May 2012

Missouri Board of Pharmacy News

Published to promote compliance of pharmacy and drug law

PO Box 625 • Jefferson City, MO 65102 • Web site: *http://pr.mo.gov/pharmacists.asp*

Board Alert

National news sources have recently reported several instances of suspected counterfeit drugs in the United States drug supply. This problem has been exacerbated by the increasing list of drug shortages. Licensees are reminded that §338.315, RSMo, prohibits any pharmacy, pharmacist, pharmacy owner, or person employed by a pharmacy from knowingly purchasing or receiving legend drugs from an unlicensed or unregistered drug distributor/pharmacy. Purchasing from licensed/registered drug distributors/pharmacies helps to ensure the integrity of Missouri's drug supply and protect Missouri patients. License/registration status may be verified on the Missouri Board of Pharmacy's Web site at *https://renew.pr.mo.gov/licensee-search.asp.*

'Compliance is Key' Resources

The following compliance resources are now available on the Board's Web site:

- **Drug Distributor Compliance Guide**
- **Missouri Pharmacy Practice Guide CE Exam:** This online exam tests your knowledge of basic compliance requirements. The exam is available at *https://renew.pr.mo.gov/pharmacistsexam.asp* and has been approved by the Board for 2.0 continuing education (CE) hours (0.2 CEUs). Review the Missouri Pharmacy Practice Guide and earn **free** CE today!

Webinars

(Webinar replays are not eligible for CE credit)

- **BNDD Regulatory Update**
- **Compliance Keys for Drug Distributors**
- **Compliance Keys for the Pharmacist-in-Charge and Pharmacist Managers/Supervisors**

It's Renewal Time

The 2012 pharmacist renewal period is quickly approaching. Avoid renewal delays by updating your name and address with the Board now. Updates can be completed online at *https://renew.pr.mo.gov/pharmacists-coa.asp* or by calling 573/751-0092 (pharmacists). **Remember:** To renew, pharmacists must have **completed 30 hours of CE between September 1, 2010 and August 31, 2012.** Do not wait, finish your CE now!

Inspection Tip

Is your pharmacy storing confidential pharmacy records off site? If so, are you in compliance with 20 CSR 2220-2.010(1)(J), which requires the following:

- Off-site location must provide adequate security to protect confidentiality of records from unauthorized access.
- Off-site location must have an alarm system.
- Any breach in security must be reported to the Board within 15 days.
- No records less than two years old may be stored off site.
- All records stored off site must be made available for inspection within two business days if requested.
- Notification of the off-site location to the Board office.

The storing of records at another pharmacy is considered off site and must be in compliance with these requirements. Notifications to the Board office must include the name/permit number of the pharmacy, name/full address/hours of operations of off-site location, and a statement that the off-site location meets the above requirements.

Technician Renewals

All pharmacy technician registrations will expire on May 31. Technicians may not work if their registration is not renewed by May 31. Due to volume, the Board cannot ensure renewal by May 31 if the renewal application is received after **May 15.** Technicians are encouraged to renew online at *https://renew.pr.mo.gov/renew-default.asp.*

Gold Certificates

The following pharmacists will receive gold certificates in honor of maintaining a license with the Board for 50 years. Congratulations to those who have served the public as a pharmacist for 50 years!

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DEA Provides Information Regarding Carisoprodol Prescriptions

A Drug Enforcement Administration (DEA) announcement provides information regarding the scheduling of carisoprodol, effective as of January 11, 2012. The DEA Final Rule making the drug a Schedule IV controlled substance was published December 12, 2011, and states that effective January 11, 2012, all prescriptions for drugs containing carisoprodol shall comply with DEA regulations. Specifically, a pharmacy may only fill or refill a prescription for a drug containing carisoprodol if all of the following requirements are met:

- the prescription was issued for a legitimate medical purpose by a DEA-registered practitioner acting in the usual course of professional practice (21 CFR §1306.04);
- the prescription contains all the information required by 21 CFR §1306.05; and
- the number of refills authorized by the prescribing practitioner is five or less (21 USC §829(b)).

The full text of the notice is available on the DEA Web site at *www.deadiversion.usdoj.gov/drugs_concern/carisoprodol/index.html.*

Pfizer Recalls Several Lots of Two Oral Contraceptive Products

Pfizer Inc recalled 14 lots of Lo/Ovral®-28 (norgestrel and ethinyl estradiol) tablets and 14 lots of norgestrel and ethinyl estradiol tablets (generic) due to potential for inexact count and out-of-sequence tablets. A Pfizer investigation found that some blister packs of the affected products may contain an inexact count of inert or active ingredient tablets and that the tablets may be out of sequence. As a result of this packaging error, the daily regimen for these oral contraceptives may be incorrect and could leave women without adequate contraception, and at risk for unintended pregnancy. Food and Drug Administration (FDA) advises that patients who have the affected product should notify their physician and return the product to the pharmacy. A Pfizer press release includes a list of the affected products with the National Drug Code (NDC) number, lot number, and expiration date for each, and is available at *www.fda.gov/Safety/Recalls/ucm289770.htm.*

Changes in Medication Appearance Should Prompt Investigation by Pharmacists and Patients

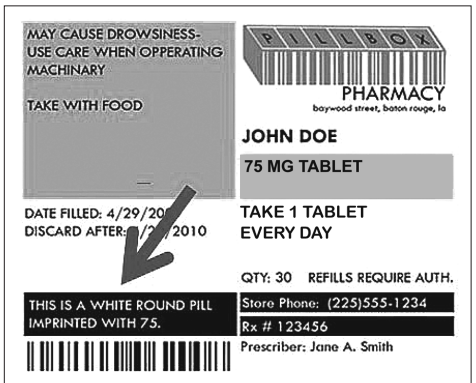
This column was prepared by the Institute for Safe Medication Practices (ISMP). ISMP is an independent nonprofit agency that analyzes medication errors, near misses, and potentially hazardous conditions as reported by pharmacists and other practitioners. ISMP then makes appropriate contacts with companies and regulators, gathers expert opinion about prevention measures, and publishes its recommendations. To read about the risk reduction strategies that you can put into practice today, subscribe to ISMP Medication Safety Alert!® Community/Ambulatory Care Edition by visiting www.ismp.org. *ISMP is a federally certified patient safety organization, providing legal protection and confidentiality for submitted patient safety data and error reports. ISMP is also an FDA MedWatch partner. Call 1-800/FAIL-SAF(E) to report medication errors to the ISMP Medication Errors Reporting Program or report online at* www.ismp.org. *ISMP address: 200 Lakeside Dr, Suite 200, Horsham, PA 19044. Phone: 215/947-7797. E-mail: ismpinfo@ismp.org.*

As the numbers of generic products continue to increase, it seems that both patients and practitioners have become desensitized to changes in medication appearance. So much so that patients may not question a change or, when they do, practitioners may simply reassure them that it was due to a change in manufacturer without actively investigating the reason. It is not uncommon for ISMP to receive reports from both practitioners and consumers where a change in medication appearance was not fully investigated and subsequently contributed to an error.

In one case, a man shared an account of what his 86-year-old father experienced over the course of nine days after his prescription for minoxidil was mistakenly refilled with another medication. He had been taking minoxidil 2.5 mg for years at a dose of 5 mg (2 tablets) twice daily. Due to failing vision, he did not realize that his minoxidil tablets looked different. His daughter noticed the change, but was unconcerned since the tablets had previously changed appearance. The pharmacy was contacted about the change and a staff member explained that it was a different generic for minoxidil, and that the pills could be exchanged for those that he usually received. There was no mention of a mistake being made when the medication was exchanged. He was taken to the hospital the following day, when he could barely walk.

After this incident was explained to hospital staff, they contacted the pharmacy. It was then revealed that he was given methotrexate by mistake because the bottles were stored next to each other. By this time, the man had taken 36 methotrexate 2.5 mg tablets, his white blood cell and platelet counts were extremely low, and he was in critical condition. We later learned that he passed away during that hospital visit.

Your pharmacy may be providing an important patient safety tool on the prescription label that may be overlooked by patients and their caregivers: a description of the shape, color, and imprint code of the medication that should be inside. This information can help ensure accuracy since it's based on the NDC number. Teach patients to look for this description and question any differences. In addition, the patient needs to know if the medication name on the pharmacy generated label is the medication he or she was expecting to receive. Even if the generic manufacturer is different each time the prescription is renewed, the description on the label should match the NDC number and thus the product inside.



With so much information on prescription labels such as patient and doctor name, drug name, instructions, and warnings – this added information can easily be missed. But it's important, so look for it and put it to use!

FDA Reminder: Purchasing Unapproved Injectable Cancer Medications Threatens Patient Safety

FDA is reminding health care providers to obtain and use only FDA-approved injectable cancer medications purchased directly from the manufacturer or from wholesale distributors licensed in the United States. FDA explains that "current shortages of injectable cancer medications may present an opportunity for unscrupulous individuals to introduce non-FDA approved products into the drug supply, which could result in

serious harm to patients." FDA reports that the agency is aware of promotions and sales of unapproved injectable cancer medications directly to clinics in the US and that the medications were likely administered to patients. Examples of products include unapproved versions of FDA-approved medications such as Faslodex® (fulvestrant), Neupogen® (filgrastim), Rituxan® (rituximab), and Herceptin® (trastuzumab). FDA stresses the risks to patients when such unapproved medications are used. The agency outlines several steps health care providers should take to ensure patient safety:

1. Obtain and use only FDA-approved injectable cancer medications purchased directly from the manufacturer or from wholesale distributors licensed in the US. An FDA Web page, *www.fda.gov/Drugs/DrugSafety/DrugIntegrityandSupplyChainSecurity/ucm281446.htm,* provides the online resource for each state for verifying that a wholesale distributor is appropriately licensed.
2. Determine if the medication you have received is FDA-approved by checking the Orange Book or searching the Drugs@FDA database.
3. Question whether a price sounds too good to be true. Deep discounts may be offered because the product is stolen, counterfeit, or unapproved.
4. Carefully inspect the product and packaging and be alert for signs that the product is not FDA approved, such as if the packaging looks different or the dosing recommendations are unfamiliar.

FDA also notes that if a health care provider receives multiple complaints about the same product, such as a new side effect or lack of therapeutic effect, these may signal a product quality issue.

FDA reminds health care providers that in certain circumstances the agency may authorize limited importation of medications that are in short supply. Such medications are imported from approved international sources and distributed in the US through a controlled network, and would not be sold in direct-to-clinic solicitations. If FDA has arranged for limited importation of the foreign version of a medication, information on obtaining that medication will be available in the Drug Shortages section of the FDA Web site, *www.fda.gov/Drugs/DrugSafety/DrugShortages/ucm050792.htm.*

Additional details are provided in an FDA Drug Safety Communication, available at *www.fda.gov/downloads/Drugs/DrugSafety/DrugIntegrityandSupplyChainSecurity/UCM287717.pdf.*

Insulin Pens Should Not Be Used for Multiple Patients, Stresses CDC

Centers for Disease Control and Prevention (CDC) issued a notice, reminding health care providers that insulin pens are intended for use by a single patient, and should never be used on more than one patient. CDC indicates that the agency has become "increasingly aware of reports of improper use of insulin pens, which places individuals at risk of infection with pathogens including hepatitis viruses and human immunodeficiency virus (HIV)." The notice explains that regurgitation of blood into the insulin cartridge can occur after injection, creating a risk of bloodborne pathogen transmission if the pen is used for more than one person, even when the needle is changed. CDC provides the following recommendations to help protect patient safety:

- Insulin pens containing multiple doses of insulin are meant for use on a single person only, and should never be used for more than one person, even when the needle is changed.
- Insulin pens should be clearly labeled with the person's name or other identifying information to ensure that the correct pen is used only on the correct individual.
- Hospitals and other facilities should review their policies and educate their staff regarding safe use of insulin pens and similar devices.
- If reuse is identified, exposed persons should be promptly notified and offered appropriate follow-up including bloodborne pathogen testing.

The notice may be downloaded from the CDC Web site at *www.cdc.gov/injectionsafety/PDF/Clinical-Reminder-insulin-pen.pdf.*

US Public Health Service Report Supports Maximizing the Scope of the Pharmacist as Part of Health Care Team

Presenting an evidence-based discussion of the comprehensive patient care services that pharmacists currently provide, a new government report calls for expanded support for such pharmacist-delivered patient care models. The report, *Improving Patient and Health System Outcomes through Advanced Pharmacy Practice,* prepared by the Office of the Chief Pharmacist, US Public Health Service (PHS), is organized into four focus points as follows:

- Focus point 1 discusses how pharmacists are integrated in many practice settings as health care providers, such as through collaborative practice agreements, and provides data showing interprofessional support for such models.
- Focus points 2 and 3 support recognition of pharmacists as health care providers and compensation models that will allow pharmacists to continue to improve patient and health care system outcomes.
- Focus point 4 presents a review of numerous peer-reviewed studies that demonstrate favorable outcomes from pharmacist-delivered care.

RADM Scott Giberson, chief professional officer, PHS Pharmacists, and the primary author of the report, stated that "one of the most evidence-based and cost-effective decisions we can make as a nation is to maximize the expertise and scope of pharmacists, and minimize expansion barriers to successful health care delivery models." The report may be downloaded from the US PHS Web site at *www.usphs.gov/corpslinks/pharmacy/comms/pdf/2011AdvancedPharmacyPracticeReporttotheUSSG.pdf.*

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Alexander, Robert S. ..... Branson, MO
Bangert, Philip A. ..... Camdenton, MO
Bell, Ola L. ..... St Louis, MO
Buck, Jr, Harry E. ..... Jacksonville, IL
Cushman, Bobby J. ..... Lee's Summit, MO
Dempster, David R. ..... St Louis, MO
Dolan, Timothy C. ..... Manchester, MO
Galluzzo, William J. ..... St Charles, MO
Gardner, Richard L. ..... Raytown, MO
Garrison, Thomas J. ..... Gladstone, MO
Graham, Dale E. ..... Fayette, MO
Hammontree, Charles H. ..... Denton, TX
Hitschler, Michael B. ..... Kirkwood, MO
Hudson, Ellen J. ..... Maysville, MO
Ingram, Jr, Edwin B. ..... Independence, MO
Johnston, David E. ..... Dar Denne Prairie, MO
Mackay, George R. ..... Lee's Summit, MO
Mcwhirt, Billy G. ..... Sedalia, MO
Muchnick, Barry A. ..... Chesterfield, MO
Palma, Salvatore F. ..... Gladstone, MO
Roehrs, Robert E. ..... Fort Worth, TX
Rowland, Loy F. ..... Blue Springs, MO
Ruedin, Gary A. ..... Eaton, CO
Schmidt, Jr, James R. ..... Richmond, MO
Shea, Joseph A. ..... Perryville, MO
Shultz, Jr, John M. ..... Sedalia, MO
Stamm II, Edwin L. ..... St Louis, MO
Stamper, George L. ..... Four Seasons, MO
Stoltz, Jr, Wayne W. ..... Florissant, MO
Wilson, Barry A. ..... St Louis, MO
Wolfangel, Robert G. ..... Manchester, MO
Wolff, Donald R. ..... Chesterfield, MO

Disciplinary Action

Pharmacists

Sung "Sam" Y. Bae, #044678 – St Louis, MO – March 20, 2012. Three (3) years probation. While pharmacist-in-charge, misbranding by overfilling stock bottles, dispensing adulterated drug products, failed to maintain complete controlled substance inventories, prescriptions processed by technician without a pharmacist on duty, allowed unlicensed personnel independent access to pharmacy, record keeping violations, and failed to supervise pharmacy personnel to assure compliance. Section 338.055.2(5), (6), (10), (13), and (15), RSMo.

Abbey C. Beckett, #045170 – Camdenton, MO – March 28, 2012. Suspended thirty (30) days followed by probation for five (5) years. As pharmacist-in-charge, misappropriated controlled substances from pharmacy for personal use, forged controlled substance prescriptions, and failed to timely file loss reports. Section 338.055.2(1), (5), (6), (13), (15), and (17), RSMo.

William R. Buntin, #027483 – Moberly, MO – June 10, 2012. Suspended for three (3) months followed by probation for five (5) years. While pharmacist-in-charge, violation of discipline involving outdated drugs in pharmacy, incomplete controlled substance inventory, failure to timely respond to inspection compliance notice, compounding log and product label did not contain active/therapeutic ingredients, expired license displayed, sold pseudoephedrine products without a current Methamphetamine Epidemic Self-Certification, failed to maintain updated electronic record of controlled substance shipments. Section 338.055.2(5), (6), (13), and (15), RSMo.

Hoa K. Do, #045281 – Overland Park, KS – March 29, 2012. Censure of license. As pharmacist-in-charge, controlled substance losses, failure to maintain adequate security, failure to supervise personnel to assure compliance with laws/regulations. Section 338.055.2(5), (6), (13), and (15), RSMo.

Douglas E. Griggs, #040707 – St Louis, MO – March 29, 2012. Suspended for six (6) months followed by probation for five (5) years. Misappropriated controlled substances from employer for personal use, impaired. Section 338.055.2(5), (6), (13), and (15), RSMo.

David B. Holman, #040714 – Farmington, MO – March 2, 2012. Probation for three (3) years. While pharmacist-in-charge and pharmacy owner, controlled substance record keeping violations, losses of controlled substances, incorrect expiration dating, overfilled stock bottles, and Schedule II controlled substance on open pharmacy shelf. Section 338.055.2(5), (6), (13), and (15), RSMo.

Ellen J. Hudson, #026800 – Maysville, MO – March 28, 2012. Censure of license. As pharmacist-in-charge, dispensed controlled substance prescriptions written by a physician assistant not yet authorized to prescribe controlled substances, record keeping violations, and failed to supervise pharmacy personnel to assure compliance. Section 338.055.2(5), (6), (13), and (15), RSMo.

Victoria R. Robinson Walker, #045042 – St Louis, MO – February 22, 2012. Probation for two (2) years. While pharmacist-in-charge, loss of controlled substances, failed to provide effective security controls/procedures to guard against theft/diversion of controlled substances. Section 338.055.2(6), (13), and (15), RSMo (2000).

Kristina L. Stark, #2002022650 – Taylorville, IL – March 2, 2012. Revoked and cannot reapply for seven (7) years. Violated discipline by failing to return licenses to Board office, failing to submit six-month compliance reports,

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failing to submit to urinalysis testing, failing to complete alcohol/drug treatment program requirements, and failing to obtain mental health evaluation. Section 338.055.2(1), (5), (6), (13), (15), and (17), RSMo.

Terry E. Sullivan, #2011001988 – Buncombe, IL – March 1, 2012. Voluntary surrender of license. Misappropriated controlled substances from employer for personal use. Section 338.055.2(1), (5), (15), and (17), RSMo.

Kevin J. Trackwell, #2001030148 – Maryville, IL – January 28, 2012. Censure of license. Loss of controlled substances from pharmacy where served as pharmacist-in-charge; failed to maintain adequate security for controlled substances; failed to supervise personnel to assure compliance with laws/regulations; failed to implement/enforce policies and procedures. Section 338.055.2(5), (6), (13), and (15), RSMo.

Jill D. Williams Winowiecki, #2001007711 – Columbia, MO – March 2, 2012. Suspension for ninety (90) days followed by probation for five (5) years. Pled guilty to one felony count of theft of a controlled substance. Section 338.065.1 RSMo 2000.

Pharmacies

Buntins Pharmacy, #003884 – Moberly, MO – March 15, 2012. Probation for five (5) years. Violation of discipline involving outdated drugs in pharmacy, controlled substance not included in controlled substance inventory, failure to timely respond to inspection compliance notice, compounding log and product label did not contain active/therapeutic ingredients for a compounded product, expired pharmacist license displayed, sold pseudoephedrine products without a current Methamphetamine Epidemic Self-Certification, failed to maintain updated electronic record of controlled substance shipments. Section 338.055.2(5), (6), (13), and (15), RSMo.

Excelsior Springs Hospital, #003468 – Excelsior Springs, MO – February 2, 2012. Censure of permit. Loss of controlled substances, failed to provide adequate security controls, record keeping, and controlled substance inventory violations. Section 338.055.2(6), (13), and (15), RSMo.

Pharmacy Solutions, Inc, #2002005329 – St Louis, MO – February 22, 2012. Probation for one (1) year. Compounding without a prescription, unable to substantiate representations regarding compounded products, compounded commercially available products, compounding for office stock, release of risk level 3 products prior to end-product test completion, failure to investigate test results, failure to validate beyond-use dates beyond 30 days, and compounded with products restricted by Food and Drug Administration (FDA). Section 338.055.2(5), (6), (13), (14), and (15), RSMo.

Target Pharmacy T-1515, #2005030727 – St Louis, MO – February 22, 2012. Probation for five (5) years. Loss of controlled substances and failed to provide adequate security to prevent employee theft of controlled substances. Section 338.055.2(5), (6), (13), and (15), RSMo.

Walgreens, #002966 – St Louis, MO – March 29, 2012. Probation for three (3) years. Loss of controlled substances, and failure to maintain adequate security to deter theft of controlled substances. Section 338.055.2(5), (6), and (15), RSMo.

Drug Distributors

Interlock Pharmacy Systems, #2009033411 – Florissant, MO – March 20, 2012. Probation for three (3) years. Violation of discipline involving transfilling medical liquid oxygen without an FDA registration. Section 338.055.2(5), (6), (13), and (15), RSMo.

McCoy Health Science Supply, #2010005578 – Maryland Heights, MO – April 6, 2012. Probation for four (4) years. Operated prior to obtaining a drug distributor license. Section 338.055.2(5), (6), (10), (12), and (13), RSMo.

Praxair Distribution, Inc, #900771 – Sedalia, MO – April 6, 2012. Voluntary surrender of license. Participated in unlicensed distributor activities. Section 338.055.2(5), (6), (10), (12), and (13), RSMo.

The *Missouri Board of Pharmacy News* is published by the Missouri Board of Pharmacy and the National Association of Boards of Pharmacy Foundation, Inc, to promote 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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