July 2012

Oklahoma State Board of Pharmacy News

Published to promote compliance of pharmacy and drug law

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Fred T. Mahaffey Award

The Oklahoma State Board of Pharmacy was awarded the prestigious National Association of Boards of Pharmacy® (NABP®) Fred T. Mahaffey Award in ceremonies at the NABP 108th Annual Meeting in Philadelphia, PA, in May. Gordon Richards, DPh, Board president, accepted the award on behalf of the Board.

The Fred T. Mahaffey Award recognizes the Oklahoma Board's outstanding accomplishments in the protection of the health, safety, and welfare of the citizens of Oklahoma, most notably through the development of the "Road to Nowhere" drug abuse prevention program established for school age children. The "Road to Nowhere" video is in its third edition since 2010, with well over 2,000 DVDs and tens-of-thousands of informational bookmarks distributed nationwide. The program has been presented in seminars nationally and several states are using the program materials for drug abuse education. The program's costs were substantially funded by the Board and program materials are available without charge. Oklahoma pharmacists throughout the state have volunteered to present the program to schools, youth groups, football camps, and adult education seminars. In his remarks at the Annual Meeting award ceremony, President Richards noted the hard work that the Board, Board Attorney Brinda White, Oklahoma Pharmacists Association, National Association of Drug Diversion Investigators, and the Oklahoma Pharmacy Educational Foundation have invested in the continuing project. More information about the program, including a link to the video, is available on the Board Web site.

NABP is an international association of state boards of pharmacy in the United States, Puerto Rico, and other US protectorates, Australia, and many Canadian provinces. NABP administers the North American Pharmacist Licensure Examination® and the Multistate Pharmacy Jurisprudence Examination® for pharmacist licensure as well as coordinating the reciprocation of pharmacist licensure and other important services.

Board Compliance Officer Named 'Oklahoma Health-System Pharmacist of the Year'

Compliance Officer **Chelsea O. Church, DPh, PharmD, BCPS,** of Tuttle, OK, was named Health-System Pharmacist of the Year at the Oklahoma Society of Health-System Pharmacists (OSHP) Annual Meeting on March 30, 2012. This is the highest and most prestigious award given by the OSHP. Chelsea has been actively involved with the movement for health care collaboration in the state of Oklahoma. She is on the planning committee for the Pharmacy Health Fair held annually at the state Capitol for the legislators and their staff. Chelsea was also involved in the establishment of "AOkPharm," the Alliance of Oklahoma Pharmacists for Appropriate and Responsible Medication.

12.14. Long-Term Care Emergency Boxes

New rules allowing a pharmacy to place an emergency stock of medications in long-term care facilities have been approved by the legislature and signed by the governor. These rules are based upon legislation passed last year. The Board will have an application for placement of the emergency boxes available on the Board Web site in July. The emergency box will remain the property and responsi-

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FDA Warned Medical Practices About Counterfeits in US and Risks to Patients

In April 2012, Food and Drug Administration (FDA) sent letters to medical practices in several states requesting that they stop administering drugs purchased from any foreign or unlicensed source. FDA's letters were sent in response to the discovery that the medical practices purchased medications from foreign or unlicensed suppliers that sold illegal prescription medications. FDA has advised that these medical practices are putting patients at risk of exposure to medications that may be counterfeit, contaminated, improperly stored and transported, ineffective, and dangerous.

In an FDA statement, the agency urges the health care community "to examine their purchasing practices to ensure that they buy directly from the manufacturer or from licensed wholesale drug distributors in the United States." Further, FDA reminds health care providers, pharmacies, and wholesalers/distributors that they are valuable partners in protecting consumers from the threat of unsafe or ineffective products that may be stolen, counterfeit, contaminated, or improperly stored and transported. FDA advises that the receipt of suspicious or unsolicited offers from unknown suppliers should be questioned, and extra caution should be taken when considering such offers.

FDA notes that the "Verify Wholesale Drug Distributor Licenses" FDA Web page, available at *www.fda.gov/Drugs/DrugSafety/DrugIntegrityandSupplyChainSecurity/ucm281446.htm,* may be used to verify that a wholesale drug distributor is licensed in the state(s) where it is conducting business.

The FDA warning letters were sent following two incidences of counterfeit injectable cancer drugs found in US medical practices, one in February 2012, involving counterfeit Avastin® 400 mg/16 mL, and another in April 2012, involving a counterfeit version of Roche's Altuzan® 400 mg/16 ml (bevacizumab).

More information and a list of the medical practices that were sent warning letters are available on the FDA Web site at *www.fda.gov/Drugs/DrugSafety/DrugIntegrityandSupplyChainSecurity/ucm299920.htm.*

Rethink the Vial

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.*

Recently, ISMP has been receiving many reports from consumers who report the pharmacy "shorted them" on a variety of opioid prescriptions. They report that when they call the pharmacy to complain about the missing number of tablets or capsules the pharmacy staff insists the proper quantity was dispensed. ISMP also receives reports from pharmacists reporting this same situation. The concern is that pharmacy personnel may be diverting the medication, the patient may be seeking more medication than what was prescribed, or some of the medication may be taken by someone else in the patient's home.

In the US, we dispense almost all oral solid drugs as loose tablets or capsules in a plastic vial that is labeled for the patient. This manner of dispensing makes diversion of a few tablets or capsules relatively easy. However, in many other countries, unit-dose and unit-of-use packaging is widely used.

It seems to reason that if unit-of-use, manufacturer-sealed containers or individual unit-dose packages of medications were used in the US for these drugs, diversion and/or speculation of diversion could be reduced. Manufacturers could produce unit-dose or unit-of-use packages, in numbered strips for ease of inventory and dispensing. Patients could be asked to sign for and agree to the amount dispensed at the point-of-sale. The numbered packaging would also help patients at home know if they had taken their medication or possibly alert them to diversion within their home. Of course, prescribers would need to prescribe quantities available in patient compliance packs or in multiples of that packaging, and insurance companies would have to pay for this specialized packaging.

Unit-of-use packs would provide other safety benefits. For example, patients would be able to verify the drug name on the label for each dose, which would add a redundancy in checking the pharmacy label to what was actually dispensed. Also, the manufacturer could print and attach the patient information sheet and/or medication guide to the package the patient receives, eliminating extra work in the pharmacy to print and supply these mandated education sheets to the patient.

It is evident that further steps must be taken to reduce and minimize abuse of prescription drugs. It is critical that education be provided to patients, caregivers, and health care providers to increase awareness about the dangers of prescription drug abuse and about ways to appropriately prescribe, dispense, store, and dispose of prescription medications. Development and deployment of consumer-friendly and environmentally responsible prescription drug disposal programs may also help to limit diversion (as well as reduce the risk of accidental ingestion) of drugs by family members and friends. FDA must continue its efforts to require new concepts for risk evaluation and mitigation strategies and provider education for opioid drugs. For more information on understanding prescription drug abuse, and to request *Parents' Guide to Understanding Prescription Drug Abuse* brochures for distribution to your patients, visit *www.SafeguardMyMeds.org.*

Counterfeit Vicodin ES Sold Via Rogue Internet Drug Outlet, Abbott Reports

In March 2012, Abbott warned consumers and health care providers about counterfeit Vicodin® ES purchased via the Internet. Abbott reports that the counterfeit product drug and package do not match that of Abbott's FDA-approved Vicodin ES (hydrocodone bitartrate and acetaminophen). Descriptions and images of the counterfeit product and authentic Vicodin ES are shown in a consumer alert posted on the Abbott Web site at *www.abbott.com/vicodin-consumer-alert.htm.* Abbott advises that anyone who has the counterfeit ver-

sion should stop taking the product. Further, consumers who suspect a product to be counterfeit or have questions about the legitimacy of Vicodin ES are encouraged to make a report to FDA Office of Criminal Investigations (OCI) by calling 800/551-3989 or by completing the online form on the OCI Web site at *www.accessdata.fda.gov/scripts/email/oc/oci/contact.cfm.*

PSM LEADER's Guide Offers Tips for Protecting Patients from Counterfeits

The Partnership for Safe Medicines (PSM) released a guide to assist health care providers in protecting patients from counterfeit drugs and recognizing the signs that may indicate use of counterfeits. Three versions of the *LEADER's Guide* – including one for nurses, one for doctors, and another specific to pharmacists – are available for download from the PSM Web site at *www.safemedicines.org/resources-for-healthcare-professionals.html*. Each guide provides tips specific to these health care provider roles and includes guidance for safe sourcing of medications, evaluating suspect medications, educating patients about counterfeit drugs and the risks of ordering drugs online, and reporting suspected counterfeit drugs.

FDA Urges Providers to Help Prevent Children's Accidental Exposure to Fentanyl Patches

FDA issued a safety alert reminding patients, caregivers, and health care providers to appropriately store, use, and dispose of fentanyl patches to prevent children's accidental exposure to the medication, which is potentially life-threatening. FDA recently evaluated a series of 26 cases of pediatric accidental exposures to fentanyl patches reported over the past 15 years, and determined that 10 of the cases resulted in death, and 12 in hospitalization. In addition, 16 of the 26 cases occurred in children two years old or younger.

FDA warns that young children may be at risk for accidental exposure when fentanyl patches are discarded in trash receptacles, or when children find lost or improperly stored patches. Young children can be harmed when they place the patches in their mouths or stick the patches to their skin. In addition, young children are at risk of exposure when being held by someone wearing a partially detached patch that can then transfer to the child. Exposure of young children to a fentanyl patch can lead to serious adverse events and even death, due to the amount of fentanyl present in the patches. FDA stresses that harm can even occur with used patches because they may still contain a considerable amount of fentanyl.

To prevent accidental exposure, FDA advises that patients securely store needed fentanyl patches out of children's reach and sight. When applying a patch, FDA also recommends that patients consider covering the fentanyl patch with an adhesive film to make sure the patch does not come off. Finally, FDA recommends checking throughout the day to make sure that the patch is still in place.

Further, FDA advises that used or unneeded patches are properly disposed. FDA recommends that the adhesive side of the patch should be folded together and then the patch should be flushed down the toilet. FDA notes that the agency "recognizes that there are environmental concerns about flushing medicines down the toilet. However, FDA believes that the risk associated with accidental exposure to this strong narcotic medicine outweighs any potential risk associated with disposal by flushing. When the patches are no longer needed, disposing by flushing completely eliminates the risk of harm to people in the home."

FDA urges health care providers to educate patients and their caregivers about the appropriate use and disposal of fentanyl patches. FDA's consumer Web page provides detailed information for patients and caregivers and is available at *www.fda.gov/ForConsumers/ConsumerUpdates/ucm300803.htm.* Providers, patients, and caregivers are also encouraged to review the fentanyl patch product label for instructions. The FDA safety alert is available at *www.fda.gov/Drugs/DrugSafety/ucm300747.htm.* Additional consumer information about safe medication use and storage, and the importance of proper disposal of unneeded medications, is available on the AWAR$_x$E® Web site at *www.awarerx.org/informedSiteMap.php.*

Providers Asked to Advise Patients of Acetaminophen Safe Use Steps

With a world of conditions and hundreds of medicines, the Acetaminophen Awareness Coalition asks pharmacists and other health care providers to educate patients and caregivers about the proper use of medications containing acetaminophen. As the most common drug ingredient in America, acetaminophen can be found in over 600 medicines, including many prescription and over-the-counter medicines. The coalition notes that when used as directed, acetaminophen is safe and effective. The coalition asks providers to advise patients that there is a daily dosage limit for acetaminophen and that taking more than directed is an overdose and can lead to liver damage.

The coalition calls on health care providers to participate in the Know Your Dose campaign, by reminding all patients and caregivers to (1) always read and follow the labels on their medicines; (2) know if a medicine contains acetaminophen; and (3) never take or administer two medicines that contain acetaminophen at the same time. Additional medication safety tips for consumers and more information about the Know Your Dose campaign are available on the "OTC Medication Use" page of the AWAR$_x$E Web site at *www.awarerx.org/OTCMedUse.php*. The AWAR$_x$E consumer protection program and the National Association of Boards of Pharmacy® (NABP®) are part of the Acetaminophen Awareness Coalition.

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bility of the pharmacy that supplies the medications. Very specific guidelines must be followed in the development of the emergency stock formulary and in the required policies and procedures for the use of the emergency medications. Please check the Board's Web site to view the rules. The Board would like to thank the volunteer committee, chaired by Dr Gary Porter and composed of Oklahoma pharmacists familiar with the unique needs of long-term care facilities, for their hard work in writing the rule language.

12.15. Electronic CDS Prescriptions

Drug Enforcement Administration (DEA) has a very specific definition of an "electronic prescription" in their regulation, which allows electronic transmission of controlled dangerous substance (CDS) prescriptions. Some important points to note:

1. A faxed CDS prescription is **not** an electronic prescription and must be manually signed by the prescriber before being faxed.
2. All "refill requests" for a CDS are considered "new prescriptions" and must be manually signed by the prescriber before being faxed.
3. A CDS prescription printed in the office with an electronic image of the prescriber's signature, or a prescription sent by e-mail or on a non-DEA-certified system with an electronic image of the prescriber's signature, is not an electronic prescription. These prescriptions must be manually signed by the practitioner.
4. A pharmacist must call the prescriber and create a verbal order for unsigned prescriptions received in the situations noted in No. 3 above.

As of June 1, 2012, the Board is not aware of any software systems available in Oklahoma that are approved by DEA for transmission of CDS prescriptions. Approved systems must comply with the following DEA requirements:

1. The software program vendor must supply both the practitioner and the pharmacy a copy of the software certification if requested.
2. Prescribers must be "identity-proofed" and receive a hard token and password for the software system they are using.
3. Only the prescriber who has been issued the hard token and password may transmit prescriptions using the system. This cannot be delegated.
4. CDS prescriptions transmitted using unapproved software are **not** valid.

Practitioners who transmit invalid CDS prescriptions over non-DEA-certified software and pharmacies that fill these invalid prescriptions will be subject to both DEA and Oklahoma Bureau of Narcotics and Dangerous Drugs (OBNDD) enforcement action. DEA regulations allow a fine of up to $25,000 per instance for each violation. Practitioners and pharmacy personnel should review CFR 1306.21 for more information.

From the Inspector's Desk

- ***12.16. Tramadol Classified as C-IV:*** Effective November 1, 2012, tramadol and all tramadol-containing products will be classified as Schedule IV in the state of Oklahoma. Pharmacies are required to take an inventory of their tramadol products on November 1, and keep it with their annual CDS inventory. Make sure that you start submitting all tramadol prescription information to the prescription monitoring program as required per OBNDD rules beginning November 1, as well.
- ***12.17. Prescription Data Input:*** It is important that pharmacists-in-charge confirm that the computer software programs their pharmacy is using does not allow a non-pharmacist to "override" or "clear" medication allergy or interaction information. Many software systems have the ability to establish "levels" of authorization for overriding or clearing edits generated by the interaction/allergy review system and these systems must be set to restrict this level to pharmacists. In all cases, interaction, allergy, and duplicate therapy information must be reviewed and authorization action taken only by a pharmacist. The system should also have the ability to identify the pharmacist that authorized the specific override action. In any situation where the system does not identify the specific pharmacist responsible for the override action, the pharmacist-in-charge assumes liability.
- ***12.18. Updated OBNDD Waiver Requirements:*** This updated OBNDD rule is effective June 25, 2012. There is no grandfathering clause for current employees who were not required to receive a waiver under the previous OBNDD waiver rule.

  OAC 475:20-1-5(g)(h). Other security controls for nonpractitioner registrants

  (g) No registrant shall knowingly employ as an agent or employee any person who will have access to controlled dangerous substances if such person has been convicted, pled guilty or nolo contendere or otherwise ordered to complete a period of probation or supervision for a misdemeanor or felony relating to any controlled dangerous substances as defined by the Uniform Controlled Dangerous Substances Act in this state, any other state, or the United States, or any person convicted, pled guilty or nolo contendere or otherwise ordered to complete a period of probation or supervision for any felony of this state, any other state, or the United States, unless, after full review of the circumstances, the Director waives this requirement in writing with respect to each such person on a case-by-case basis.

  (h) The registrant shall immediately notify OBN and seek authorization to employ any individual as specified above.

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- ***12.19. Vaccinations:*** When administering vaccinations, the opened vial should be labeled with the date opened and if not completely used within 28 days then you should treat it as an expired drug.
- ***12.20. Prescription Labeling:*** It is important that only the correct and accurate prescription label be on the vial or prescription packaging that is dispensed to a patient. Any previous labeling or inaccurate labeling must be removed from the vial or packaging. Prescription labels must not be applied over previous prescription labeling.

Disciplinary Actions

For more information you may view hearing minutes at *www.pharmacy.ok.gov.*

12.21. April 26, 2012 Board Hearing

Candace Cook, Tech #9080 – Case 1107: Admitted to theft. **Revoked.** (Agreed Order.)

Ryan Edmond Fanning, Tech #15817 – Case 1108: Admitted to theft and providing false information on technician application regarding charges and convictions. **Revoked.** (Agreed Order.)

Timothy Joel Fishburn, Tech #4505 – Case 1094: Found guilty of CDS theft and providing false information on technician renewal regarding charges and convictions. **Revoked.**

Nhi Lam, Tech #15170 – Case 1109: Admitted to theft, possession of a CDS without a prescription. **Revoked.** (Agreed Order.)

Daniel Margalski, Tech #12535 – Case 1110: Admitted to theft, possession of a CDS without a prescription. **Revoked.** (Agreed Order.)

Impaired Pharmacist #13357 – Case 1091: Admitted to 51 specific violations of the Pharmacy Act and Rules, including theft of at least 3,200 doses of C-II CDS and 1,000 doses of C-III CDS; possession of a CDS without a prescription; failure to guard against drug diversion resulting in audit shortages of up to 15,322 doses of C-II CDS and 3,241 doses of C-III/IV CDS during a 160-day time frame; unlawful distribution of CDS; filling a prescription without authorization and additional counts. **License suspended 10 years until April 26, 2022. Respondent may request license to be placed on probation at a future time. Fine: $5,000. Board required 10-year contract with Oklahoma Pharmacists Helping Pharmacists (OPHP). Must attend a law seminar in the years 2012, 2013, and 2014 in addition to the annual required 15 hours of continuing education (CE). All required CE through the year 2021 must be obtained in live seminars.** (Agreed Order.)

Westchase Compounding Pharmacy LLC, Tampa, FL #99-5815 – Case 1111: Admitted to shipping patient-specific prescriptions to a physician's office. **$6,400 fine.** (Agreed Order.)

Calendar Notes

The Board will meet on Wednesday, **August 15.** The Board will be closed Monday, **September 3,** for Labor Day. Future Board dates will be available at *www.pharmacy.ok.gov* and will be noted in the October *Newsletter.*

Change of Address or Employment?

All pharmacists, technicians, and interns must notify the Board in writing within 10 days of a change of address or change of employment. Online updates through the license renewal page are also accepted as official notification.

Special Notice About the Newsletter

The Oklahoma State Board of Pharmacy *Newsletter* is an official method of notification to pharmacies, pharmacists, pharmacy interns, and pharmacy technicians registered by the Board. Please read them carefully. The Board encourages you to keep them for future reference.

Oklahoma Pharmacists Helping Pharmacists

If you or a pharmacist you care about is suffering from chemical dependency, there is a solution. OPHP is readily available for help. Pharmacists in Oklahoma, Texas, and Louisiana may call the OPHP help-line at 1-800/260-7574, ext 5773. All calls are confidential.

"This publication is issued by the Oklahoma State Board of Pharmacy as authorized by Title 59 O.S. 353.7. Copies have not been printed but are available through the agency website."

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