June 2018

Wyoming State Board of Pharmacy News

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New Face at the Board Office

Robin Kus is the new senior office support specialist at the Wyoming State Board of Pharmacy. She is a native of Wyoming and earned a degree at the University of Maine. She previously worked at another state agency and has experience in positions in mental health and accounting. She and her husband have a toddler daughter, and she enjoys spending time with family as well as reading and crafts. Robin lists cooking as a stress reliever and studied culinary arts. She looks forward to meeting all the pharmacists and pharmacy technicians in Wyoming.

2018 Wyoming Legislative Update

Senate File (SF) 0075 – Biological products-pharmacies. (Effective July 1, 2018)

The Wyoming Pharmacy Act was revised in the following areas:

1. Wyoming Statute (W.S.) 33-24-147 Definitions (iv) "Substitute" means to dispense a generically equivalent drug or interchangeable biological product in place of the prescription ordered or prescribed.
2. If a biological product is deemed interchangeable by Food and Drug Administration (FDA), a pharmacist may dispense the interchangeable biological product. The label on the prescription container must have the name of the dispensed biological product or drug, and the National Drug Code number or manufacturer must be noted on the prescription record or entry by the pharmacist. No later than five business days after dispensing a biological product, the dispensing pharmacist must make an entry of the specific product dispensed to the patient that is electronically accessible to the practitioner through (i) an interoperable electronic medical records system, (ii) electronic prescribing technology, (iii) a pharmacy benefit management system, or (iv) a pharmacy record.

Current Center for Drug and Evaluation and Research Biosimilars List (February 15, 2018)

Product (Proper) Name	Proprietary Name (Year of Licensure)	Interchangeable (I)/Biosimilar (B)	Pharmacologic Category
adalimumab*	Humira® (2002)	–	Antirheumatic, disease modifying; gastrointestinal agent; monoclonal antibody; TNF blocking agent
adalimumab-adbm	Cyltezo® (2017)	B	
adalimumab-atto	Amjevita® (2016)	B	
bevacizumab*	Avastin® (2004)	–	Antineoplastic, monoclonal antibody, VEGF inhibitor
bevacizumab-awwb	Mvasi® (2017)	B	
etanercept*	Enbrel® (1998)	–	Antirheumatic, disease modifying; TNF blocking agent
etanercept-szzs	Erelzi® (2016)	B	
filgrastim*	Neupogen® (1991)	–	Colony stimulating agent; hematopoietic agent
filgrastim-sndz	Zarxio® (2015)	B	
infliximab*	Remicade® (1998)	–	Antirheumatic, disease modifying; gastrointestinal agent; immunosuppressive agent; monoclonal antibody; TNF blocking agent
infliximab-abda	Renflexis® (2017)	B	
infliximab-dyyb	Inflectra® (2016)	B	
infliximab-qbtx	Ixifi® (2017)	B	
trastuzumab*	Herceptin® (1998)	–	Antineoplastic agent, anti-HER2, monoclonal antibody
trastuzumab-dkst	Ogivri® (2017)	B	

*Reference biologic product; TNF: tumor necrosis factor; VEGF: vascular endothelial growth factor

Source: FDA "Purple Book" (2018)

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National Pharmacy Compliance News

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NABPF
National Association of Boards of Pharmacy Foundation

FDA Requires Labeling Update on Opioid-Containing Cough and Cold Medicines

In January 2018, Food and Drug Administration (FDA) announced that the agency is requiring safety labeling changes to limit the use of prescription opioid cough and cold medicines containing codeine or hydrocodone in children younger than 18 years old because the serious risks of these medicines outweigh their potential benefits in this population. After safety labeling changes are made, these products will no longer be indicated for use to treat cough in any pediatric population and will be labeled for use only in adults aged 18 years and older. In addition, labeling for the medications will be updated with additional safety information for adult use. This update will include an expanded Boxed Warning notifying consumers about the risks of misuse, abuse, addiction, overdose and death, and slowed or difficult breathing that can result from exposure to codeine or hydrocodone. Additional information is available in FDA's news release at *www.fda.gov/NewsEvents/Newsroom/PressAnnouncements/ucm592109.htm.*

Latest NDTA Shows Opioids Pose Significant Impact to Public Health

Drug Enforcement Administration (DEA) indicates a significant shift in the overall drug threat reported by law enforcement over the last 10 years with opioids (including controlled prescription drugs, fentanyl and other synthetic opioids, and heroin) reaching epidemic levels and impacting significant portions of the United States. According to the *2017 National Drug Threat Assessment (NDTA)* report, every year since 2001, controlled prescription drugs, specifically opioid analgesics, have been linked to the largest number of overdose deaths of any illicit drug class, outpacing those for cocaine and heroin combined.

From 2007 to 2010, responses to the National Drug Threat Survey indicate cocaine was the greatest national drug threat, followed by a significant decline as the heroin threat increased between 2010 and 2016, eventually becoming the greatest national drug threat in 2015.

Illicit fentanyl and other synthetic opioids, primarily sourced from China and Mexico and shipped directly to the US or trafficked overland via Mexico and Canada, are contributing factors in the current synthetic opioid overdose epidemic. Traffickers in the US usually mix fentanyl into heroin products and sometimes other illicit drugs or press it into counterfeit prescription pills, often without users' awareness, which leads to overdose incidents, notes the *2017 NDTA.* To access the *2017 NDTA,* visit *www.dea.gov/divisions/hq/2017/hq102317.shtml.*

FDA Recognizes Eight European Drug Regulatory Authorities Capable of Conducting Inspections

FDA has determined it will recognize eight European drug regulatory authorities as capable of conducting inspections of manufacturing facilities that meet FDA requirements. The eight regulatory authorities found to be capable are those located in Austria, Croatia, France, Italy, Malta, Spain, Sweden, and the United Kingdom. This achievement marks an important milestone to successful implementation and operationalization of the amended Pharmaceutical Annex to the 1998 US-European Union (EU) Mutual Recognition Agreement, which enables US and EU regulators to utilize each other's good manufacturing practice inspections of pharmaceutical manufacturing facilities. "By partnering with these countries, we can create greater efficiencies and better fulfill our public health goals, relying on the expertise of our colleagues and refocusing our resources on inspections in higher risk countries," said FDA Commissioner Scott Gottlieb, MD, in a news release located at *www.fda.gov/NewsEvents/Newsroom/PressAnnouncements/ucm583057.htm.*

Incorrect Use of Insulin Pens at Home Can Cause Severe Hyperglycemia

The National Coordinating Council for Medication Error Reporting and Prevention has issued an alert on the incorrect use of insulin pens at home causing severe hyperglycemia in patients, including one reported fatality. The Institute for Safe Medication Practices National Medication Errors Reporting Program has received several reports of patients who failed to remove the inner cover of standard insulin pen needles prior to administering insulin. In the latest such event, a patient with type 1 diabetes did not know to remove the standard needle cover and was unaware she was using the pen incorrectly and had not been receiving any of the insulin doses; the patient developed diabetic ketoacidosis as a result and died.

Since insulin pens may differ between pens with automatic needle retraction devices and those with standard needle covers that require manual removal before administering insulin, it is imperative that removal of

needle covers be explained to patients who are issued standard insulin pens during their diabetes education. Pharmacists should verify that a patient understands the appropriate administration technique whenever pens and insulin needles are dispensed, notes the alert, which can be viewed at *www.nccmerp.org/sites/default/files/nan-20171012.pdf.*

FDA Advises on Opioid Addiction Medications and Benzodiazepines

Opioid addiction medications – buprenorphine and methadone – should not be withheld from patients taking benzodiazepines or other drugs that depress the central nervous system (CNS), advises FDA. The combined use of these drugs increases the risk of serious side effects; however, the harm caused by untreated opioid addiction usually outweighs these risks. Careful medication management by health care providers can reduce these risks, notes a safety alert. FDA is requiring this information to be added to the buprenorphine and methadone drug labels along with detailed recommendations for minimizing the use of medication-assisted treatment drugs and benzodiazepines together.

Health care providers should take several actions and precautions and should develop a treatment plan when buprenorphine or methadone is used in combination with benzodiazepines or other CNS depressants. Additional information may be found at *www.fda.gov/Drugs/DrugSafety/ucm575307.htm.*

Only About 3% of Pharmacies and Other Entities Voluntarily Maintain a Prescription Drug Disposal Bin, GAO Reports

In response to the US Senate Judiciary Committee's request to review DEA's requirements for authorized collectors of prescription drugs and participation rates, the US Government Accountability Office (GAO) found that only about 3% of pharmacies and other entities eligible to collect unused prescription drugs for disposal have volunteered to do so. As of April 2017, 2,233 of the 89,550 eligible entities had registered with DEA to use disposal bins to collect unused prescription drugs. The majority of the authorized collectors were pharmacies, followed by hospitals or clinics. Factors that affected voluntary participation in maintaining disposal bins for the public included cost, uncertainty of proper implementation, and participation in other drug disposal efforts.

GAO found that participation rates varied by state. Connecticut, Missouri, and Maine had the lowest participation rates as of April 2017. North Dakota had the highest participation rate, followed by Alaska. The report, *Preventing Drug Abuse: Low Participation by Pharmacies and Other Entities as Voluntary Collectors of Unused Prescription Drugs,* is located on the GAO website at *www.gao.gov/products/GAO-18-25.*

One in Five Drivers Uses a Prescription Drug That Can Impair Driving Despite Receiving Warnings

A new study that analyzes data from the National Roadside Survey of Alcohol and Drug Use, 2013-2014, found that one in five drivers has taken prescription drugs that could impair driving despite having been warned about the risks. The authors of the study, "Receipt of Warnings Regarding Potentially Impairing Prescription Medications and Associated Risk Perceptions in a National Sample of U.S. Drivers," indicate that of the 7,405 random drivers who completed the prescription drug portion of the survey, almost 20% reported recent use (within the past two days) of a potentially impairing prescription drug.

Compared to people who were prescribed antidepressants (62.6%) and stimulants (57.7%), those who were prescribed sedatives (85.8%) and narcotics (85.1%) were most likely to report receiving warnings about the potential of these drugs to affect driving from their health care provider, pharmacy staff, or medication label.

Several European countries have introduced color-coded categories (ie, no, minor, moderate, and major influence on driving) to drug labeling to increase patient safety. Beyond labeling, the authors of the study note it is important that health care providers consistently communicate with patients about their medications' driving-related risks. The study was published online in the *Journal of Studies on Alcohol and Drugs* on October 31, 2017, and can be found at *https://doi.org/10.15288/jsad.2017.78.805.*

PTCB CPhT Program Earns Accreditation From the American National Standards Institute

The Pharmacy Technician Certification Board's (PTCB's) Certified Pharmacy Technician (CPhT) Program has earned accreditation from the American National Standards Institute (ANSI) Personnel Certification Accreditation Program through December 2022. ANSI is the first personnel certification accreditation body in the US to meet internationally accepted practices for accreditation. "We were the first pharmacy technician certification program to receive accreditation by the National Commission for Certifying Agencies (NCCA) in 2006, and now we are the first and only program to achieve ANSI accreditation," said PTCB Executive Director and Chief Executive Officer William Schimmel in a news release. More details are available in PTCB's December 18, 2017 news release, which can be found in the News Room section of *www.ptcb.org.*

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SF 0083 – Controlled substance prescription tracking. (Effective March 14, 2018)

W.S. 35-7-1025 is changed in the following ways:

1. Mandatory registration in the Wyoming Online Prescription Database (WORx), the state's prescription drug monitoring program (PDMP). "The board shall enroll any practitioner registered under this subsection in the controlled substance prescription tracking program maintained by the board under W.S. 35-7-1060 if the practitioner is authorized to dispense any controlled substances in Schedules II through V." The definitions of "practitioner," "dispense," and "dispenser" were discussed by the Legislature from other areas of the Controlled Substances Act.
2. Schedule V controlled substances (CS) must now be reported to WORx by dispensers. The prescriptions of Schedule V drugs are already being reported by several Wyoming pharmacies and will be included in the patient reports when you search. Pharmacists-in-charge need to ensure their software is now reporting Schedule V prescriptions to WORx.
3. "A dispenser shall electronically file with the board information regarding any prescription for a schedule II, III, IV or V controlled substance dispensed by the dispenser no later than the close of business on the business day immediately following the day the controlled substance was dispensed."

The Board is working with other professional licensing boards that license practitioners to promulgate rules pertaining to these changes.

SF 0078 – Opioid addiction task force.

This bill creates a temporary task force to consider:

(i) PDMPs and electronic prescribing systems;
(ii) grants relating to substance abuse education, prevention, and treatment;
(iii) the availability and use of naloxone;
(iv) the quality of treatment for opioid addiction and overdoses;
(v) strategies to reduce the administration of opioids, including promotion of alternative treatments and possible limits on the quantity of opioids that a health care provider is authorized to prescribe;
(vi) authorized uses of opioids;
(vii) strategies for community engagement;
(viii) strategies for opioid education prevention and treatment;
(ix) prescriber education relating to opioids;
(x) necessary law enforcement strategies and tools; and
(xi) any other matter relating to opioids determined to be relevant.

The task force will submit a report on or before October 1, 2019, to legislative committees and the governor. The task force will terminate on December 31, 2019. Members include:

- Senator Eli Bebout (chair)
- Representative Albert Sommers (vice chair)
- Senator Fred Baldwin
- Representative Scott Clem
- Representative Tim Hallinan (legislative alternate)

Appointed by the governor are:

- Paul Beaupré
- Melinda Carroll (pharmacist)
- Alexia Harrist
- Gregory Marino
- Scott Matheny
- Art Merrell
- Peter Michael
- Mary Phillips
- Brenda Upton (pharmacist)

House Bill 0099 – Prescription and possession of FDA approved drugs. (Effective July 1, 2018)

This revision to the Controlled Substances Act in W.S. 35-7-1031 specifies that no prescription or practitioner's order for marijuana, tetrahydrocannabinol (THC), or synthetic equivalents of marijuana or THC shall be valid unless the prescription is for a drug that has received final approval from FDA, including dronabinol. There are several products derived from marijuana under review by FDA, such as Epidiolex® for severe epilepsy.

Recent Disciplinary Actions

J.V., Pharmacist License #3045: Conditional pharmacist license for obtaining CS by fraudulent means. Administrative penalty of $500 plus additional six hours of continuing education on the topic of pharmacy law.

Pharmacy License #R10000: Medication error with administrative penalty of $500 plus written plan to prevent future medication errors.

Pharmacy License #52-01099: Allowing a pharmacy technician to perform pharmacy functions without a Wyoming license. Administrative penalty of $2,000 and a written policy to prevent future unlicensed practice.

Pharmacy License #52-03473: Failure to report all CS dispensed to the WORx program plus allowing a pharmacy technician to perform pharmacy functions without a Wyoming license. Administrative penalty of $1,500 and a written plan to prevent such violations in the future.

Happy Retirement to Beverly Fontaine

A retirement open house will be held at the Board office on July 6, 2018, from 2 PM to 4 PM in honor of Beverly Fontaine, who is retiring after eight years at the Board. Beverly has improved many processes and is the Board expert on "rules." She has enjoyed getting to know all the licensees and says that she would love to visit if you can come to the party at 1712 Carey Ave, Ste 200, Cheyenne, WY. You can also send best wishes by email to BOP@wyo.gov.

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CBD Oil Update

The 2018 Wyoming Legislature did not change the status of cannabidiol (CBD) oil or hemp extracts. In a press release on April 12, 2018, the Wyoming Division of Criminal Investigation (DCI) reminded that Wyoming law makes it illegal for anyone to possess, use, and/or distribute any substance containing any amount of THC, which is a Schedule I CS. The only exception to this is if the individual possesses a "Hemp Extract Registration Card" issued by the Wyoming Department of Health. Numerous questions have come to the Board regarding the legality of CBD oil, which allegedly contains very low or no THC, the psychoactive active ingredient in marijuana. Recent DCI laboratory analysis confirmed the presence of THC in many items received for analysis and distributed from pet stores, convenience stores, and grocery stores.

50-Year Pharmacist Licensees

The following pharmacists have held a Wyoming pharmacist license for 50 years and will be honored at the Wyoming Pharmacy Association convention in Sheridan, WY, on June 22-24, 2018:

- Robert B. Avery #1731
- William Burleson #1732
- Lynn Hendershott #1727
- Stanley Hren #1725
- Bill Rathburn #1724
- Stephen Rogers #1736

Congratulations!

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