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Wyoming State Board of Pharmacy News

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New Board Members Kerri Kilgore and Jim Massengill

Kerri is from Torrington, WY, and received her doctor of pharmacy degree from the University of Minnesota. She has 31 years of pharmacy experience in various types of pharmacy practice including hospital, retail, pediatrics, assistant professor (University of Nebraska Medical Center and the University of Wyoming School of Pharmacy), residency coordinator, and consulting. Her current position is as the pharmacy senior manager with the Torrington Community Hospital (Banner Health). When asked what made her decide to join the Wyoming State Board of Pharmacy, Kerri stated that pharmacy will continue to grow with more non-traditional positions as the health care environment is forced to adapt to the needs of our aging population. Due to this, she believes that her experience would be an asset to the Board when dealing with these areas while also helping to manage the dispensing side of pharmacy practice. Kerri's hobbies include reading, crocheting, and volunteering.

Jim is from Cheyenne, WY, and received his pharmacy degree from the University of Wyoming. Jim has obtained several types of pharmacy-related experience including IV infusion, telepharmacy, retail, state lobbying to improve pharmacy practice, president of the Laramie County Pharmaceutical Association, president of RxPlus, and an adjunct faculty member with the University of Wyoming School of Pharmacy. His current title is owner and operator of Hoy's Drug in Cheyenne. When asked what areas within the Board he can contribute to, Jim stated that he wants to be an advocate for both pharmacists and technicians to ensure the profession evolves properly by being on the forefront of writing the changes, not adapting to them. In this way, Jim would like pharmacy to maintain a strong community presence in health care for all demographics and citizens of Wyoming. Jim's hobbies include scuba diving, snowmobiling, and coaching swimming.

Buprenorphine-Related Products

By Craig Dana, PharmD Candidate

Buprenorphine (Subutex®) and buprenorphine/naloxone (Suboxone®) are medications Food and Drug Administration (FDA) approved for the treatment of opioid dependence. There has been an increase in the number of emergency department (ED) visits due to buprenorphine-containing products, and EDs have seen a substantial increase in buprenorphine-related ED visits between the years 2006 and 2010. In 2006, ED visits involving non-medical use (eg, taking more than the prescribed dose, deliberate poisoning, taking someone else's medication) of buprenorphine-containing products was estimated at 4,400 visits. In 2010, ED visits involving non-medical use of buprenorphine-containing products was estimated at 15,778 visits, a 255% increase in ED visits over a five-year period. The question at hand is why we have seen such a huge increase in the number of buprenorphine-related ED visits over the past five years. Buprenorphine products accounted for only 2.2% of all retail opioid prescriptions dispensed and 0.16% of all retail prescriptions in 2009. Unfortunately, ED visits related to buprenorphine products are not only affecting our adult population, but ED visits in children are also on the rise. The Centers for Disease Control and Prevention has reported that unsupervised ingestion of buprenorphine-containing products by children is a current and growing concern. During 2010 and 2011, it has been estimated that 1,499 children under the age of six were evaluated in United States EDs for buprenorphine-containing product ingestion as compared to zero case reports in 2004. Ingestion of buprenorphine-containing products by children is serious, and fatalities in children have been reported after a single dose of buprenorphine-containing products.

In order to be able to prescribe buprenorphine-containing products for opioid dependence, physicians must apply for the Drug Addiction Treatment Act of 2000 (DATA 2000) waiver along with meeting certain qualifying requirements. A DATA 2000 waiver allows qualified physicians to prescribe Schedule III, IV, and V narcotic controlled drugs approved by FDA for maintenance or detoxification, and these physicians can be identified by the "X" in the physician's DEA number. Under DATA 2000, physicians are limited to the number of patients they can treat at any one time (100 patients), but DATA 2000 does not include any restrictions on the amount of approved drug that may be prescribed to any one patient that is under the care of a physician approved to prescribe products for opioid dependence. Of note, only a physician may acquire a DATA 2000 waiver.

Buprenorphine-containing products being prescribed for off-label indications such as pain management do not require prescribers to obtain a DATA 2000 waiver. As long as prescribers have both federal and state authority to prescribe controlled substances (CS), they may prescribe buprenorphine-containing products. The pharmacist is then responsible for determining if buprenorphine-containing products are being prescribed for opioid dependence or off-label indications. The Substance Abuse & Mental Health Services Administration has a Web site that lists prescribers within the state of Wyoming that are able to prescribe buprenorphine-containing products for opioid dependence at *http://buprenorphine*

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FDA Issues New Guidelines for Sleep Aids Containing Zolpidem

Food and Drug Administration (FDA) has issued new dosing recommendations for sleep aids containing zolpidem. The new recommendations are based upon new data that shows that when taken at night, blood levels of zolpidem remain high enough in the morning to impair activities that require alertness, such as driving. The new guidelines halve the dosage for women because the new data showed that their bodies take longer to eliminate the drug.

FDA urges drug manufacturers and health care providers to follow the new dosing instructions, which apply to brand name and generic drugs containing zolpidem:

- Ambien®, Edluar™, and Zolpimist®: 5 mg for women, 5 mg or 10 mg for men
- Ambien CR®: 6.25 mg for women, 6.25 mg or 12.5 mg for men

Additionally, manufacturers of these drugs have been instructed to follow the new guidelines and print new patient information drug labels containing the new recommendations.

The recommended doses of Intermezzo®, a lower dose zolpidem product approved for middle-of-the-night awakenings, are not changing. At the time of Intermezzo's approval in November 2011, the label already recommended a lower dosage for women than for men. Additional details are available in an FDA Drug Safety Communication, available at *www.fda.gov/Drugs/DrugSafety/ucm334033.htm.*

What is the National Medication Error Rate? What Standards Are Available for Benchmarking?

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.*

A national or other regional medication error rate does not exist. It is not possible to establish a national medication error rate or set a benchmark for medication error rates. Each pharmacy organization is different. The rates that are tracked are a measure of the number of **reports** at a given organization, not the actual number of **events** or the quality of the care given. Most systems for measuring medication errors rely on voluntary reporting of errors and near-miss events. Studies have shown that even in good systems, voluntary reporting only captures the "tip of the iceberg." For this reason, counting **reported** errors yields limited information about how safe a pharmacy actually is. It is very possible that a pharmacy organization with a good reporting system, and thus what appears to be a high error "rate," may have a safer system.

The National Coordinating Council for Medication Error Reporting and Prevention published a statement refuting the use of medication error rates. The statement, which is posted on the council's Web site (*www.nccmerp.org*), states the "Use of medication error rates to compare health care organizations is of no value." The council has taken this position for the following reasons:

- Differences in **culture** among health care organizations can lead to significant differences in the level of reporting of medication errors.
- Differences in the **definition** of a medication error among health care organizations can lead to significant differences in the reporting and classification of medication errors.
- Differences in the **patient populations** served by various health care organizations can lead to significant differences in the number and severity of medication errors occurring among organizations.
- Differences in the **type(s) of reporting and detection systems** for medication errors among health care organizations can lead to significant differences in the number of medication errors recorded.

According to the statement, the council believes that there are no acceptable incidence rates for medication errors. The goal of every health care organization should be to continually improve systems to prevent harm to patients due to medication errors. Pharmacies should monitor actual and potential medication errors that occur within their organization, and investigate the root cause of errors with the goal of identifying ways to improve the medication-use system to prevent future errors and potential patient harm. The value of medication error reporting and other data gathering strategies is to provide the information that allows an organization to identify weaknesses in its medication-use system and to apply lessons learned to improve the system. The sheer number of error reports is less important than the quality of the information collected in the reports, the organization's analysis of the information, and its actions to improve the system to prevent harm to patients.

It is more important to create the open environment that encourages the reporting of errors and near errors than to develop less meaningful comparative error rates.

ISMP Launches Program to Track Vaccine Errors

ISMP has launched a National Vaccine Error Reporting Program (VERP) that allows health care providers to confidentially report vaccine administration errors and near misses. Health care providers from all practice settings, including pharmacies and physicians' offices, are encouraged to report all mistakes related to vaccines, regardless of whether any harm resulted from the incident. The program will help ISMP "better quantify the sources of errors and advocate for vaccine name, labeling, device, information, and other needed product changes to ensure patient safety," stated Michael Cohen, ISMP president. The ISMP VERP was designed with the assistance of the California Department of Public Health and with input from experts in the field, indicates ISMP. Reports sent to the ISMP VERP will be shared with FDA and forwarded to the vaccine manufacturer when applicable. ISMP also plans to work with the Centers for Disease Control and Prevention on information received to address vaccine-related safety. VERP can be accessed at *http://verp.ismp.org/.*

Providers Should Ensure Only Diluted Forms of Acetic Acid Are Used, ISMP Warns

ISMP has issued a National Alert Network (NAN) notice advising that health care organizations should take immediate steps to ensure that only diluted acetic acid solutions are used in patient care. ISMP advises that the use and purchase of glacial acetic acid, the most concentrated form of acetic acid available, should be eliminated. Several cases of severe burns, scarring, and other permanent damage to skin or mucous membranes due to the inadvertent application of glacial acetic acid have been reported to the National Medication Errors Reporting Program operated by ISMP. ISMP provides the following steps for preventing further such events:

- Remove glacial acetic acid, which has no use in its current form in clinical medicine, from the pharmacy and replace with vinegar (5% solution) or commercially available diluted acetic acid 0.25% (for irrigation) or 2% (for otic use).
- Restrict purchasing so that pharmacy staff is purchasing acetic acid for all procedural areas.
- Restrict choices for purchasing so that glacial acetic acid is not selected by mistake.
- Ensure the correct strength is ordered.
- Educate staff about the differences between glacial acetic acid and diluted forms of acetic acid.
- Order 5% as "vinegar," which reduces the potential for confusion with glacial acetic acid.
- Verify the product by requiring an independent double-check of acetic acid solutions before dispensing or applying the product.

Information on the cases reported and common reasons for the cases are included in the NAN alert, which is available on the ISMP Web site at *www.ismp.org/NAN/files/20130121.pdf.*

New FDA Training Video

FDA Drug Info Rounds, a series of online training videos, provides important and timely drug information to practicing clinical and community pharmacists so they can help patients make better medication decisions. In the latest Drug Info Rounds video, pharmacists discuss how FDA Drug Safety Communications let health care providers, patients, and consumers know about newly observed potential risks of FDA-approved drugs. Drug Info Rounds videos are developed with contributions from pharmacists in FDA's Center for Drug Evaluation and Research, Office of Communications, and Division of Drug Information and are available on the FDA Web site at *www.fda.gov/Drugs/ResourcesForYou/HealthProfessionals/ucm211957.htm.*

Progress Made in Implementing Recommendations Intended to Prevent Acetaminophen Overdose

Compelling progress has been made by stakeholders seeking to address the public health issue of acetaminophen overdose, indicates a white paper published by the National Council for Prescription Drug Programs (NCPDP). In 2011, NCPDP made recommendations that the health care industry take actions to support the safe use of acetaminophen, including recommending that pharmacies produce prescription labels with the complete spelling of acetaminophen and eliminating use of abbreviations such as "acet" or "APAP." Previous to that, in July 2010, the National Association of Boards of Pharmacy® (NABP®) recommended that "state boards of pharmacy prohibit the use of the abbreviation 'APAP' on prescription labels, and require that 'acetaminophen' be spelled out to assist in preventing the well-recognized danger of acetaminophen induced hepatotoxicity." The recommendation was based on established policy and a letter, sent by FDA to state boards of pharmacy, regarding the pharmacist's role in educating patients about acetaminophen induced hepatotoxicity caused by unintentional overdose. The recommendation was also consistent with the report of the NABP Task Force on Uniform Prescription Labeling Requirements, which made recommendations to encourage use of prescription labels that are organized in a patient-centered manner. NCPDP reports that pharmacy retailers "estimated to collectively represent more than half of the prescriptions dispensed in 2011, have either implemented or committed to a phased implementation" of the recommendation to use the complete spelling of acetaminophen on prescription labels. "This update to our white paper provides additional guidance for those industry stakeholders who have not yet implemented the new pharmacy labeling practices for acetaminophen-containing medicines," states Lee Ann Stember, president, NCPDP. The updated white paper is accompanied by a bulletin (PDF), available at *www.ncpdp.org/pdf/wp/NCPDPAcetaminophenInfoBulletin_PharmacyStakeholders.pdf,* developed for pharmacists that summarizes some of NCPDP's key recommendations regarding acetaminophen. In addition, the white paper, available for download at *www.ncpdp.org/ind_WP.aspx,* includes a list of resources for pharmacists to use in educating staff and pharmacy staff to use in educating patients (see Appendix D of the white paper). More information is available in an NCPDP news release available at *www.ncpdp.org/press/013113_NCPDP_Acetaminophen%20WP_FINAL.pdf.*

Pharmacists Rated High for Honesty and Ethical Standards in Gallup's 2012 Poll

Pharmacists ranked as the second most trusted profession in the 2012 Gallup Poll that asked consumers to rate 22 professions according to their honesty and ethical standards. Pharmacists were ranked as very high or high in this category by 75% of those surveyed, with nurses ranking first at 85%, and medical doctors third at 70%. Additional information on the results of the 2012 poll is available on the Gallup Web site at *www.gallup.com/poll/159035/congress-retains-low-honesty-rating.aspx*.

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Legislative Update 2013

House Bill 0094 was introduced and passed with several amendments during the Wyoming Legislative Session that ended in March 2013. The bill provides for changes to the statute W.S. 33-24-157 pertaining to immunizations by pharmacists. Pharmacists will be able to prescribe and administer immunizations to healthy individuals age seven and older rather than the current age of 19 and older. Parental consent shall be required as will recording the vaccine in the registry operated by the Wyoming Department of Health (Wyoming Immunization Registry). The Boards of Pharmacy and Medicine have met to discuss rules including which vaccines will be specified and the requirements for a "private space" where immunizations may be administered by a pharmacist or intern. The bill has a provision stating:

> Nothing in this subsection shall be deemed to require any pharmacist to administer immunizations to individuals who are less than thirteen (13) years of age. No employer shall discriminate against a pharmacist on the basis that the pharmacist determines not to administer immunizations to individuals who are less than thirteen (13) years of age.

Pharmacists will need to obtain proof of education regarding immunizations in the pediatric population. A session will be offered by the Wyoming Pharmacy Association at their annual meeting on June 21-22, 2013, in Laramie, WY.

Recent Disciplinary Actions

Note: All fines are payable to the county treasurer where the action occurred for the credit of the public school fund in that county pursuant to Wyoming Statute §33-24-113(f).

A.P. Pharmacy Technician License #2056T: Administrative penalty of $500 for working as a pharmacy technician-in-training with an expired permit. Additional continuing education required.

C.B. Pharmacy Technician License #2071T: Pharmacy technician license suspended, then the suspension is stayed under conditions due to judgment and sentence for driving while under the influence and possession of CS.

What's on Your Label?

By Shannon Thomas, PharmD Candidate

Even more than what is in the bottle, patients trust the pharmacist to tell them how to take the medication they are receiving. What we may forget about or need a reminder of, is the label affixed to the patient's medication. What do our patients really read on the label after the trip to the pharmacy? It should be a label that is understandable and conducive to patient health, not a label that presents confusion.

Recently, the United States Pharmacopeia and The National Formulary (USP-NF) created and released a new general chapter to address the need for standardized labels for medications going directly to patients. These standards may include the use of the number in the directions as opposed to the alphabetic character stating the amount of tablets to take (eg, 1 tablet versus one tablet) or the use of directions more centered to the time of day for their medications (eg, take 1 tablet in the morning and 1 tablet in the evening versus take 1 tablet twice daily). The methods discussed by the USP chapter are all centered on making the patient's understanding of the label appropriate and less error prone. The patient-centered label is all about the patient. The information on the label should be strictly what the patient needs to increase safety and efficacy in taking the medication.

The label is a simple requirement for any medication but the impact it may make on a person's health is not measurable. Creation of a simple, easy-to-read label is just one step of many that may be taken to ensure our patients' best possible health outcomes as opposed to potentially creating confusion and a reason for nonadherence to the medication.

Board Member Changes

Terry Carr, RPh, has completed a six-year term including two years as president. Terry is a pharmacist in Gillette, WY, who plans to spend more time with his granddaughters and golf clubs. Robert J. "Rick" Davis, MD, has completed a total of eight years on the Board. Rick has been a strong advocate for defining the practice of pharmacy and promoting medication safety. The Board members and staff appreciate the efforts and commitment of these individuals.

The *Wyoming State Board of Pharmacy News* is published by the Wyoming State Board of Pharmacy and the National Association of Boards of Pharmacy Foundation, Inc, 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 the Foundation or the Board unless expressly so stated.

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