patient product and the manufacturer's product(s) used.

NIH Develops Community Drug Alert Bulletin

The National Institute on Drug Abuse, as part of the National Institutes of Health (NIH), has developed a new Community Drug Alert Bulletin that addresses the latest scientific research on the non-medical use of prescription drugs of abuse and addiction.

This bulletin is geared toward parents, teachers, counselors, school nurses, and health professionals who are associated with those at risk from prescription drug abuse for non-medical purposes. It summarizes the growing problem in the US and the trend of non-medical use of prescription drugs. For more information on this bulletin visit www.nida.nih.gov/PrescripAlert/index.html.

Implementation of the Anabolic Steroid Control Act of 2004

According to the December 16, 2005 *Federal Register*, effective January 20, 2005, the Anabolic Steroid Control Act of 2004 amended the Controlled Substances Act (CSA) and replaced the existing definition of "anabolic steroid" with a new definition. This new definition changed the basis for all future administrative scheduling actions relating to the control of the anabolic steroids as Schedule III controlled substances (CS) by eliminating the requirement to prove muscle growth. Also, the Act lists 59 substances as being anabolic steroids; these substances and their salts, esters, and ethers are Schedule III CS. The Act also revised the language of the CSA requiring exclusion of certain over-the-counter products from regulation as CS.

According to the House Report, the purpose of the Act is "to prevent the abuse of steroids by professional athletes. It will also address the widespread use of steroids and steroid precursors by college, high school, and even middle school students."

The changes to the definition include the following:

- Correction of the listing of steroid names resulting from the passage of the Anabolic Steroid Control Act of 1990.
- Replacement of the list of 23 steroids with a list of 59 steroids, including both intrinsically active steroids as well as steroid metabolic precursors.
- Automatic scheduling of the salts, esters, and ethers of Schedule III anabolic steroids without the need to prove that these salts, esters, or ethers promote muscle growth.
- Removal of the automatic scheduling of isomers of steroids listed as Schedule III anabolic steroids.
- Addition of dehydroepiandrosterone to the list of excluded substances.

FDA Unveils New Package Insert Format

On January 18, 2006, FDA unveiled a major revision to the format of prescription drug information, commonly called the package insert, which will give health care professionals clear and concise prescribing information. This new format was developed in order to manage the risks of medication use and reduce medical errors; the new package insert will provide the most up-to-date information in an easy-to-read format. This new format will also make prescription information more accessible for use with electronic prescribing tools and other electronic information resources.

Revised for the first time in more than 25 years, the new format requires that the prescription information for new and recently approved products meet specific graphical requirements and includes the reorganization of critical information so physicians can find the information they need quickly. Some of the more important changes include:

- A new section called *Highlights* to provide immediate access to the most important prescribing information about benefits and risks.
- A table of contents for easy reference to detailed safety and efficacy information.
- The date of initial product approval, making it easier to determine how long a product has been on the market.
- A toll-free number and Internet reporting information for suspected adverse events to encourage more widespread reporting of suspected side effects.

This new format will be integrated into FDA's other e-Health initiatives and standards-settings through a variety of ongoing initiatives at FDA. For more information please visit www.fda.gov/cder/regulatory/physLabel/default.htm.

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in the synthesis of methamphetamine, as well as a host of new laws governing the sale of the decongestant. Meanwhile, a drug of choice is slipping under the radar. The newest party accessory for adolescents is much less expensive than fashionable clothes and shoes and it can be found on pharmacy shelves, grocery shelves, convenient store shelves, and various other retailers.

Dextromethorphan (DXM) is a cough suppressant found in as many as 70 OTC cough and cold formulations. Typically, this drug is used to relieve non-productive coughs; however, it has become one of the latest sources of a "high" amongst young people nationwide. Currently there are no laws governing the sale of products containing DXM, despite the fact that it is a chemical related to morphine. It lacks narcotic properties, except in the instance of overdose.

DXM acts centrally to elevate the threshold for coughing. At recommended doses the drug is safe and effective; however, at higher doses it produces dissociative effects similar to those of phencyclidine, also known as PCP, and ketamine. The positive effects of DXM use include: euphoria, enhanced awareness, dissociation of the mind from the body, creative dreamlike experiences, and warm feelings toward others. These are the effects that are sought by those using this drug recreationally. The negative, and often disregarded, effects of DXM use include: tachycardia, fever, nausea and/or vomiting, diarrhea, and dizziness. Over consumption of this drug can lead to seizures, psychosis, brain damage, coma, and death.

As with any drug of abuse, there is a certain language that is used in connection with DXM use. Some of the most common phrases are: Orange Crush, Triple Cs, Red Devils, Skittles, DXM, Dex, Vitamin D, Robo, Robo-trippin, and Robo-dosing. The "Robo-" terminology relates to the widely recognized source of DXM, Robitussin® products. Two terms that may not be as familiar are "Skittles" and "Red Devils," which relate to Coricidin, which are small, round, red tablets. Hence, the term "skittling" refers to someone that is under the influence of DXM. These tablets look so much like little red candies that teens have reported consuming these tablets while in school without anyone realizing it.

Prolonged use of DXM may result in tolerance and physical dependence. It is believed by clinicians that there is also a strong psychological component of DXM addiction. Withdrawal symptoms include: restlessness, muscle or bone aches, insomnia, diarrhea, vomiting, and cold flashes with goose bumps ("cold turkey"). It may take months for some of these symptoms to dissipate.

Not only is there concern over the possibility that adolescents will overdose on DXM, but also other ingredients in the DXM source. Many cold and cough preparations also contain active ingredients such as acetaminophen, antihistamines, and pseudoephedrine. FDA has determined that acetaminophen overdoses lead to more than 56,000 emergency room visits a year. Coupled with the other ingredients in the cold medications, adolescents abusing DXM are at increased risk of requiring hospitalization.

While not currently regulated by the government, there are many steps that the pharmacy profession can take to control the sale of DXM containing products. The most logical step is to move these products behind the counter, especially those that contain DXM as the sole ingredient. This would also help to decrease the theft of these products. Another deterrent to adolescent DXM abuse is to make it a "store policy" that sales are made to adults only. While these may seem obvious, these are just a few things pharmacists can do to help lessen abuse of DXM by today's youth.

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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