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News

Arizona State Board of Pharmacy

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Board Members

Board Mission

The Arizona State Board of Pharmacy protects the health, safety, and welfare of the citizens of Arizona by regulating the practice of pharmacy and the distribution, sale, and storage of prescription medications and devices and nonprescription medications.

The Board accomplishes its mission by:

- Issuing licenses to pharmacists, pharmacy interns, and pharmacy technicians;
- Issuing permits to pharmacies, manufacturers, wholesalers, and distributors;
- Conducting compliance inspections of permitted facilities;
- Investigating complaints and adjudicating violations of applicable state and federal laws and rules; and
- Promulgating and reviewing state rules and regulations.

Board Member Update

Congratulations to Kevin Dang on his appointment.

Kevin graduated from the University of Connecticut School of Pharmacy in May 2003 with a doctor of pharmacy degree, and has been working as a clinical pharmacist in hospital and acute care settings ever since. In addition to working as a pharmacist, he is also a part-time adjunct faculty member at Grand Canyon University in Phoenix, AZ.

At the age of 10, Kevin and his parents migrated to the United States from Vietnam. He was the first in his family to attend college. As a minority growing up in poverty, he witnessed the tremendous health disparities experienced by people from different socioeconomic and ethnic backgrounds. Through his childhood experiences, he became inspired to pursue a health care profession that would equip him with the knowledge and clinical skills necessary to become an effective advocate for the medically underserved and low-income populations.

After 12 years working in the pharmaceutical field, Kevin's strong desire to contribute his knowledge and experience to the state of Arizona's health care system ignited his interest in becoming more actively involved in the community's social activities. In April 2015, Kevin was appointed by Governor Doug Ducey to serve in the Arizona Health Facilities Authority's Board of Directors.

With an appointment of a new member, the Board sadly has to see a Board member go. John Musil is a graduate of the University of Arizona and has spent his career defining creative ways to care for patients. He founded The Apothecary Shops and provided patient-centered care for humans and pets. He grew the business to include specialty pharmaceuticals, and it became Avella Specialty Pharmacy. Avella is now a multistate operation and a national leader in patient-centered specialty care. He is a past president of the Arizona Pharmacy Alliance, and a recognized expert in United States Pharmacopeia Chapters <795> and <797> nonsterile and sterile compounding processes. He provided much support to the Board in these areas, including chairing the sterile compounding subcommittee. John was a valuable member of the Board, and his gentle manner and expertise will be greatly missed.

Assisted Living Facilities – Dispensing Prescriptions

The Board has become aware of certain practices by pharmacies servicing assisted living facilities (ALFs) in a manner that may be out of compliance with Board rules. Specifically, pharmacies servicing ALFs have been dispensing prescription medications pursuant to faxed prescription orders without first receiving an original, written prescription. These practices have apparently become common as pharmacies servicing both ALFs and long-term care facilities (LTCFs) implement similar policies and procedures regarding the receipt and dispensing of faxed prescription orders, even though Arizona laws and regulations only permit faxed prescription orders from LTCFs to serve as an original, written prescription order. The Board is aware that pharmacies have been erroneously treating faxed prescription orders

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Discontinue Use of Chen Shwezin Sterile Drug Products, FDA Warns

In October 2015, the United States Food and Drug Administration (FDA) issued a statement alerting health care providers and patients not to use drug products intended to be sterile that were made and distributed by Chen Shwezin, Inc, dba Park Compounding Pharmacy of Westlake Village, CA, because of lack of sterility assurance. Following an FDA inspection during which investigators observed unsanitary conditions, including poor sterile production practices, FDA recommended that Park Compounding Pharmacy cease sterile operations and recall all of its non-expired sterile drug products. However, the company had refused to recall its products, according to an FDA safety alert.

At this time, FDA has not received reports of any adverse events associated with the use of products from Park Compounding Pharmacy. FDA recommends that health care providers check their medical supplies, quarantine any sterile drug products from Park Compounding Pharmacy, and not administer them to patients.

More information is available in the FDA safety alert, available at *www.fda.gov/Safety/MedWatch/SafetyInformation/SafetyAlertsforHumanMedicalProducts/ucm465582.htm.*

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.*

This is the final article of a three-part series on seven persistent safety gaffes of 2014.

6) Compounded Pain Creams: High Profit Margin and Danger

Some compounding pharmacies have been heavily marketing compounded pain creams directly to consumers via unsolicited calls, suggesting that the creams are more effective and safer than oral or injectable pain medications. Many of the creams contain drugs that can cause central nervous system depression or adverse cardiac effects, and most have not been FDA-approved for use in combination with each other or for topical use. Patients are charged per ingredient, with many creams containing numerous, expensive medications. Toxicity from the creams has been reported to poison control centers, including cases of accidental child exposures and intentional use for multiple family members. Patients are often unaware of the dangers with using the creams, which include unsafe packaging in containers without child-resistant closures. ISMP is specifically concerned about some statements that may be unproven, such as the products' safe use with children. Compounded pain creams need prominent warnings on labels that describe the potential for toxicity, and physicians and pharmacists who prescribe and dispense the creams must provide patients with instructions about possible adverse effects, safe storage, and proper use. ISMP believes regulatory or licensing oversight is necessary.

7) Clear Care: Still Causing Severe Eye Injuries Five Years Later

Since early 2010, ISMP has received scores of reports of painful eye injuries from patients using CLEAR CARE® Cleaning & Disinfecting Solution for contact lenses by Alcon (formerly CIBA VISION), a Novartis company, and similar store-brand products. Hundreds more can be found on Internet listservs. Located on store shelves near other lens disinfectants and solutions, these disinfecting products differ from other commonly used solutions in that they must be used with a special lens case in order to neutralize the 3% hydrogen peroxide component of the solution over at least six hours before putting the lenses back into the eyes. However, many patients have inadvertently used the solution to soak their lenses in a standard lens case, or thought the solution was saline and instilled it directly into their eyes. This has caused severe eye burning, leading many to seek out emergency medical care for corneal burns. In 2012, Alcon made a label enhancement to warn customers to use the special lens case, but the label change has been ineffective. Neither the company nor FDA's Medical Devices division have been persuaded to make effective label improvements before permanent eye injury or blindness occurs. If the labeling and packaging cannot be improved to reduce the harm being reported, perhaps these products should be pulled from the market or available only behind the pharmacy counter.

Risk of Dose Confusion and Medication Errors With Avycaz, FDA Cautions

Confusion about the drug strength displayed on the vial and carton labels has led to some dosing errors with the intravenous antibacterial drug Avycaz™ (ceftazidime and avibactam), warned FDA in September 2015. The agency explained that Avycaz was initially approved with the vial and carton labels displaying the individual strengths of the two active ingredients (2 g/0.5 g); however, the product is dosed based on the sum of the active ingredients (2.5 g). To prevent medication errors, FDA revised the labels to indicate that each

vial contains Avycaz 2.5 g, equivalent to ceftazidime 2 g and avibactam 0.5 g, according to an FDA safety alert.

As of September 2015, FDA had received reports of three medication error cases related to confusion on how the strength was displayed on the Avycaz vial and carton labels. Two cases stated that the errors occurred during preparation of the dose in the pharmacy. The third case described concern about the potential for confusion because the strength displayed for Avycaz differs from how the strength is displayed for other beta-lactam/beta-lactamase drugs. Based on the information provided in the reports, FDA is aware that at least one of the patients received a higher-than-intended dose of Avycaz. As of September 2015, no adverse events were reported.

More details are included in the FDA safety alert, available at *www.fda.gov/Safety/MedWatch/SafetyInformation/SafetyAlertsforHumanMedicalProducts/ucm463595.htm.*

US Compounding, Inc, Recalls All Lots of Sterile Compounded Products

In September 2015, US Compounding, Inc, of Conway, AR, issued a voluntary recall of all lots of sterile products aseptically compounded and packaged by the company, and that remain within expiry, because of a lack of sterility assurance. The affected sterile products were distributed nationwide to patients, providers, hospitals, and clinics between March 14, 2015, and September 9, 2015. The recall does not apply to any nonsterile compounded medications prepared by US Compounding. Providers are advised to discontinue use of the products, quarantine any unused product, and contact US Compounding to arrange the return of any unused sterile compounded products using the information provided in the FDA press release, available at *www.fda.gov/Safety/Recalls/ucm464071.htm.*

The company issued this recall out of an abundance of caution. Providers who have dispensed any sterile product distributed by US Compounding should contact patients to whom product was dispensed and notify them of this recall. A list of all sterile compounded products that have been recalled is provided on FDA's website at *www.fda.gov/Safety/Recalls/ucm464072.htm.*

FDA Investigates the Risks of Using Pain Medicine Tramadol in Young Patients

As of September 2015, FDA is investigating the use of the pain medicine tramadol in young patients because of the rare but serious risk of slowed or difficult breathing. This risk may be increased in patients treated with tramadol for pain after surgery to remove their tonsils and/or adenoids. Tramadol is not FDA-approved for use in patients aged 17 years or younger; however, data show it is being used "off-label" in the pediatric population, according to the safety alert on FDA's website, available at *www.fda.gov/Safety/MedWatch/SafetyInformation/SafetyAlertsforHumanMedicalProducts/ucm463499.htm.*

FDA is evaluating all available information and will communicate final conclusions and recommendations to the public when the review is complete. Health care providers are encouraged to report adverse events or side effects related to the use of these products to FDA's MedWatch Safety Information and Adverse Event Reporting Program.

Decreased Potency Reported in Drugs Stored in Becton-Dickinson Syringes

In September 2015, FDA expanded its alert regarding compounded or repackaged drugs stored in Becton-Dickinson (BD) general use syringes to include certain additional syringe sizes including 1 mL, 10 mL, 20 mL, and 30 mL BD syringes, and BD oral syringes. FDA's original alert applied to compounded or repackaged drugs that have been stored in 3 mL and 5 mL BD syringes. The agency expanded the alert based on BD reports that an interaction with the rubber stopper in certain lots of these syringes can cause some drugs stored in these syringes to lose potency if filled and not used immediately. BD reports that the following drugs in particular can be affected by the stoppers, but it does not know whether other drugs can be affected: fentanyl, rocuronium, neostigmine, morphine, midazolam, methadone, atropine, hydromorphone, cisatracurium, and remifentanil. This safety alert does not pertain to BD prefilled, prefillable, heparin flush, saline flush, or insulin syringes, indicates BD in an alert notice. Further, BD's alert notice also has a search tool to assist customers in determining if their lots are affected. FDA advises hospital pharmacies and staff to contact any outsourcers to determine if affected lots of BD syringes were used for compounded or repackaged products. Hospital pharmacies and staff should not administer compounded or repackaged drugs that have been stored in any of these syringes unless there is no suitable alternative available. Adverse reactions may be reported to FDA's MedWatch Safety Information and Adverse Event Reporting program.

More details are included in the FDA Safety Alert, available at *www.fda.gov/Drugs/DrugSafety/ucm458952.htm.*

MediStat Pharmacy Issues Recall of Sterile Drug Products

MediStat Pharmacy, a 503B outsourcing facility in Foley, AL, has initiated a national recall of all sterile injectable products distributed between November 1, 2014, and September 3, 2015. The recall is based on the identification of various pathogens within the compounding environment. Health care providers should check their medical supplies, quarantine any drug products marketed as sterile from MediStat, and not administer them to patients. FDA has received reports of several adverse events that are potentially associated with the drug products made by MediStat. MediStat voluntarily ceased sterile compounding operations in September 2015. FDA asks health care providers and patients to report adverse reactions or quality problems experienced with the use of these products to the FDA's MedWatch Adverse Event Reporting program.

More details are included in an FDA press release, available at *www.fda.gov/Safety/Recalls/ucm461939.htm.*

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from ALFs as an original, written prescription. Accordingly, the Board seeks to reiterate the requirements and regulations pertaining to faxed prescriptions from both LTCFs and ALFs.

Pursuant to Arizona Administrative Code R4-23-407(E)(1)(b)(ii), pharmacies may receive, fill, and dispense Schedule III, IV, or V controlled substance (CS) and non-controlled prescriptions faxed directly from LTCFs and may treat the fax as the original prescription order. Further, pharmacies may treat a faxed prescription order for a Schedule II CS as an original, written prescription order if the prescription order is for a resident of a LTCF (Arizona Revised Statues §36-2525(F)(2); Arizona Administrative Code R4-23-407(E)(2)).

Arizona laws and regulations do **not** permit pharmacies to treat faxed prescription orders from ALFs as an original, written prescription. Any faxed prescription for either a CS or non-CS originating from an ALF is not a valid prescription and may only be used for informational purposes. Consequently, a pharmacy may only dispense prescriptions for ALF patients pursuant to an original, written prescription order or a valid electronic or oral prescription order from the prescriber or the prescriber's agent. In other words, a pharmacy may prepare a prescription for dispensing based on a faxed order, but it may not dispense the prescription until the original is received or the pharmacy has obtained an oral prescription from the prescriber or prescriber's agent.

Immunization Season

The flu and pneumonia season is in full swing. The goal of a health care provider is to ensure better health for the individuals we serve. The question you should ask yourself is, "Are my patients healthier and better with me in their lives or without?" One of the major shortfalls during the immunization season is record keeping. Keeping and maintaining adequate patient records is vital to better care. Board inspectors have mentioned on numerous occasions that record keeping and informing the primary care physician is an overall opportunity to make a positive impact in patient care in Arizona. One particular section that needs extra attention, R4-23-411(F)(2), states, "The pharmacist or pharmacy or graduate intern shall provide a written report to the patient's primary care provider or physician containing the documentation required in subsection (F)(1) within 48 hours after the immunization. The pharmacy shall make the required records specified in subsection (F)(1) and a record of compliance with this subsection available in the pharmacy for inspection by the Board or its designee."

Continuing Education

Continuing education (CE) is a topic that is under discussion across the country. The biggest dilemma involves whether CE is of value and is it enough to maintain or improve pharmacists' knowledge of the changes in patient needs? Currently, the Board has pharmacy licensees who fail to meet the basic requirements under R4-23-204 (pharmacists) and R4-23-1106 (technicians). During the November 2015 Board meeting, it was discussed and decided to implement the following disciplinary actions.

Pharmacists:

- $100 fine per each deficient hour of CE. (Example: Licensee completed 25 contact hours, leaving him or her five contact hours short. Fine: $100 x 5 = $500.)
- $25 fine for administration/investigational fee.
- One and one half times additional CE required for next renewal.
- Automatic audit at next renewal.
- Failure to agree to consent will result in a hearing.
- Repeat offense will result in Board appearance.

Technicians:

- $25 fine per each deficient hour of CE. (Example: Licensee completed 15 contact hours, leaving him or her five contact hours short. Fine: $25 x 5 = $125.)
- $25 fine for administration/investigational fee.
- One and one half times additional CE required for next renewal.
- Automatic audit at next renewal.
- Failure to agree to consent will result in a hearing.
- Repeat offense will result in Board appearance.

Disciplinary Actions and Updates

Pharmacists

Battle (Egwu), Eberenna (S016791) – Consent agreement offered for reinstatement with the respondent being placed on probation until the requirements of the previous consent are completed. The requirements of the previous consent agreement required the respondent to complete six hours of CE on error prevention and pay a $1,000 civil penalty within 120 days. The respondent must appear to remove the probation. Effective August 19, 2015.

Goebig, Thomas (S013463) – Probation terminated. Effective November 18, 2015.

King (Brown), Natalee (S012798) – Probation terminated. Effective June 24, 2015.

Lieb, Karen (S008619) – Probation terminated. Effective November 18, 2015.

McComb, Bailey (S019903) – Suspension terminated. The respondent will be placed on probation for four and one half years and must comply with all terms of her consent agreement. Effective November 18, 2015.

Soraya, Sohelia (S009159) – Consent agreement offered to the respondent with the following terms: 12 months' probation, no pharmacist-in-charge duties while on probation, pay a civil penalty of $10,000, and pass one random pharmacy inspection with the respondent bearing the cost of the inspection. Effective November 18, 1015.

Troller, Ralph (S020355) – Amended consent agreement suspending the respondent's license for six months followed by probation for five years and the signing of a new five-year Pharmacists Assisting Pharmacists of Arizona (PAPA) contract. Effective August 19, 2015.

Intern

Gerber, Colin (I011780) – Amended consent agreement placing the respondent on probation for five years and the signing of a new five-year PAPA contract. Effective August 19, 2015.

Pharmacy Technicians

Edwards, Marvin (T045776) – Application denied. Effective August 19, 2015.

Richardson, Joshua (T046481) – Application denied. Effective August 19, 2015.

Thurlkill, James (T035288) – Consent agreement offered to the respondent with the following terms: five-year PAPA contract excluding the 30-day inpatient treatment program and six-month practice suspension.

Permit

Sina Health (W002468) and Sohelia Soraya (S009159), Co-Owner – Consent agreement offered to the respondents with the following terms: $5,000 civil penalty, provide a copy of the consultant's report to the Board, and pass one random

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wholesale inspection with the respondents bearing the cost of the inspection. Effective November 18, 1015.

Disciplinary Actions and Updates – Other Health Boards

Arizona Medical Board

Michael M. Abraham, PA-C #2249 – *Interim Consent Agreement for Practice Limitation and Assessment.* Respondent is prohibited from engaging in the performance of health care tasks in the state of Arizona until he applies to the executive director and receives affirmative permission to do so. Respondent may not apply for relief from this interim consent agreement until he has completed a current health assessment administered through the Board's Physician Health Program (PHP) contractor. Effective August 25, 2015.

Michael S. Biscoe, MD #20915 – *Interim Consent Agreement for Practice Restriction.* Respondent is prohibited from engaging in the practice of medicine in the state of Arizona until he applies to the executive director and receives permission to do so. Respondent may not request release from or modification of this interim consent agreement for practice restriction until he has completed the relapse evaluation and any and all recommended treatment. Effective September 22, 2015.

Wendy E. Cohen, MD #15096 – *Interim Findings of Fact, Conclusions of Law and Order for Summary of Suspension of License.* It is ordered that on the effective date of the Board's final order in this matter, license number 15096 for the practice of allopathic medicine in Arizona previously issued to Respondent Wendy E. Cohen, MD, is **suspended** for a period of 10 years. If respondent wishes to practice medicine in the state during the period of suspension, respondent may request reinstatement of her license from the Board. Effective August 10, 2015.

Gordon Joseph Cuzner, MD #17172 – *Interim Consent Agreement for Practice Restriction.* Respondent is prohibited from engaging in the practice of medicine in the state of Arizona until he applies to the executive director and receives permission to do so. Respondent may not request release from or modification of this interim consent agreement for practice restriction until after he has completed any and all recommended treatment. Effective August 3, 2015.

Nora D. Ellis, PA-C #3675 – *Interim Consent Agreement for Practice Limitation and Assessment (Non-Disciplinary).* Respondent is prohibited from engaging in the performance of health care tasks in the state of Arizona until she applies to the executive director and receives affirmative permission to do so. Respondent may not apply for relief from this interim consent agreement until she has completed a current health assessment administered through the Board's PHP. Effective October 16, 2015.

Syed A. Jaffery, MD #33192 – *Interim Consent Agreement for Practice Restriction.* Respondent is prohibited from engaging in the practice of medicine in the state of Arizona until he applies to the executive director and receives permission to do so. Respondent may not request release from or modification of this interim consent agreement for practice restriction until after the resolution of the criminal charges pending against him or the final resolution of the pending New Jersey State Board of Medical Examiners investigation, whichever occurs first. Effective August 3, 2015.

Jonathan C. Komar, MD #31330 – *Interim Consent Agreement for Practice Restriction.* Respondent is prohibited from engaging in the practice of medicine in the state of Arizona until he applies to the executive director and receives permission to do so. The executive director, in consultation with and agreement of the lead Board member and the chief medical consultant, has the discretion to determine whether it is appropriate to release respondent from this interim consent agreement. Effective August 10, 2015.

Randal J. Lewis, MD #50616 – *Interim Consent Agreement for Practice Restriction.* Respondent is prohibited from engaging in the practice of medicine in the state of Arizona until he applies to the Board and receives permission to do so. Effective October 14, 2015.

Steven Matthew Rayle, MD #17733 – *Interim Consent Agreement for Practice Limitation (Non-Disciplinary).* Respondent is prohibited from engaging in the practice of medicine in the state of Arizona until he applies to the executive director and receives affirmative permission to do so. Respondent may not apply for relief from this interim consent agreement until he has completed an independent, in-person, comprehensive substance abuse and psychiatric evaluation at a Board-approved evaluation center. Effective October 13, 2015.

Sally Van Snepson-Barnett, PA #5181 – *Request for License Inactivation With Cause and Order Inactivating License With Cause.* License number 5181, Sally Van Snepson-Barnett, PA, is inactivated with cause. Before respondent can request that her license be reactivated, she shall successfully complete a long-term care residential or inpatient hospital treatment program or both. Effective September 22, 2015.

Robert A. Williams, MD #12287 – *Findings of Fact, Conclusions of Law and Order for Decree of Censure and Probation.* Respondent is issued a decree of censure. Respondent's license is placed on probation for a minimum period of three years with terms and conditions. Effective October 9, 2015.

Arizona State Board of Nursing

Dana Lillestol Rosdahl, RN #AP0313 – *Consent for Entry of Voluntary Surrender.* The Board accepts the voluntary surrender of registered nurse license number RN057911 and advanced practice certificate number AP0313 issued to Dana Lillestol Rosdahl. Effective September 30, 2015.

Arizona State Board of Osteopathic Examiners

Norman Gramstad, DO #3181 – *Consent Agreement and Order for Practice Restrictions; Prohibition Against the Clinical Practice of Medicine.* It is hereby ordered that for Norman Gramstad, DO, holder of osteopathic medical license number 3181, beginning on the date of this consent agreement and order, his license to practice osteopathic medicine is restricted in that he shall no longer practice clinical medicine. Respondent shall not evaluate/examine patients, order or interpret diagnostic testing, make referrals, perform medical procedures, prescribe medications, offer medical advice, or diagnose medical conditions. Effective December 8, 2015.

Travis Stiegler, DO #005517 – *Consent Agreement and Interim Order for Practice Restrictions, Interim Findings of Fact and Interim Conclusions of Law.* The following is hereby ordered that effective the date of this agreement, Travis Stiegler, DO, is placed on a practice restriction that prohibits him from prescribing any CS, including SUBOXONE®. Effective December 8, 2015.

The *Arizona State Board of Pharmacy News* is published by the Arizona State Board of Pharmacy and the National Association of Boards of Pharmacy Foundation™ (NABPF™) to promote compliance of pharmacy and drug law. The opinions and views expressed in this publication do not necessarily reflect the official views, opinions, or policies of NABPF or the Board unless expressly so stated.

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