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Arizona State Board of Pharmacy News

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Compliance Officer and Executive Secretary Hired

Karol Hess, PharmD, RPh, a 2003 graduate of Midwestern University College of Pharmacy – Glendale, has been hired to replace Ed Hunter as compliance officer in the Phoenix, AZ, area. Dr Hess participated in and completed an administrative rotation at the Arizona State Board of Pharmacy office as part of her curriculum. She informed the interviewers that she had just been waiting for an opening so she could return and will be moving her home and family from Tucson, AZ, soon. There were over 20 qualified applications for the position.

Jennifer Mitchell also recently joined the Board staff as executive secretary. She previously was engaged in state service for more than 12 years at the Arizona Board of Chiropractic Examiners and for a shorter stint at the Arizona State Board of Technical Registration. She was responsible for administering the fingerprint background checks, among her list of duties at both agencies. She will also revamp the policy and procedure manual at the Board in partial response to recent audit recommendations. Ms Mitchell is a graduate of both Arizona State University West and, after "seeing the light," the University of Arizona, where she obtained a master's degree in information resources and library science.

Good luck to both Ms Mitchell and Dr Hess in their new positions.

NABP 110th Annual Meeting Held in Phoenix in May

The National Association of Boards of Pharmacy® (NABP®) held its 110th Annual Meeting at the Sheraton Phoenix Downtown Hotel in May 2014, returning to Arizona for the first time in 14 years. The Arizona Board has been a member of NABP since its inception in 1904 (Arizona was still a United States territory and was not a state until February 1912). A good summary of the meeting will be available in the 2014 Special Issue of the *NABP Newsletter,* which will be posted at *www.nabp.net/publications/nabp-newsletter* in mid-July.

Board Members Past and Present

The Board ordered three large plaques in copper and black to commemorate all who have served as Board members or executive directors (and a few who served as both) since territorial days. The first plaque lists those individuals who served from 1903 to 1953, the second covers the period from 1954 to 2003, while the third lists those who served from 2004 until the not-so-far-off date of 2053. The plaques were presented at the June Board meeting. Every effort was made to invite all living members and directors who served to attend the unveiling celebration in June.

Arizona 51st Legislative Update

The Board's bills, both sponsored by state Senator Nancy Barto representing Legislative District 15, become law on July 24, 2014. A brief **summary** of each bill and amendment follows.

Senate Bill 1314 (Was Senate Bill 1041)

Currently, the Board was scheduled to terminate on July 1, 2014 (A.R.S. §41-3014.02). During the 2013 interim, the House of Representatives Health Committee and the Senate Health and Human Services Committee of Reference met and recommended the Board be continued for eight years. The bill

- Continues the Board for eight years until July 1, 2022,
- Contains a purpose clause, and
- Applies retroactively to July 1, 2014.

Senate Bill 1043

- Allows naturopathic physicians to prescribe any drug that is reclassified from Drug Enforcement Administration Schedule III to Schedule II after January 1, 2014.

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New Educational Video for Pharmacists Addresses Prescription Drug Abuse

The National Association of Boards of Pharmacy® (NABP®) and the Anti-Diversion Industry Working Group (ADIWG), a consortium of pharmaceutical manufacturers and distributors of controlled substances (CS), have released an educational video for pharmacists to help them identify the warning signs of prescription drug abuse and diversion when dispensing CS prescriptions. The video, entitled "Red Flags," encourages pharmacists to help combat this national problem by exercising their professional judgment to ensure that the prescriptions they dispense were written for a legitimate medical purpose, and to act upon any unusual behavior they observe.

Drug Enforcement Administration and various state pharmacy boards have described "red flags" as circumstances surrounding the presentation of a CS prescription that should raise reasonable suspicion about the validity of that prescription. The video highlights a number of these potential warning signs, some of which are not easy to spot, by weaving personal narratives with interactions between pharmacists and customers.

The video is available in the Pharmacists section of the AWAR$_X$E® Prescription Drug Safety website at *www.AWARERX.ORG/pharmacists*.

Root Causes: A Roadmap to Action

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 Error Reporting Program Report online at* www.ismp.org. *E-mail: ismpinfo@ismp.org.*

Errors are almost never caused by the failure of a **single** element in the system. More often, there are **multiple** underlying system failures that lead to an error, many of which can be identified when the involved health care providers take the time to uncover them.

Consider the following error: A doctor sent a hand-written order for car**bam**azepine 400 mg twice daily for an adult patient with a history of seizures.

The pharmacist entered the medication into the profile of a four-year-old child with the same last name as the adult patient for whom the medication had been prescribed.

The pharmacist failed to notice that the patient was a child, as age was not in a prominent location on the order entry screen. The nurse failed to recognize that the dose was too high and administered 400 mg of car**bam**azepine to the child. She also never thought to question why the pharmacy would send oral tablets for a four-year-old child, considering that the drug is available in chewable tablets and as a liquid suspension.

The nurse **assumed** that the child was receiving the medication because he had a history of seizures. However, the nurse did not check the patient's medical record. In fact, the child did **not** have a history of seizures.

The parents had a very limited understanding of English, so they were unable to intervene to correct the erroneous seizure history.

The error was finally detected after the child became lethargic and developed nausea and vomiting. At the time of discovery, the child's car**bam**azepine level was 18 mcg/mL; levels greater than 12 in pediatric patients are supratherapeutic.[i]

It may be discouraging to see how many things go wrong when a medication error reaches a patient. However, a thorough root cause analysis (RCA) can uncover the latent failures and produce an action plan to avoid future errors.

ISMP, through a generous grant from the National Association of Boards of Pharmacy Foundation™, has developed the *Root Cause Analysis Workbook for Community/Ambulatory Pharmacy.* The workbook is designed to assist community pharmacy personnel in completing RCA for a sentinel event that may have occurred in their pharmacy. The RCA workbook uses a specific set of steps and associated tools to identify the primary causes of the **sentinel event.**

The goal of the RCA is to create an action plan framework, including risk-reduction strategies, communication and implementation strategies, and measurement of effectiveness.

RCA for **sentinel events** is required in the Center for Pharmacy Practice Accreditation's standards developed by NABP, American Pharmacists Association, and American Society of Health-System Pharmacists Association, as well as by several boards of pharmacy in conjunction with their continuous quality improvement regulations.

This ISMP RCA workbook is suitable for use in community pharmacy, mail-order pharmacy, or other ambulatory pharmacy practice settings that need to investigate a **sentinel event.** For more information and to access the **free** workbook, visit *www.ismp.org/tools/rca/.*

[i] *http://pediatrics.aappublications.org/content/113/2/406.abstract*

FDA Withdraws Approval of Some High Dose Acetaminophen Products

Food and Drug Administration (FDA) is withdrawing approval of 108 abbreviated new drug applications (ANDAs) for prescription combination drug products containing more than 325 mg of acetaminophen per dosage unit. For the 108 ANDAs, the manufacturers asked to withdraw their applications, as announced in the March 27, 2014 *Federal Register* notice. A second *Federal Register* notice addresses the applications of six manufacturers who have discontinued marketing their products, but who have not withdrawn their applications. The notice also announces FDA's intention to begin the process of withdrawing approval of those applications.

In light of these announcements, and to protect patients from inadvertent acetaminophen overdose, NABP advises that pharmacies no longer dispense combination drugs containing more than 325 mg of acetaminophen per dosage unit. NABP also advises that pharmacists consult with prescribers to discuss alternative products with lower acetaminophen doses.

FDA asked manufacturers to voluntarily withdraw these products from the market to reduce the risk of severe liver injury from inadvertent acetaminophen overdose. In January 2014, FDA recommended that providers consider prescribing acetaminophen products containing 325 mg or less per dose. The original announcement may be found in the Drug Safety and Availability section of FDA's website at *www.fda.gov/Drugs/DrugSafety*.

NCPDP Recommends Standardized Metric Measurements on Oral Liquid Medication Labels

The National Council for Prescription Drug Programs (NCPDP) has issued new recommendations and guidance for standardizing the dosing designation used on prescription container labels of oral liquid medications dispensed by community pharmacies in order to reduce dosing errors. NCPDP notes that such errors have been "a source of concern for many years," and that dosing errors involving young children are of particular concern because they may be more susceptible to harm from measurement errors and overdoses. The paper outlines the following recommendations for the dosing designation on prescription container labels for oral liquid medications:

- The millimeter (mL) should be used as a standard unit of measurement.
- Dose amounts should always use leading zeros before decimal points for amounts less than one and should not use trailing zeros after a decimal point.
- Dosing devices with numeric graduations and units corresponding to the container label should be made easily and universally available. For example, a device should be included with each dispensed medication.

The white paper was developed following a meeting with stakeholders representing 27 participants, including NABP. In addition to its general recommendations, the white paper also issued calls to action for relevant stakeholders, including government agencies, standards organizations, pharmacists and pharmacy technicians, pharmacy leadership, and health care associations. The white paper, *NCPDP Recommendations and Guidance for Standardizing the Dosing Designations on Prescription Container Labels of Oral Liquid Medications,* is available for download from the NCPDP website at *http://ncpdp.org/Education/Whitepaper*.

USP Proposes New General Chapter Addressing Compounding of Hazardous Drugs

In an effort to protect health care providers and personnel who handle hazardous drugs, United States Pharmacopeial Convention (USP) has proposed new General Chapter <800> Hazardous Drugs–Handling in Healthcare Settings. The new proposed chapter addresses standards that apply to all personnel who compound hazardous drug preparations and all places where hazardous drugs are prepared, stored, transported, and administered. The new chapter also covers standards for receiving, storing, compounding, dispensing, administering, and disposing of nonsterile and sterile products and preparations. The proposed chapter applies to all personnel who are involved in handling hazardous drugs, including health care providers and staff, occupational health and safety specialists, and human resources. General Chapter <800> was published in the May/June issue of *Pharmacopeial Forum,* and may currently be viewed on the USP website at *www.usp.org/usp-nf*. Comments will be accepted until July 31, 2014.

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- Requires applicants for an initial pharmacist, intern, or technician license to submit to the Board a full set of fingerprints for the purpose of obtaining a state and federal criminal records check.
- Allows the Arizona Department of Public Safety to exchange fingerprints with the Federal Bureau of Investigation regarding criminal records checks for pharmacists.
- Removes language requiring the Board to establish a list of drugs that must not be used by dispensing pharmacists as generic equivalents and establish a two-letter code on solid dosage forms.
- Makes technical and conforming changes.

Amendments in House Committee on Health

- Outlines requirements regarding the application for a permit to operate a pharmacy, drug manufacturing facility, or wholesale facility outside of the state that will dispense, sell, transfer, or distribute drugs into Arizona. Removes the requirement for having an Arizona-licensed pharmacist for nonresident pharmacies and manufacturers.
- Codifies current authority under the practice of pharmacy relating to collaborative agreements and immunizations. Establishes (finally) that pharmacists are health care professionals.

Disciplinary Actions and Updates

Pharmacists

Abramchick, Hyman (S012245) – Probation terminated. Effective April 9, 2014.

Makai, Gerwyn (S016844) – Probation terminated. Effective April 9, 2014.

McKee, Mark (S012049) – Request for removal of lifetime Pharmacists Assisting Pharmacists of Arizona (PAPA) monitoring denied. Effective April 9, 2014.

Troller, Ralph (S020355) – Five year probation, PAPA contract, no preceptor or pharmacist-in-charge while on probation. Effective April 9, 2014.

Pharmacy Technician Trainees and Certified Pharmacy Technicians

Palumbo, Annette (T008144 and T038900) – Due to lapsed technician license and criminal conviction; Board agreed to five-year probation, enrollment in PAPA, 20 hours of continuing education to be issued a technician trainee license. Must also retake the Pharmacy Technician Certification Exam; upon passing, the original technician license will be re-opened. Effective April 17, 2014.

Shaw, Rebecca (T000424) – Probation terminated. Effective April 9, 2014.

Permit

CBSChem Ltd (W001940) – Surrendered permit. Effective April 9, 2014.

Disciplinary Actions and Updates – Other Health Boards

Arizona Board of Medicine (MDs)

Rick J. Gomez, MD #33677 – *Order for Surrender of License and Consent to the Same.* License surrendered. Effective April 21, 2014.

Peter Tsai, MD #45470 – *Interim Consent Agreement for Practice Restriction.* Respondent shall not practice clinical medicine or any medicine involving patient care, and is prohibited from prescribing any form of treatment including prescription medications, until he applies to the Board and receives permission to do so. Effective April 21, 2014.

Arizona Board of Osteopathic Examiners (DOs)

Afeworki Kidane, DO #4458 – *Order.* Respondent shall be restricted from prescribing opioid medications, Class 2 and 3, and may not issue any medical marijuana certifications. This restriction includes that any allied health professionals supervised by respondent are also prohibited from prescribing these medications. Respondent may request the Osteopathic Board reinstate his prescribing privileges after completing an evaluation of his pain management practice and the recommendations made by that evaluation. Effective March 4, 2014.

Shawn Platt, DO #3313 – *Consent Agreement and Order for Decree of Censure and Probation.* Issued a decree of censure and placed on probation for one year subject to specified terms. One of the terms restricts respondent from providing pain management care to chronic pain patients that results in prescribing opioid medications, Class 2, 3, 4, or 5, or medical marijuana certification. Effective May 14, 2014.

Richard Settles, DO #2686 – *Consent Agreement and Order for Voluntary Surrender of License.* License surrendered. Effective May 12, 2014.

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