Board Welcomes New Member

Dr Mark St Cyr, DPh, of Jones, OK, was appointed for a five-year term that began on July 1, 2015, and ends June 30, 2020. Dr St Cyr replaces Oklahoma State Board of Pharmacy member Dr Dorothy Gourley, DPh.

Dr St Cyr was the director of pharmacy at the University of Oklahoma (OU) Medical Center and OU Medical Center Edmond for many years, and is currently a pharmacy clinical specialist with HCA Information Technology and Services. In addition, he is an adjunct assistant professor at the OU College of Pharmacy and a member of the OU National Advisory Board. He is a member and past president of the Oklahoma Society of Health-System Pharmacists (OSHP) and a member of the Oklahoma Pharmacists Association (OPhA) and the American Society of Health-System Pharmacists. Dr St Cyr earned his bachelor of science degree in pharmacy in 1977 from OU, and a master of public health in health administration in 1980 from OU. Dr St Cyr has served on several Board rules committees, and co-chaired the Technician Rules Review Committee.

Board Member Named 2015 OSHP Pharmacist of the Year

Dr Dorothy Gourley has been named the 2015 Pharmacist of the Year by OSHP. She received the award at the OSHP 2015 Annual Meeting. Dr Gourley has been a champion of pharmacy and pharmacist practice through her active participation in many facets of pharmacy. She has been a contributing member and chaired several Board rules committees, and has been a driving force for the Board-sponsored continuing education presentations featuring national speakers. During her decade of service as a Board member, she served for two years as president of the Board. Dr Gourley was a member of the Board’s Building Committee and the Art in Public Places selection committee. She has served as president of OPhA, and is the only OPhA president who was able to coordinate a Cozumel, Mexico cruise as the venue for the OPhA Annual Meeting. Dr Gourley was honored with the Bowl of Hygeia Award in 2011.

From the Inspector’s Desk

♦ 15.11. Electronic Prescription Reminder: Electronic controlled dangerous substances (CDS) prescriptions may not be sent by facsimile. Faxed prescriptions must be manually signed by the prescriber.
♦ 15.12. Phantom PICs: Several Oklahoma-licensed pharmacists have been approached by out-of-state pharmacies asking them to be employed as their pharmacist-in-charge (PIC) without requiring them to actually work at the pharmacy. PIC duties include accepting full responsibility of all aspects of the pharmacy’s operation, including, but not limited to:
  ◊ Supervision of all employees as they relate to the practice of pharmacy
  ◊ Maintaining a proper record-keeping system for the purchase, sale, delivery, possession, storage, and safekeeping of drugs

Oklahoma rules require that a pharmacy manager shall work sufficient hours in a pharmacy to exercise control and meet the responsibilities of the pharmacy manager. It would not be possible for a PIC to fulfill his or her responsibilities without being physically present in the pharmacy.
♦ 15.13. California Driver’s Licenses: The state of California began to issue driver’s licenses to persons even if they were unable to prove that they are residing in the United States legally. If their driver license states “Federal Limits Apply” and has a longer advisory on the back, the Oklahoma Bureau of Narcotics and Dangerous Drugs (OBNDD) does not consider this to be a valid form of identification, according to Title 63, for the purchase of controlled substances (CS) or pseudoephedrine.
♦ 15.14. Schedule II Prescriptions – Additions: Drug Enforcement Administration (DEA) has conflicting policies about what can be added to a Schedule II prescription. There is a policy letter dated October 15, 2008, from DEA that instructs pharmacists to adhere to state regulations until DEA can resolve the conflict through future rulemaking. The OBNNDD allows the following additions to be made to a Schedule II prescription upon consultation with the prescriber:
  ◊ Physician’s DEA number
  ◊ Drug strength, dosage form, or whether it is to be compounded
  ◊ Directions or quantity

No changes may be made to a Schedule II prescription.
Counterfeit Botox Found in the United States, FDA Warns

On April 16, 2015, Food and Drug Administration (FDA) alerted health care providers that a counterfeit version of Botox® was found in the United States and may have been sold to doctors’ offices and clinics throughout the country. The counterfeit products may be identified by a missing lot number on the vial, missing information on the carton (next to LOT, MFG, and EXP), and a displayed active ingredient as “Botulinum Toxin Type A” instead of “OnabotulinumtoxinA.” The counterfeit products were sold by an unlicensed supplier who is not authorized to ship or distribute drug products in the US, according to an FDA Drug Safety Alert. The agency advises health care providers to confirm that the distributor from which they purchase Botox is authorized by Allergan, the drug’s manufacturer. No adverse events related to this product have been reported to FDA.

Medical practices that purchase and administer counterfeit, illegal, and unapproved medications from unlicensed or foreign sources are putting patients’ health at risk, as patients may not be getting proper treatment, warns FDA. Wholesale drug distributors must be licensed in the states where they conduct business. Suspicious Botox products may be reported to FDA’s Office of Criminal Investigations. More information is available on the FDA website at www.fda.gov/Drugs/DrugSafety/ucm443217.htm.

One way pharmacies can be assured of the legitimacy of a wholesale distributor is to look for the National Association of Boards of Pharmacy® (NABP®) Verified-Accredited Wholesale Distributors® (VAWD®) Seal. Wholesale distributors that achieve VAWD accreditation are in compliance with state and federal laws, as well as NABP’s VAWD criteria. Wholesale distributors that display the VAWD Seal as part of their accreditation have undergone a criteria compliance review, including a rigorous review of their operating policies and procedures, licensure verification, survey of facility and operations, background checks, and screening through the NABP Clearinghouse. Accredited facilities are reviewed annually and undergo an on-site survey every three years. Created in 2004, the accreditation program plays a pivotal role in preventing counterfeit drugs from entering the US drug supply.

Seven Persistent Safety Gaffes in Community/ Ambulatory Settings That Need to Be Resolved!

This column was prepared by the Institute for Safe Medication Practices (ISMP). ISMP is an independent nonprofit agency and federally certified patient safety organization 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 provides legal protection and confidentiality for submitted patient safety data and error reports. Help others by reporting actual and potential medication errors to the ISMP National Medication Errors Reporting Program Report online at www.ismp.org. Email: ismpinfo@ismp.org.

ISMP has been reflecting on the strength and resolve of many across the nation who have demonstrated an unparalleled commitment to keeping patients safe. Despite the many safety accomplishments in 2014, ISMP cannot help but mull over persistent medication safety gaffes that continue to be unresolved. ISMP would like to share seven persistent safety gaffes of 2014, in three parts, with NABP National Pharmacy Compliance News readers with the hope that they will join ISMP in bringing attention to these crucial issues and the compelling need for their resolution. Part one of the three-part series is below.

1) Patient Counseling: Still Only a Veiled “Offer” in Many States

The effectiveness of patient counseling in a community pharmacy to detect and prevent medication errors, and its link to improved medication adherence and positive clinical outcomes have been well documented in the literature. Yet, studies have placed patient counseling rates at only eight percent to 42%. An increase in the frequency and quality of patient counseling has been linked to state-specific regulations that require patient counseling for new prescriptions coupled with strict enforcement surveillance. States that require an “offer” to counsel have very low patient counseling rates. Patients often fail to recognize an offer to counsel when simply asked, “Do you have any questions?” or told to “Please sign here.” They may not even know what to ask. This means that, with few exceptions, pharmacies in states that require only an offer to counsel will likely dispense a powerful opioid such as fentanyl transdermal patches and allow the patient or caregiver to walk out of the pharmacy without even a brief discussion about safe use and disposal. ISMP has long promoted mandatory patient counseling in community pharmacies for prescriptions for targeted high-alert medications.

For a list of high alert community medications, please visit www.ismp.org/communityRx/tools/ambulatory/highalert.asp. ISMP hopes you will use this list to determine which medications require mandatory patient education in order to reduce the risk of errors and minimize harm.

2) Patients Impacted by Dispensing Errors: Callous Response From Pharmacists

When patients report dispensing errors to ISMP, they are usually more upset about the response they received when contacting the pharmacist or pharmacy manager than the actual error itself. All too often, consumers tell ISMP that pharmacy staff have responded in a callous manner when confronted with the possibility of a dispensing error, demonstrating a lack of empathy and concern for the adverse effects the patient might have experienced. While pharmacy staff may want to be more responsive to patients who report errors, they are often following corporate policies that are focused on legal concerns. As patients are continually encouraged to be active participants in their health care, they want and deserve honest disclosure of errors, and knowledge that there is an action plan to reduce the risk of it happening again.

Flurbiprofen-Containing Topical Medication May Be Dangerous to Pets, Cautions FDA

People who use topical medications containing flurbiprofen, a nonsteroidal anti-inflammatory drug (NSAID), should take care to prevent their pets from being exposed to the drug, recommended FDA in an April 2015 Safety Alert. The warning is in response to reports of cats in two separate households that became ill or died after their owners used topical medications containing flurbiprofen to treat...
muscle, joint, or other pain. Two cats in one household developed kidney failure and recovered with veterinary care. Two cats in a second household developed symptoms that included reluctance to eat, lethargy, vomiting, melena, anemia, and dilute urine, and subsequently died despite veterinary care. A third cat in the second household also died after the owner stopped using the medication. Necropsies on the three cats found evidence that were consistent with NSAID toxicity. The pet owners had applied the drug to their own neck or feet, and not directly to the pet, and it is not known exactly how the cats became exposed to the medication, the Safety Alert notes.

Health care providers who prescribe or dispense topical pain medications containing flurbiprofen should advise patients with pets to take steps to prevent exposure of the pets to the medication. Additional information is available in the FDA Safety Alert available at www.fda.gov/Safety/MedWatch/SafetyInformation/SafetyAlertsForHumanMedicalProducts/ucm443386.htm.

**New FDA Drug Info Rounds Videos Available**

FDA Drug Info Rounds, a series of online videos, provides important and timely drug information to practicing clinical and community pharmacists so they can help patients make better decisions. The latest Drug Info Rounds videos are as follows.

♦ In “NDC Directory,” pharmacists demonstrate how to use this quick, easy, online resource.
♦ In “FAERS,” pharmacists discuss the FDA Adverse Event Reporting System (FAERS) and review three ways FAERS data is made available to the public.

Drug Info Rounds is developed with contributions from pharmacists in FDA’s Center for Drug Evaluation and Research, Office of Communications, Division of Drug Information. These videos and previous Drug Info Rounds resources are available on the FDA website at www.fda.gov/Drugs/ResourcesForYou/HealthProfessionals/ucm211957.htm.

**Mucinex Cold, Sinus, and Flu Medications Recalled Due to Possible Labeling Error**

In April 2015, RB (formerly Reckitt Benckiser) of Parsippany, NJ, issued a voluntary recall of certain lots of liquid Mucinex® due to a potential error involving the over-the-counter medications’ drug facts labels. While the front label of the recalled lots correctly lists the name of the product as well as the active ingredients, some bottles may not have the correct corresponding drug facts label on the back. The recall was initiated after a confirmed report from a retailer. The recalled medications include:

♦ MUCINEX FAST-MAX Night-Time Cold & Flu;  
♦ MUCINEX FAST-MAX Cold & Sinus;  
♦ MUCINEX FAST-MAX Severe Congestion & Cough; and  
♦ MUCINEX FAST-MAX Cold, Flu & Sore Throat.

If mislabeled, consumers who purchase these products may be unaware of the side effects and potential risks associated with active ingredients such as acetaminophen, dextromethorphan, guaifenesin, phenylephrine, and/or diphenhydramine. RB is recalling these products as a precautionary measure to ensure consumers have all relevant facts and warnings; the company asks consumers to dispose of any unused product.

Additional information about the recall, including the lot numbers and expiration dates for the recalled medications and guidelines for safe disposal, is available on the FDA website at www.fda.gov/Safety/Recalls/ucm444028.htm.

**Pharmacists Are Performing More Patient Care Activities, National Survey Indicates**

Pharmacists are performing more patient care activities in a variety of health care settings and are spending less time in traditional dispensing roles, indicates the 2014 National Pharmacist Workforce Survey. Specifically, the report found that 60% of pharmacists provided medication therapy management, and 53% performed immunizations in 2014, indicates a press release from the American Association of Colleges of Pharmacy (AACP). The survey was created using a random sample of 5,200 individuals selected from a list of 7,000 licensed pharmacists in the US. Response rate to the survey was 48%.

Additional details, including the full results of the survey and an executive summary, are available through the Resources section of the AACP website, www.aacp.org.

**Potentially Lethal Drug Sold Globally as Diet Supplement, Warns INTERPOL**

INTERPOL has issued a global alert for a drug known as 2,4-dinitrophenol (DNP), an illicit and potentially lethal drug sold as a dieting and body building aid. The “Orange Notice” warning about DNP was published in May 2015, following the death of a woman in the United Kingdom and the serious illness of a man in France. In the 1930s, DNP was used to boost metabolism and encourage weight loss, but it was taken out of circulation due to several deaths. Sold as a plain yellow powder, capsules, or cream, DNP is often illegally manufactured and sold via the Internet; unsafe manufacturing of the drug and potential contamination may be magnifying the dangers of taking the drug, notes INTERPOL.

Additional information is available on the INTERPOL website at www.interpol.int/News-and-media/News/2015/N2015-050.

**HHS Announces New Interactive Training on Safe Opioid Use**

The Department of Health and Human Services (HHS) has announced a new, interactive training course that teaches health care providers how to talk to patients about safely using opioids to manage chronic pain. The course, “Pathways to Safer Opioid Use,” also teaches implementation strategies for meeting the opioid-related recommendations from the National Action Plan for Adverse Drug Event Prevention. Adverse drug events (ADEs) are the largest contributor to hospital-related complications and account for more than 3.5 million physician office visits each year, according to HHS. The training, which is offered at no cost, includes self-guided interactive videos with decision points to help users learn how to apply health literacy strategies to help patients understand and act on information to prevent opioid-related ADEs; identify individual risk factors, opioid medications, and interactions that place individuals with chronic pain at increased risk for opioid-related ADEs; recognize the importance of a multidisciplinary team-based approach to treating patients with chronic pain; and demonstrate the ability to combine the principles of the Health Literate Care Model and the biopsychosocial model.

Additional information, including a link to the National Action Plan for Adverse Drug Event Prevention, is available on the course website at http://health.gov/hcq/training.asp#pathways.
15.15. Closed Door Pharmacies: Closed door pharmacies must adhere to the pharmacist-to-technician ratio (2:1). Technicians and clerks are also still required to wear proper identification.

15.16. Compounding Pharmacies: Compounding pharmacies may not compound products that are commercially available unless there is documentation that they are unavailable. Furthermore, medically necessary variations of commercially available products, such as dye-free or lactose-free, must be documented by the prescriber. This documentation must be readily available (eg, attaching it to the prescription or the compounding log).

Compounding a product that is essentially a copy of a Food and Drug Administration (FDA)-approved drug or making slight variations to save the patient money is not a valid reason to compound a similar product. For example, hydrocodone extended-release with 100 mg acetaminophen is not a valid alternative because the dose of acetaminophen is subtherapeutic. Sildenafil 115 mg is not considered to be enough of a variation to justify its usage.

A bulk chemical must be approved for human use if it is to be used in a compounded prescription for humans. Under no circumstances would it be allowable for a pharmacy to bill an insurance company for the commercial product and dispense a compounded product.

Pharmacies may not compound sterile products for office use at all, effective approximately August 27, 2015. (Visit the “Rules” page at www.pharmacy.ok.gov to view rule documents.) Businesses wishing to compound sterile products for office use must be licensed as outsourcing facilities with FDA and the Board.

Nonsterile products for office use may not be redispensed by physicians or hospitals. They must be administered in the office or hospital.

15.17 Patient Counseling

Patient counseling is a hallmark of the profession of pharmacy. Only a pharmacist is allowed to counsel patients on their medications, and counseling by technicians and clerks is expressly prohibited by multiple state and federal laws. Counseling is required for some prescriptions, either by law or insurer contract, and often by pharmacy policy. It is also one of the most important aspects of dispensing error prevention. During the patient counseling, pharmacists are able to talk with the patient about the medication’s use and adverse effects, and often discover issues with the medication or directions at this last point of contact that can be corrected before the prescription leaves the pharmacy.

The Board has had numerous cases involving dispensing issues that would likely never have occurred if the pharmacist had counseled the patient. Some examples of dispensing issues that would very likely have been discovered include a large tube of erythromycin acne cream that was dispensed with directions for use in the eyes of a newborn baby; an opioid prescription that had a fourfold increase in dose from the previous prescription; and prescriptions for the wrong person being sold. In all these cases, the patients actually used the medications and experienced untoward effects. The Board acknowledges the legal responsibility of the pharmacy and the PIC to ensure that state and federal laws and the pharmacy’s policies and procedures on counseling are being followed in the pharmacy.

As Board compliance officers visit pharmacies for inspections, they observe the pharmacy operations and are noting compliance with counseling regulations. Compliance officers will be asking pharmacists and technicians about the store policies on counseling and reviewing compliance. It is vital that PICs ensure that technicians and clerks understand counseling regulations, responsibilities, and store policies. Counseling patients is a privilege, a legal responsibility, and an essential safety step that must never be taken lightly.

Disciplinary Actions

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

15.18. April 22, 2015 Board Hearing

Impaired Pharmacist #893 – Case No. 1298: Suspension of license is stayed and placed on probation until November 19, 2024. Respondent must enter into and remain compliant with a lifetime contract with Oklahoma Pharmacists Helping Pharmacists (OPHP) and shall be tested weekly for drugs the first six months of probation until October 22, 2015.

Impaired Pharmacist #13212 – Case No. 1308: Suspension of license is stayed and placed on probation indefinitely.

Medco Health Solutions of Dublin, #99-633 – Case No. 1310: Neither admitted nor denied guilt on eight counts including failing to timely apply for a new license due to changes of name or ownership and failing, as a nonresident pharmacy, to make an application and receive an annual nonresident pharmacy license at a fee set by the Board. $24,000 fine.

Medco Health, #99-631 – Case No. 1311: Neither admitted nor denied guilt on eight counts including failing to timely apply for a new license due to changes of name or ownership and failing, as a nonresident pharmacy, to make an application and receive an annual nonresident pharmacy license at a fee set by the Board. $24,000 fine.

Medco Health, #99-625 – Case No. 1312: Neither admitted nor denied guilt on eight counts including failing to timely apply for a new license due to changes of name or ownership and failing, as a nonresident pharmacy, to make an application and receive an annual nonresident pharmacy license at a fee set by the Board. $24,000 fine.

Medco Health Solutions of Indiana, LLC, #99-1429 – Case No. 1313: Neither admitted nor denied guilt on eight counts including failing to timely apply for a new license due to changes of name or ownership and failing, as a nonresident pharmacy, to make an application and receive an annual nonresident pharmacy license at a fee set by the Board. $24,000 fine.

Medco Health Solutions of Las Vegas, LLC, #99-629 – Case No. 1314: Neither admitted nor denied guilt on eight counts including failing to timely apply for a new license due to changes of name or ownership and failing, as a nonresident pharmacy, to make an application and receive an annual nonresident pharmacy license at a fee set by the Board. $24,000 fine.

Medco Health Solutions of Irving, #99-637 – Case No. 1315: Neither admitted nor denied guilt on two counts including failing to timely apply for a new license due to changes of name or ownership and failing, as a nonresident pharmacy, to make an application and receive an annual nonresident pharmacy license at a fee set by the Board. $6,000 fine.

Medco Health, #99-627 – Case No. 1316: Neither admitted nor denied guilt on eight counts including failing to timely apply for a new license due to changes of name or ownership and failing, as a nonresident pharmacy, to make an application and receive an annual nonresident pharmacy license at a fee set by the Board. $24,000 fine.
Continued from page 4

Tra'Shad Owens, Technician #19403 – Case No. 1318: Found guilty on five counts including having an arrest, charge, plea of nolo contendere, or conviction, or deferred sentence for any misdemeanor or felony offense and furnishing false or fraudulent material in an application made to the Board. **Revoked.**

Impaired Pharmacist #14832 – Case No. 1321: Suspension of license is stayed and placed on probation indefinitely.

Justun Bell, Technician #19620 – Case No. 1322: Admitted to guilt on three counts including possession of a CDS without a valid prescription and committing theft while working as a pharmacist. **Revoked.**

Shanda Twitty, Technician #8544 – Case No. 1326: Neither admitted nor denied guilt on five counts including possession of a CDS without a valid prescription, theft while working as a pharmacist, and failing to notify the Board, in writing, within 10 days of a change of employment. **Revoked.**

Leslie Caldwell, Technician #6511 – Case No. 1327: Found guilty on four counts including furnishing fictitious, false, misleading, or fraudulent material in any application (original, new, or renewal) or failing to provide information relevant to this application and abusing alcohol or drugs, using an illegal CDS, and/or testing positive for such substance or its metabolite. **Revoked.**

Teresa Hamilton, Technician #9484 – Case No. 1328: Admitted to guilt on five counts including furnishing false or fraudulent material in an application made to the Board and having an arrest, charge, plea of nolo contendere, or conviction, or deferred sentence for any misdemeanor or felony offense. **Placed on probation for one year until April 22, 2016.**

Chad Hartman, Technician #18920 – Case No. 1329: Admitted to guilt on four counts including possession of a CDS without a valid prescription, committing theft while working as a pharmacist, and unlawfully distributing, dispensing, transporting with intent to distribute or dispense, or possessing with intent to manufacture, distribute, or dispense a CDS. **Revoked.**

Betty Mansfield, Technician #16804 – Case No. 1330: Admitted to guilt on four counts including possession of a CDS without a valid prescription and failing to establish and maintain effective controls against the diversion of prescription drugs. **Revoked.**

Susan Reynolds, Technician #17890 – Case No. 1331: Admitted to guilt on five counts including possession of a CDS without a valid prescription and providing fraudulent billing or reports to a third-party payer of prescription drugs. **Revoked.**

Sue Ann Rogers, DPh #10308 – Case No. 1333: Admitted to guilt on 54 counts including compounding a drug product that is commercially available; making or filing a report or record that she knew or should have known to be false; knowingly billing or charging for quantities greater than delivered, or for a brand when a generic is dispensed; providing fraudulent billing or reports to a third-party payer of prescription drugs; failing to have a pharmacy manager who was responsible for all aspects of the operation related to the practice of pharmacy; failing to inventory all CS between May and July 1 of each year; failing to supervise all employees as they related to the practice of pharmacy; failing to assign the proper beyond-use dates to compounded sterile and nonsterile preparations; and failing to designate on the prescription label that it was a compounded prescription. **Placed on five years’ probation until April 22, 2020. $71,000 fine.**

**Calendar Notes**

The Board will meet on **August 19, 2015.** The Board will be closed Friday, **July 3,** for Independence Day and Monday, **September 7,** for Labor Day. Future Board dates will be available at [www.pharmacy.ok.gov](http://www.pharmacy.ok.gov) and will be noted in the October Newsletter.

**Change of Address or Employment?**

Please be diligent in keeping your information up to date and if possible, remind your coworkers and employees. This continues to be an ongoing problem and failure to notify the Board is a violation of Oklahoma pharmacy law. All pharmacists, technicians, and interns must notify the Board in writing within 10 days of a change of address or 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.

**OPHP**

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.

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John A. Foust, PharmD, DPh - State News Editor
Carmen A. Catizone, MS, RPh, DPh - National News Editor & Executive Editor
Deborah Zak - Communications Manager