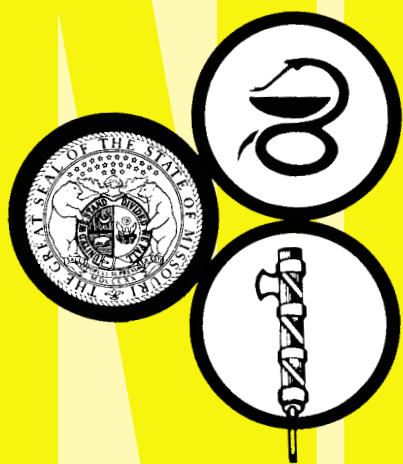


February 2005



Missouri Board of Pharmacy

Published to promote voluntary compliance of pharmacy and drug law.

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Special Notice

The Missouri Board of Pharmacy's *Newsletter* is considered one of the Board's official methods of notification to pharmacists and pharmacies. They have been and will continue to be used in hearings as proof of notification. It is important to read the *Newsletters* carefully and to retain them for future reference.

Continuing Education Audit Process

The audit process will be under way during the first quarter of 2005. Anyone who is chosen at random or who is under discipline with the Board will be audited. Correspondence explaining how to comply with submission of continuing education (CE) documentation will be sent to each person selected for auditing. It will be important to follow all directions as provided within the time frame required in order to be in compliance with licensing requirements. Failure to provide appropriate CE documentation will result in a Board review of the situation. The result of such a review could result in discipline on a license deemed to be out of compliance. It is very important to note that correspondence concerning the audit will be sent to each person affected at his/her current home address as provided for in the Board of Pharmacy licensing records. Only one mailing will be sent out. No other reminders or second attempts at a mailing will be done. Pharmacists should also begin to plan accordingly for CE requirements for the current 2004-2006 renewal period. Due to changes in the law, a specific period of time will be identified for obtaining CE credits for a renewal period. **This period began September 1, 2004, and ends on August 31, 2006.** Any CE credits to be used for the next renewal period of 2004-2006 must have been obtained during this specified time period.

Regulation Update

Regulation 4 CSR 220-3.040 **Return and Re-use** was amended to allow for several situations where drugs may be returned and re-used within specific standards. The amendments went into effect November 30, 2004. The rule may be accessed through the Board's Web site at www.pr.mo.gov/pharmacists.asp, clicking on the rules and statutes link, and then clicking on the rules and regulations link. Once on the Missouri Secretary of State site, click on Division 220, then click on Chapter 3, and look for the rule number noted above.

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Awards and Accomplishments

Mike Kidd, RPh, inspector for the Board of Pharmacy, received recognition for 20 years of service at the December 2004 Board meeting. A gold pin with diamond studs representing his many years of service was presented to him. Kevin Kinkade, executive director, received similar recognition earlier in 2004 for 20 years of service.

Licensing Actions

Pharmacists

Daniel T. Bowlin, #29052, Salt Lake City, UT – November 11, 2004. Suspension for one (1) month, followed by Probation for five (5) years when licensee returns to live and work in Missouri. Violated and assisted or enabled another person to violate Missouri laws by improperly supervising a pharmacy technician, failure to verify accuracy of technician work, incomplete/inaccurate compounding records, inaccurate compound and expiration dates, unsigned and undated controlled substance prescriptions, outdated items found in the pharmacy, incomplete labeled and outdated compounding chemicals found in the pharmacy. Section 338.055.2(6) and (15), RSMo Supp. 2002.

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The Effects of the Flu Vaccine Shortage

In early October 2004, Chiron Corporation, one of two major pharmaceutical manufacturers of influenza vaccine, informed the Centers for Disease Control and Prevention (CDC) that it would be unable to distribute its estimated 48 million doses of Fluvirin® in time for the 2004-05 flu season. The United Kingdom's Medicines and Healthcare products Regulatory Agency temporarily suspended Chiron's license for its Liverpool facility that was scheduled to produce Fluvirin for distribution throughout the United States.

During the 2003-04 flu season, approximately 87 million doses of influenza vaccine were administered. Before Chiron's announcement, it was expected that 100 million doses would be available during this season, with Aventis, the other major influenza vaccine (Fluzone®) producer, contributing 54 million doses. Aventis has indicated that it will be able to produce an additional 2.6 million doses of influenza vaccine by January 2005.

Shortly after this announcement CDC convened its Advisory Committee on Immunization Practices to issue recommendations to prioritize the existing supply of influenza vaccine. In summary, the CDC recommends that the following priority groups be given available doses first due to their increased risk of complications from influenza infection:

- ◆ Persons aged 65 years or older;
- ◆ Children six to 23 months of age;
- ◆ Residents of long-term care facilities and nursing homes;
- ◆ Persons two to 64 years of age with chronic medical conditions;
- ◆ Health care workers involved in direct patient care;
- ◆ Household contacts and out-of-home caregivers of children less than six months of age;
- ◆ Children and teenagers between the ages of six months and 18 years who are receiving aspirin therapy; and
- ◆ Pregnant women.

Although not appropriate for everyone, FluMist® (MedImmune), the intranasal influenza vaccine, may be a good alternative for healthy persons between the ages of five and 49. Unlike Fluvirin and Fluzone injectables, which are inactivated influenza vaccines, FluMist is a live attenuated virus, which, if administered to at-risk groups, particularly those with compromised immune systems, may in rare instances actually cause disease.

Other alternatives include antiviral medications, which may be used to prevent and treat influenza infection. The antiviral agents rimantadine, Tamiflu® (oseltamivir), and amantadine are Food and Drug Administration (FDA) approved for treatment and prophylaxis of influenza. Relenza® (zanamivir) is only approved for influenza treatment. To help minimize resistance, CDC currently encourages the use of amantadine or rimantadine for influenza prevention while using the other antivirals oseltamivir or zanamivir for treatment.

Although vaccination and other pharmacologic interventions are extremely beneficial, health care professionals should educate patients on practical measures that can be taken to prevent the spread of influenza. These include:

- ◆ Washing your hands frequently to avoid the spread of viruses and bacteria;
- ◆ Avoiding contact with people who may be sick;
- ◆ Cleaning telephones, door knobs, and other environmental surfaces with disinfecting agents to help prevent the spread of viruses and bacteria;
- ◆ Covering your mouth and nose when coughing or sneezing;

- ◆ Staying home from work and/or school when you are sick and limiting/eliminating contact with those who have compromised immune systems.

In late August 2004, US Department of Health and Human Services (HHS) Secretary Tommy G. Thompson released preliminary plans for a National Pandemic Influenza Preparedness Plan that details a national strategy to prepare for and respond to an influenza pandemic and provides action steps that should be taken at the national, state, and local levels during a pandemic. At press time, the draft plan was located at www.hhs.gov/nvpo/pandemic-plan. Pharmacists have become increasingly active in efforts to increase the public access to immunizations; according to National Association of Board's of Pharmacy® (NABP®) 2003-2004 *Survey of Pharmacy Law*, more than half of the states allow pharmacists to administer immunizations.

Because of the influenza vaccine shortage, many have expressed concerns about the possibility of counterfeit influenza vaccines. Pharmacies and health care institutions should only secure product from reputable resources and immediately report any suspect product. Also, many pharmacies have reported that the price of influenza injectable vaccines from some distributors has more than doubled since the shortage. In mid-October 2004, HHS Secretary Thompson urged the state attorneys general to prosecute those who were price gouging the cost of influenza vaccines.

For more information visit these Web sites:

FDA Flu Information – www.fda.gov/oc/opacom/hottopics/flu.html.

CDC Influenza Information (including vaccination information and Antiviral Medication Usage Guidelines) – www.cdc.gov/flu.

FDA Urges Consumer Education About Counterfeit Drugs

In an interim report, FDA's Anti-Counterfeiting Task Force stressed the importance of increasing awareness and education of stakeholders including the public concerning counterfeit drugs. The report called for increasing efforts of FDA and other government agencies to educate consumers and health care professionals on how to reduce the risk of obtaining counterfeit drugs before the event occurs; educating consumers and health care professionals on how to identify counterfeit drugs; and improving and coordinating FDA and industry messages and efforts to address and contain a counterfeit event. At press time, FDA had available on its Web site (www.fda.gov/cder/consumerinfo/counterfeit_all_resources.htm) public service announcements that can be printed for consumers as well as educational articles to inform the public.

One recent high-profile case concerned Viagra® (sildenafil citrate) that was dispensed from two pharmacies located in California. The counterfeit product closely resembled genuine Viagra tablets with respect to size, shape, color, and imprinting; however, the counterfeit drugs had subtle differences in tablet edging, film coating, imprinting font, and packaging. At press time, FDA, along with Pfizer, Inc, the legitimate manufacturer of Viagra, was analyzing the counterfeit product to determine its true composition and whether or not it posed any health risks; fortunately, no injuries had been reported. For comparative photos of the counterfeit drug and genuine Viagra, refer to Pfizer's "Dear Pharmacist" letter posted on the company's Web site at www.pfizer.com as well as FDA's distributed a press release that is now available at www.fda.gov.



Exactly one month after the counterfeit Viagra product was discovered, FDA expressed concern regarding counterfeit versions of the prescription drugs Zocor® (simvastatin) and carisoprodol, which were imported from Mexico by US citizens. Tests of these products revealed that the counterfeit Zocor, reportedly purchased at Mexican border-town pharmacies and sold under the name Zocor 40/mg (lot number K9784, expiration date November 2004, and lot number K9901, expiration date December 2006), did not contain any active ingredient. Likewise, the counterfeit carisoprodol 350/mg (lot number 68348A) test results indicated that the products differed significantly in potency when compared to the authentic product. FDA continues to investigate this matter and is working with Mexican authorities to ensure that further sale and importation of these products are halted. For more information on counterfeit Zocor, visit www.fda.gov/bbs/topics/ANSWERS/2004/ANS01303.html.



Diabetes or Alzheimer's Disease?

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.

Several reports of mix-ups have been reported in which the antidiabetic agent AMARYL® (glimepiride) had been dispensed to geriatric patients instead of the Alzheimer's Disease medication REMINYL® (galantamine). Each drug is available in a 4 mg tablet, although other tablet strengths are also available for each.

In one case, a 78-year-old woman with a history of Alzheimer's disease was admitted to the hospital with hypoglycemia (blood glucose on admission 27 mg/dL). A review of the medications she was taking at home revealed that her pharmacist dispensed Amaryl 4 mg, which she took twice daily instead of Reminyl 4 mg BID. In another case, an 89-year-old female received Amaryl instead of Reminyl for three days, eventually requiring hospitalization for treatment of severe hypoglycemia. A third patient received Amaryl instead of Reminyl while in the hospital, leading to severe hypoglycemia. All patients recovered with treatment. These events have been linked to poor prescriber handwriting and sound-alike, look-alike names. It is possible that prescriptions for Amaryl are more commonly encountered than those for Reminyl. Thus, confirmation bias (seeing that which is most familiar, while overlooking any disconfirming evidence) may lead pharmacists or nurses into "automatically" believing a Reminyl prescription is for Amaryl.

Obviously, accidental administration of Amaryl poses great danger to any patient, especially an older patient, who may be more sensitive to its hypoglycemic effects. Practitioners should be alerted to the potential for confusion between Amaryl and Reminyl. Prescribers should be reminded to indicate the medication's purpose on prescriptions. Consider building alerts about potential confusion into computer

order entry systems and/or adding reminder labels to pharmacy containers. Patients (or caregivers) should be educated about all of their medications so they are familiar with each product's name, purpose, and expected appearance. Most importantly, at all times pharmacists and nurses should confirm that patients are diabetic before dispensing or administering any antidiabetic medication, including Amaryl. FDA, Aventis (Amaryl), and Janssen Pharmaceutica Products LP (Reminyl) are aware of these reports and will be taking action to help reduce the potential for errors.

Medication Safety Videos Available Free

FDA's Center for Devices and Radiological Health has been producing a monthly series of patient safety videos available via the Internet. ISMP and FDA's Division of Medication Errors and Technical Support, Office of Drug Safety, has been cooperating in this effort. Access www.ismp.org/Pages/FDAVideos.htm for videos related to medication errors. See www.accessdata.fda.gov/scripts/cdrh/cfdocs/psn/viewbroadcasts.cfm for a complete list of all broadcasts.

2005 Survey of Pharmacy Law Now Available

NABP's 2005 Survey of Pharmacy Law CD-ROM is now available. Eight new questions were added to this year's Survey; topics include the formatting requirements of prescription pads, laws/regulations on the disposal of medications, and whether or not pharmacists are allowed to dispense emergency contraception without a prescription.

The Survey can be obtained for \$20 from NABP by downloading the publication order form from www.nabp.net and mailing in the form and a check or money order to NABP. The CD-ROM is provided free of charge to all final-year pharmacy students through a grant from GlaxoSmithKline. If you do not have Web access or would like more information on the Survey, please contact NABP at 847/391-4406 or via e-mail at custserv@nabp.net.

NABP Headquarters Moves to New Location

NABP has moved its Headquarters to 1600 Feehanville Drive, Mount Prospect, IL 60056. The new phone number is 847/391-4406 and the new fax number is 847/391-4502. All printed communications can be sent to the Feehanville Drive address. If you have any questions concerning the Association's new Headquarters, please contact the Customer Service Department at custserv@nabp.net or call 847/391-4406.

Register Now for NABP's 101st Annual Meeting

Register now for NABP's 101st Annual Meeting, May 21-24, 2005, at the Sheraton New Orleans Hotel, New Orleans, LA, so you can take advantage of the chance to earn up to five hours of continuing education (CE).

This year, CE sessions will focus on topics that fall under the Meeting's theme, "A Medley for Patient Safety: Accreditation, Self Assessment, Quality Care." Other events include the Educational Presentation Area and Poster Session, the President's Welcome Reception, NABP's annual business sessions, and the Annual Awards Dinner. In addition, you and your spouse or guest will have the opportunity to participate in a special recreational tour and the annual Fun Run/Walk.

For more information visit NABP's Web site at www.nabp.net, or contact NABP at 847/391-4406 or custserv@nabp.net.

Continued from page 1

Richard J. Drury, #28299, St Louis, MO – December 28, 2004. Suspension for one (1) year from December 28, 2004, followed by Probation for five (5) years. Cooperated with several pharmacies, two of which he maintained a financial interest in, to return drugs that had been received at Easy Returns, a licensed facility of which he was PIC [pharmacist-in-charge], without an identified source from which the drugs were obtained. Credit for the drugs was then obtained from drug manufacturers. Section 338.055.2(4), RSMo.

Charles W. Marsh, #28481, Drexel, MO – December 9, 2004. Probation for three (3) years. Employed pharmacy technician without timely registration; unsanitary handling of medications; knowingly dispensing drugs to long-term care patients without a proper permit classification; dispensed drugs with extended expiration dates beyond one-year; multiple dispensing errors; failure to provide effective controls to guard against theft of controlled substances; and failure to timely report theft of controlled substances to proper authorities. Section 338.055.2(5), (6), (10), (13), and (15), RSMo Supp. 2002.

A. James Reid, #28660, Fulton, MO – November 16, 2004. Probation for one (1) year from November 16, 2004. Failure to conduct/maintain annual controlled substance inventory, loss of controlled substances, failure to timely report losses, misbranded drugs, outdated drugs in active inventory, batch compounding off-site, lack of patient counseling. Section 338.055.2(15), RSMo Supp. 2002.

Pharmacies

Drexel Pharmacy, permit #3190, Drexel, MO – October 15, 2004. Probation for three (3) years from October 15, 2004. Employed pharmacy technician without timely registration; unsanitary handling of medications; knowingly dispensing drugs to long-term care patients without a proper permit classification; dispensed drugs with extended expiration dates beyond one-year; multiple dispensing errors; failure to provide effective controls to guard against theft of controlled substances; and failure to timely report theft of controlled substances to proper authorities. Section 338.055.2 (5), (6), (10), (13), (15) and 338.285, RSMo (Supp. 2002); and 4 CSR 220-2.010(1)(N).

Medicine Shoppe, permit #2001029092, Columbia, MO – November 3, 2004. Probation for one (1) year from November 3, 2004. Failure to timely take controlled substance inventory, failure to timely and accurately report losses of controlled substances to the Bureau of Narcotics and Dangerous Drugs, overfilled manufacturer's stock bottles in active inventory, outdated drugs, batch compounding off-site, and failure to offer patient counseling. Section 338.055.2(15), Section 338.285, RSMo Supp. 2002.

Walgreens #04225, permit #6244, Blue Springs, MO – October 15, 2004. Censure of permit effective October 15, 2004. Hired employees as pharmacy technicians without registration or pending applications with the Board; unregistered pharmacy technician committed theft of a controlled substance. Section 338.055.2 (5), (6), (13), & (15) and 338.285, RSMo (Supp. 2002); and 4 CSR 220-2.010(1)(N).

Drug Distributors

Medical Gas Products, #2003025195, Kansas City, MO – October 4, 2004. Restricted license issued on Probation for three (3) years from October 4, 2004. Permanent drug distributor license issued on probation for three (3) years for failure to comply with the standards of operation for medical gas distributors. 338.055.1 and .2 (5), (13), (15); and 338.353.1 RSMo (Supp. 2002).

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