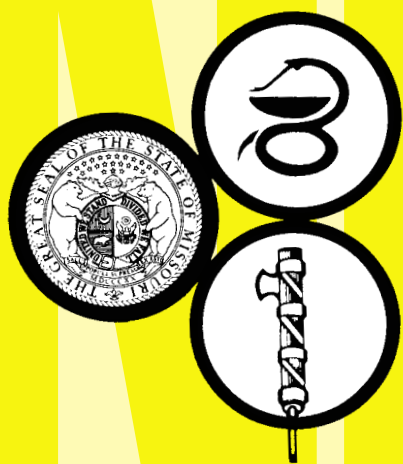


May 2005



Missouri Board of Pharmacy

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Internship Program: Big Changes on the Horizon

Beginning July 1, 2005, amendments to 4CSR 220-2.030 Educational and Licensing Requirements regulation will go into effect. A broad new relationship will then begin between the Missouri Board of Pharmacy and the two schools of pharmacy within this state. Curriculum-based experience through externships, rotations, and clerkships that total 480 hours of practical experience will fulfill the practical experience requirement to sit for the licensure examination. The hours must be evenly divided between a community/ambulatory pharmacy practice component, an institutional pharmacy practice component, and a clinical or related practice component. The schools of pharmacy shall operate all experiential programs and make determinations on whether or not students have fulfilled the requirements for practical experience. The role of the Board will be to annually review and approve or disapprove all policies and procedures used by the schools within their practical experience programs and to approve all locations and persons used as training sites and preceptors. It is anticipated that the Board will choose its April meeting of each year to meet with the schools to complete the annual review process. Students from out-of-state that apply to the Board for licensure by examination shall still be required to show proof of 1,500 hours of approved internship experience by board of pharmacy certification within the state that their school is located. The Board will no longer certify pharmacies directly as training sites, but it will still be a requirement that anyone wanting to count hours from school curricula toward completion of required practical experience must be licensed as an intern **prior** to gaining any hours.

DEA Position on Post-Dating of Schedule II Prescriptions

Refills of Schedule II prescriptions – The August 2004 Frequently Asked Questions (from Drug Enforcement Administration [DEA]) 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.*” (Italics added.) 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.C. 289 (a). However, the second part of the sentence (italicized above) 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. To do so conflicts with one of the fundamental purposes of Section 829(a). Indeed, as the factors quoted from the Rosen case indicate, writing multiple prescriptions on the same day with instructions to fill on different dates is a recurring tactic among physicians who seek to avoid detection when dispensing controlled substances for unlawful (non-medical) purposes. It is worth noting here that DEA regulations setting forth the requirements for the issuance of a controlled substance prescription are set forth in 21 CFR 1306.01 – 1306.27. There has been much confusion about what pharmacists should do when faced with post-dated Schedule II prescriptions. Based on the information at the time of drafting this *Newsletter*, DEA will not allow this procedure and prescriptions that are post-dated should not be dispensed.

Technician Application Processing

In some cases, the processing time for initial applications for technician registration is taking extra time due to the length of time taken to complete the criminal background check with the Federal Bureau of Investigation and the Missouri State Highway Patrol. The main reason for the delay is the influx of applications due to the enactment of new laws; ie, concealed weapons. While the processing time is improving, many applicants will experience a longer wait due to this issue. Applicants will still be considered as properly registered with the Board as long as they maintain a copy of their application wherever they work. This copy will act as a temporary registration until the permanent registration is issued. Another reason for lengthy processing times is incomplete or false applications. Additional correspondence is usually required when this happens and additional time will be needed to process an application. It has been stated in previous *Newsletter* articles that the pharmacist-in-charge (PIC) should review all applications for accuracy and review with all technician applicants the fact that the Board will see any and **all** criminal histories whether they resulted in a suspended imposition of sentence or not. It will also not matter what state a crime was conducted in or the time frame of occurrence. The Board has access to **all** such reports.

New Permit Classification

A new classification for compounding pharmacies has been defined by the Board based on legislation passed last year. “Class D: Non-sterile compounding” must appear on a pharmacy permit if the

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Accutane, Palladone RMPs Designed to Protect Patient Safety

Risk Management Programs (RMPs) are developed by drug manufacturers to meet the requirements of FDA's drug approval process, in conjunction with FDA, to minimize risks associated with specific drug products. To date, several specific drug products have formal risk management programs beyond labeling alone, to further ensure patient safety. Two relevant examples are Accutane® (Roche Pharmaceuticals) and Palladone Capsules (Purdue Pharma LP).

Accutane

On November 23, 2004, FDA announced changes to the RMP for isotretinoin (Accutane) that will be implemented in mid-2005 in order to reduce the risk of birth defects associated with fetal exposure to the medication. All of the manufacturers of isotretinoin have entered into an agreement with Covance, a drug development services company that currently coordinates the registry for Celgene's thalidomide. Covance's task is to develop and operate a universal enhanced RMP by mid 2005; this program will require patients, dispensing pharmacists, and prescribers to register in a single, centralized clearinghouse. The program will also mandate that a pregnancy test be performed at certified laboratories instead of home or in-office testing. According to the Accutane RMP, System to Manage Accutane Related Teratogenicity, when the registry denies an authorization to fill the prescription, the prescribing physician must explain the reason for denial to the patient; FDA specifically states that the physician is responsible for informing a woman if a pregnancy test result comes back positive.

Palladone

Due to Palladone's (hydromorphone hydrochloride) high potential for abuse and respiratory depression, the drug's manufacturer, Purdue Pharma LP, in conjunction with FDA, developed an RMP for this new extended-release analgesic. Introduced to the market in January 2005, Palladone is approved for the management of persistent, moderate to severe pain in patients requiring continuous, around-the-clock analgesia with a high potency opioid for an extended period of time (weeks to months) or longer. Palladone is to be used in patients who are already receiving opioid therapy, who have demonstrated opioid tolerance, and who require a minimum total daily dose of opiate medication equivalent to 12 mg of oral hydromorphone.

The analgesic's RMP was devised with four goals:

1. Facilitation of proper use (patient selection, dosing)
2. Avoidance of pediatric exposure
3. Minimization of abuse, and
4. Reduction of diversion

Palladone's RMP includes provisions for understandable and appropriate labeling, and proper education of health care professionals, patients, and caregivers. In addition, the manufacturer has offered training sessions to its sales representatives. The RMP provides for the observation and surveillance of abuse and, if abuse, misuse, and/or diversion occur, this program includes an array of interventions. A Medication Guide will be distributed to patients prescribed Palladone.

During the initial 18 months of Palladone's release to the market, the manufacturer will only promote Palladone to a limited number of medical practitioners experienced in prescribing opioid analgesics and will closely monitor and gather data on Palladone's use and any incidences of abuse or diversion, and report this information to FDA on a regular basis.



Metronidazole and Metformin: Names Too Close for Comfort

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.

A family practice physician in a community health center prescribed metformin 500 mg b.i.d. to a newly diagnosed diabetic man from India who did not speak English. When the patient returned to his office a few months later, he brought his medications with him, as requested. His physician quickly noticed that metformin was missing. Instead, the patient had a prescription bottle labeled as metronidazole with directions to take 500 mg twice a day. The prescription had been refilled several times. Luckily, the patient's diabetes remained stable, and he seemed to suffer no adverse effects from two months of unnecessary antimicrobial therapy. The physician notified the pharmacy of the error and asked the pharmacist to check the original prescription, which had been written clearly and correctly for metformin. Upon further investigation, the pharmacist found that the computer entry screen for selecting these medications included "METF" (for metformin) and "METR" (for metronidazole). Apparently, one of the pharmacy staff members had entered "MET" and selected the wrong medication that appeared on the screen.

In another community pharmacy, the same mix-up happened twice, one day apart. In one case, metformin was initially dispensed correctly, even though the prescription had been entered incorrectly as metronidazole – again, when the wrong mnemonic was chosen. The pharmacist who filled the prescription clearly understood that the physician had prescribed metformin, so he filled the prescription accordingly. However, he failed to notice the order entry error, as he did not compare the prescription vial label to the drug container label. Unfortunately, the initial order entry error led to subsequent erroneous refills of metronidazole, as stated on the label. In the other case, bulk containers of the medication were available from the same manufacturer, both with similar highly stylized labels. Thus, confirmation bias contributed to staff's selection of the wrong drug. After reading "MET" and "500" on the label, the staff member believed he had the correct drug.

In a hospital pharmacy, metronidazole 500 mg and metformin ER 500 mg were accidentally mixed together in the metronidazole storage bin. This resulted in dispensing metformin instead of metronidazole. Fortunately, a nurse recognized the error before giving the patient the wrong medication. Both were generic products, although the brands Flagyl® (metronidazole) and Glucophage®



(metformin) are also available. Unit-dose packages of these drugs contain bar codes, and the printed information is very small, which adds to their similar appearance.

Metronidazole-metformin mix-ups could be serious, considering the different indications and the potential for drug interactions. To avoid selecting the wrong drug from the screen, consider programming the computer to display the specific brand names along with the generic names whenever the "MET" stem is used as a mnemonic. To reduce similarity of the containers, purchase these medications from different manufacturers. Another option in hospital settings is to stock only the 250 mg tablets of metronidazole, since metformin is not available in that strength. This option allows a small risk for nurses who may administer just 250 mg when 500 mg is prescribed, but the potential for harm from giving the wrong drug is greater.

It is also a good idea to separate the storage of these products. During the dispensing process, drug names listed on written prescriptions and hospital orders should be matched to computer labels and manufacturers' products. Since metformin is used to treat a chronic condition, and metronidazole is more likely to be used for an acute condition, outpatient refills for metronidazole are less common and, therefore, bear a second look. Asking physicians to include the drug's indication on the prescription can also help prevent errors.

We have asked FDA to add these drugs to the list of nonproprietary names that would benefit from using "Tall Man" letters. Meanwhile, underline or highlight the unique letter characters in these drug names to make their differences stand out.

'Dietary Supplements' Contain Undeclared Prescription Drug Ingredient

In early November 2004, Food and Drug Administration (FDA) cautioned the public about the products Actra-Rx and Yilishen, which have been promoted via the Internet. These products, purported as "dietary supplements" to treat erectile dysfunction and enhance sexual performance, were actually found to contain the active prescription drug ingredient, sildenafil, the active drug ingredient in Viagra®, which is approved in the United States for the treatment of erectile dysfunction.

The *Journal of the American Medical Association (JAMA)* published a research letter that explained the results of a chemical analysis that found that Actra-Rx contained prescription strength quantities of sildenafil. FDA conducted its own analysis, the results of which corroborated the analysis published in *JAMA*.

Sildenafil is known to interact with a number of prescription medications. For example, sildenafil may potentiate the hypotensive effects of medications containing nitrates, which are commonly used to treat congestive heart failure and coronary artery disease.

FDA instructed those who are taking Actra-Rx and/or Yilishen to stop and consult their health care provider and warned that the use of these products could be dangerous to patients' health.

For more information, please visit the following Web site: www.fda.gov/bbs/topics/ANSWERS/2004/ANS01322.html.

NABP Releases Criteria for National Specified List of Susceptible Products, Adds One Drug to List

In late 2004, the National Association of Boards of Pharmacy® (NABP®) Executive Committee finalized the criteria that detail standards and guidance for NABP's "National Specified List of Susceptible Products" (List) based upon recommendations made by NABP's National Drug Advisory Coalition (NDAC). Also, in accordance with NDAC's recommendation, the Executive Committee decided to include Viagra® (sildenafil) on NABP's List. NABP's List, which the Association first released in early 2004, was created to help states reduce redundancy and represented a starting point for states that had an imminent need for such direction. In addition, by adopting NABP's List, states collectively would be able to recognize one national list instead of potentially 50 different lists.

The NDAC is a standing committee that was appointed by NABP's Executive Committee in accordance with the updated Model Rules for the Licensure of Wholesale Distributors, which is a part of the *Model State Pharmacy Act and Model Rules of the National Association of Boards of Pharmacy*. The Model Rules were released by the NABP Task Force on Counterfeit Drugs and Wholesale Distributors, with the aid of representatives from the pharmacy profession, government, and the wholesale distributor industry, to protect the public from the ill effects of counterfeit drugs and devices. In addition to stricter licensing requirements such as criminal background checks and due diligence procedures prior to wholesale distribution transactions, the Model Rules mandate specific pedigree requirements for products that are particularly prone to adulteration, counterfeiting, or diversion. These products, as defined in the updated Model Rules, are designated as the "National Specified List of Susceptible Products."

The updated "National Specified List of Susceptible Products" is available on NABP's Web site at www.nabp.net. NABP's List criteria that detail standards and guidance (eg, under what circumstances a product will be considered for addition to NABP's List) are also available on the Association Web's site and detailed in the February 2005 *NABP Newsletter*.

FDA Announces New CDERLearn Educational Tutorial

The US Food and Drug Administration's (FDA) Center for Drug Evaluation and Research (CDER) recently announced that its new online educational tutorial "The FDA Process for Approving Generic Drugs" is now available at <http://www.connectlive.com/events/genericdrugs/>.

This seminar provides viewers with an overview of FDA's role in the generic drug process. The tutorial also discusses various aspects of the Abbreviated New Drug Application (ANDA) process, including how FDA's approval assures that generic drugs are safe, effective, and high quality drug products.

This program meets the criteria for up to one Accreditation Council for Pharmacy Education contact hour (or 0.1 CEU).

Continued from page 1

pharmacy provides 5% or more of its prescription services through the provision of compounded products. Owners and PICs should make sure their permits are updated appropriately if the pharmacy falls within this class. Classification change forms can be downloaded from the Board's Web site.

Licensing Actions

Pharmacists

Daniel M. Freund, #40157, Farmington, MO – March 15, 2005. Probation for five (5) years until March 14, 2010. Dispensed controlled substance without a prescription; failure to take/maintain annual controlled substance inventory; improper controlled substance annual inventory; audit discrepancies; controlled substance record keeping violations; failure to timely make reports to the Bureau of Narcotics and Dangerous Drugs (BNDD); and PIC violations. Section 338.055.2(6) and (15), RSMo Supp. 2002.

Scott S. Johnk, #44856, Ozark, MO – February 25, 2005. Probation for four (4) years until February 24, 2009. Violation of discipline action: Failure to provide copy of disciplinary order to employer, acting as PIC without Board authorization, and audit discrepancies. Section 338.055.3, RSMo.

Daniel S. Williams, #29455, Belleville, IL – January 5, 2005. Revoked and cannot reapply for seven (7) years. Violation of discipline action: Failure to comply with drug testing term and failure to communicate with the Board as required within original terms of discipline. Section 338.055.3, RSMo.

Pharmacies

Medicap Pharmacy, #5880, Farmington, MO – March 15, 2005. Probation for five (5) years until March 14, 2010. Dispensed controlled substance without a prescription; failure to take/maintain annual controlled substance inventory; audit discrepancies; controlled substance record keeping violations; and failure to make timely report to BNDD. Section 338.055.2(5), (6) and (15); and Section 338.285, RSMo Supp. 2002.

TAP Pharmaceuticals, Inc d/b/a Pharmacy Solutions, #2001000487, Deerfield, IL – February 25, 2005. Probation for three (3) years from February 25, 2005. Pled guilty to one count of conspiracy by causing the sale of drug samples. Section 338.055.2(2), RSMo 2000.

Drug Distributors

Able Laboratories, Inc, #2004020887, Cranbury, NJ – February 25, 2005. Restricted permanent drug distributor license issued on Probation for five (5) years from February 25, 2005. Entered settlement agreement with the United States for failure to appropriately dispose of controlled substance waste; failure to keep current, complete, and accurate records of controlled substance disposal; failure to provide effective controls to guard against theft and diversion of controlled substances; failure to properly notify DEA regarding destruction/disposal of controlled substances. Section 338.055.2(5), (13), (15), RSMo 2000.

AstraZeneca Pharmaceuticals, LP, #2000172480, Newark, DE – February 8, 2005. Probation for three (3) years from February 8, 2005. Pled guilty in US District Court, District of Delaware, to one (1) count of conspiracy to violate the Prescription Drug Marketing Act by causing the sale of drug samples. Section 338.065.1, RSMo 2000.

Healthcare Supplies & Equipment, #901208, Camdenton, MO – January 12, 2005. Probation for three (3) years from January 12, 2005. Medical gas inspection violations, and follow-up inspection violations. Section 338.353(1) and 338.055.2 (5), (6), (13), and (15), RSMo Supp. 2002.

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