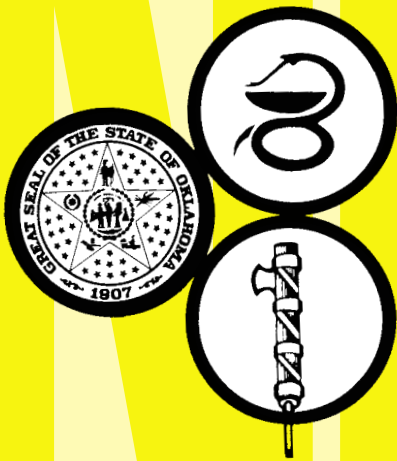


January 2005



NEWS

Oklahoma State Board of Pharmacy

Published to promote voluntary compliance of pharmacy and drug law. 4545 N Lincoln Blvd, Suite 112, Oklahoma City, OK 73105-3488

Season's Greetings

*From the Members and Staff of the
Oklahoma State Board of Pharmacy*

Board Meeting – September 15, 2004

Disciplinary Action

Linda K. Chancellor, Tech #5312 – Case 719: Charges: Theft of merchandise and embezzlement. Permit revoked.

David Jackson, Tech #5876 – Case 720: Charges: Theft of merchandise, conducting business without reasonable skill and safety by use and/or abuse of drugs, and providing false information on his technician application. Permit revoked.

The Board also took action in one (1) impaired case:

Case 603-A – DPh #11834: requested that the suspension of her license be placed on probation. Her license will be placed on probation upon meeting the reinstatement requirements and the first 80 hours of work must be supervised and documented by another pharmacist.

Board Meeting – October 26, 2004

Disciplinary Action

James Milton Swaim, DPh #8338, and Buy For Less Pharmacy at Penn, #1-3418 – Case 712: Charges: Failure to address the possible addiction or dependency of a patient; failure to resolve a situation of potential harm to the patient; filling a prescription without authorization; failure to report a violation of pharmacy law or regulation to the Oklahoma State Board of Pharmacy; failure to notify the Oklahoma State Bureau of Narcotics and Dangerous Drugs Control or local law enforcement agency of any information concerning any violations of the Oklahoma Controlled Substances Act; violating directly or indirectly provisions or terms of the Oklahoma State Board of Pharmacy, the Prescription Drug Marketing Act, the Robinson-Patman Act, or federal, state, and local laws and rules governing registrants. Mr Swaim's license was suspended for five (5) years until October 26, 2009. The suspension was stayed from October 26 until October 31, 2004. The suspension was in effect for twenty-eight (28) days beginning November 1, 2004, through November 28, 2004. The suspension was then stayed and he was placed on probation. The pharmacy was placed on probation for three (3) years until October 26, 2007. Mr Swaim also agreed to attend an approved one-day law seminar in the years 2004 and 2005. Total fine for the respondents was \$12,500.

Debra Wells, DPh #12124 – Case 724: Charges: Dispensing a Schedule II drug without first obtaining the original prescription; failure to annotate and retain the written original prescription when dispensing Schedule II drugs pursuant to a facsimile prescription. Placed on probation for one (1) year until October 26, 2005. Must attend an approved one-day law seminar in the years 2004 and 2005. One thousand two hundred fifty dollar (\$1,250) Fine.

Saffa Compounding Pharmacy, #2-4513, with George P. Saffa, DPh #8472, Owner and Person-in-Interest – Case 722: Charges: Dispensing a Schedule II drug without first obtaining the original prescription; failure to annotate and retain the written original prescription when dispensing Schedule II drugs pursuant to a facsimile prescription; failure to conduct business in conformity with all federal, state, and municipal laws. Two thousand five hundred dollar (\$2,500) Fine. Owner George Saffa was placed on probation for a period of one (1) year until October 26, 2005, and agreed to attend an approved one-day law seminar in the years 2004 and 2005.

Board Meeting – November 17, 2004

Disciplinary Action

Stephenie Conine, Tech #4994 – Case 727: Charges: Possession of a Controlled Dangerous Substance (CDS) without a valid prescription and theft of merchandise. Permit revoked.

Bobbi N. Erwin, Tech #7792 – Case 725: Charges: Possession of a CDS without a valid prescription and theft of merchandise. Permit revoked.

David Rogers, Tech #8053 – Case 726: Charges: Possession of a CDS with intent to distribute; possession of a CDS without a valid prescription; theft of merchandise. Permit revoked.

Robi Stolhand, Tech #6407 – Case 729: Charges: Possession of a CDS without a valid prescription and theft of merchandise. Permit revoked.

James Neal Bruton, DPh #8505 – Case 730: Charges: Attempting diagnosis or treatment that might infringe upon the legally constituted right or obligation of any practitioner of the healing arts; filling a prescription without authorization; failure to properly label a prescription; failure to maintain a patient record system that provides for the immediate retrieval of a list of all prescription drug orders obtained by a patient; failure to conduct business at all times in conformity with all federal, state, and municipal laws. License suspended for ten (10) years until November 17, 2014. Respondent may request probation after eighteen (18) months of suspension.



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.

Compliance News

Compliance News to a particular state or jurisdiction should not be assumed. The law of such state or jurisdiction.)



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.

From the Inspectors

- ◆ **Documentation of technician training.** During inspections, inspectors are asking to see documentation of technician training. Pharmacists need to check that they have proper documentation on all technicians. When technicians are hired that have previously worked in another pharmacy, they still need to be trained in the new pharmacy and the training documented. This is not a new requirement.
- ◆ **A change in pharmacy manager** must be reported to the Board and a CDS inventory must be taken and a copy sent to the Board.
- ◆ We are still finding **Drug Enforcement Administration 222 forms** that have not been completed when drugs are received.
- ◆ **Compounding pharmacists:** Please review the compounding rules. Compounded prescriptions must be indicated as such on the prescription label. Prescribers must indicate on the prescription that it is to be compounded or the pharmacist must obtain authorization from the prescriber to use a compounded product.

Implementation of New Pseudoephedrine (PSE) Law

The Bureau of Narcotics has indicated that the new law has significantly reduced the number of “meth” labs in Oklahoma. The Bureau appreciates the effort that pharmacies and pharmacists have made to initiate this new program. In reviewing the program, the Bureau has found a number of pharmacies are failing to obtain the data required by law and in some cases are selling in excess of the nine grams/30 days limit. **Pharmacists are responsible for the sale of a Schedule V product. A pharmacist or a pharmacy technician must make the sale of PSE. Please review your process on these sales.** The Oklahoma Board of Narcotics is working on an electronic process for tracking sales. Until that is available the pharmacist and pharmacy are responsible for the sale of this Schedule V product. Because the exempt narcotic book does not seem to accommodate the required data very well, the Board has the following suggestions:

1. Prepare a loose-leaf notebook using the guideline on the Board’s Web site.
2. Keep purchasers’ names alphabetical – it will make it easier to check the number of grams purchased in the past 30 days.
3. Keep the total in grams (make a chart converting mgs to g/number of tablets)
4. Make sure all employees understand the importance of following the law.

If we continue to see a disregard for compliance with this law and the record keeping requirements, it could be changed back to requiring that **pharmacists only** make the sales.

Utilization of Unused Medications

This Program is to Aid the Medically Indigent

Rules have been adopted. If you are working in a charitable pharmacy or working as a consultant pharmacist for a nursing home or assisted living center, you should familiarize yourself with these rules. You may review them on the Board’s Web site at www.pharmacy.state.ok.us.

Only carded or unit-dose, unexpired, **non-controlled**, unused medication from nursing homes and **Board-approved** assisted living centers may be donated.

Only charitable pharmacies, city-county pharmacies, and mental health and substance abuse clinic pharmacies may receive these medications to be used for medically indigent patients.

Pharmacies wishing to participate in this program will need to notify the Board. A list of participating pharmacies will be posted on the Board’s Web site.

Pharmacies receiving these medications will also need a current drug identification reference.

Technician Renewals

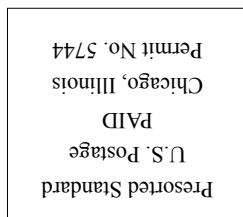
Technician permits expire January 31, 2005. Please remind your technicians.

Renewal forms are available on the Board’s Web site at www.pharmacy.state.ok.us.

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