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West Virginia Board of Pharmacy News

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Welcome, Newly Appointed Board Members

Six new West Virginia Board of Pharmacy members were appointed by Governor Earl Ray Tomblin on December 1, 2015, to fill six partial terms. The new members are, in alphabetical order:

- John "JJ" Bernabei, RPh, of Weirton, WV
- Everett Frazier, public member, of Cyclone, WV
- Chuck Jones, public member, of Charleston, WV
- Kimberly Knuckles, RPh, of Beaver, WV
- Dennis Lewis, RPh, of Chapmanville, WV
- Vicky Skaff, RPh, of South Charleston, WV

These six new board members were present for their first meeting on December 6-7, 2015, along with George Karos, RPh, who continues to serve.

After taking some time to get to know each other, the Board met in January and elected its officers and appointed committee members. Mr Lewis was elected president, Mr Bernabei was chosen to be vice president, and Mrs Skaff was elected as the secretary/treasurer. Mrs Skaff and Mr Jones were installed as the two Complaint Committee members, and Mrs Knuckles accepted a position as the Board's representative to the Continuing Pharmacy Education Committee. The new members come with varied backgrounds, bringing new perspectives and knowledge bases to the table. Welcome, and good luck to each of them as they undertake the work of the Board.

Of course, it goes without saying that gratitude is owed to prior Board members for their service. Exiting the Board were Martin Castleberry, Jody Hedrick, Rebekah Heavener, Sam Kapourales, Lydia Main, and Charles Woolcock. Each dedicated many years to serving on the Board and can count many successes over their terms. Thank you to each one of them, and good luck to each of them in their future endeavors.

A Message From the NTSB: Evidence That Pilots Are Increasingly Using Over-the-Counter, Prescription, and Illicit Drugs

The National Transportation Safety Board (NTSB) recently analyzed toxicology tests from 6,677 pilots who died in a total of 6,597 aviation accidents between 1990 and 2012. The results demonstrate a significant increase in the use of a variety of potentially impairing drugs.

The study found significantly increasing trends in the pilots' use of all drugs, potentially impairing drugs (those with a United States Food and Drug Administration (FDA) warning about sedation or behavior changes in routine use), controlled substances (CS), and illicit drugs (those defined as Schedule I by the US Drug Enforcement Administration). The final report, *Drug Use Trends in Aviation: Assessing the Risk of Pilot Impairment*, is available on the NTSB's Safety Studies and Special Reports web page under report number SS-14-01.

In this study, the pilot was considered to be positive for a drug if it could be qualitatively or quantitatively identified in blood or tissue; drugs identified only in urine or used as part of resuscitative efforts were excluded.

Overall, 98% of the study pilots were male and 96% were flying privately rather than for commercial purposes. The average age of the study pilots increased from 46 to 57 years over the study period. Over the course of the study, for fatally injured pilots, the following was found:

- The proportion of pilots testing positive for at least one drug increased from 10% to 40%.
- More than 20% of all pilots from 2008-2012 tested positive for a potentially impairing drug, and 6% of all pilots tested positive for more than one potentially impairing drug.
- Overall, the most common potentially impairing drug pilots had used was diphenhydramine, a sedating

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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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antihistamine (the active ingredient in many Benadryl® and Unisom® products).

- ♦ During the most recent five years studied, 8% of all pilots tested positive for CS; hydrocodone and diazepam each accounted for 20% of the positive findings.
- ♦ The percentage of pilots testing positive for marijuana use increased to about 3% during the study period, mostly in the last 10 years.

The large increase in the proportion of fatally injured pilots with evidence of potentially impairing drugs suggests an increasing risk of impairment in general aviation. Aviation is the only transportation mode in which a fatally injured operator (pilot) routinely undergoes extensive toxicology testing; no similar testing is routinely performed for fatally injured operators of boats, trains, trucks, or cars. Given the general increase in drug use in the population, it is likely that there has been a similar trend in drug use among operators across all modes of transportation.

Immunization Adverse Events Reporting to VAERS, With Copies to the Board and DHHR

A fax blast went out to pharmacies in December to remind them to report adverse events for immunizations as required by West Virginia Rule §15-12-6.4. For the first time, the Board received a copy (as required) of an adverse event report from a pharmacy on January 10, 2016, for an adverse event that occurred in November 2015. A patient reported having a fever for several days and then a rash five days later, as well as going to the emergency room. While it is certainly hoped that there will never be an adverse event, that is not the reality. As such, the Board expects to see more in the future. So, in an effort to drive reporting compliance, this is another reminder that the rules require that pharmacists shall report all adverse events to the Vaccine Adverse Events Reporting System (VAERS) and promptly provide a copy of all reports to the Board. In addition, pharmacists shall provide a copy of all reports to the West Virginia Department of Health and Human Resources, Bureau for Public Health, Office of Epidemiology and Prevention Services, Division of Immunization Services (DHHR/DIS), and another copy to the patient's primary care physician or other licensed health care provider as identified by the person receiving the immunization. VAERS is a national vaccine safety surveillance program co-sponsored by the Centers for Disease Control and Prevention and FDA, and is available at *http://vaers.hhs.gov/index*. So, please report adverse events to VAERS, and then send a copy to the Board, to DHHR/DIS, and to the patient's identified primary care provider.

Physician Signatures and Delegation on Written Prescriptions

It was recently reported to the Board that a registered nurse had signed a prescription on behalf of the prescribing doctor on a written prescription (ie, signing "Jane Doe, RN/John Hancock, DO (or MD)"). Obviously, staff, including a nurse, can prepare a prescription for the prescriber's signature. However, the prescriber himself or herself must sign the prescription. See rules §15-1-9.1.2 and §15-2-7, and federal law requiring a valid and lawful prescription for prescription-only drugs. If you receive such a prescription, you cannot fill it. If the prescription is not Schedule II, however, you can call the prescriber to confirm the prescription, and then treat it as an oral prescription, with appropriate documentation. If it is a Schedule II prescription, then the prescriber will either have to sign it or electronically prescribe it.

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