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I've Been Robbed . . . Now What?

By Laraine Kopetzky, PharmD Candidate 2018

Recently, pharmacies across the state of Wyoming have experienced burglaries on at least five separate occasions! Drug Enforcement Administration (DEA) reported a total of 812 robberies across the United States in 2016. The medications being sought after include: Opana®, oxycodone, methadone, Percocet®, Xanax®, and Valium®. There are many reasons criminals choose to rob a pharmacy, but the two most common reasons are to fuel their own addiction or to sell the medications on the street. It is important for pharmacies to know what they can do to protect themselves before, during, and after a pharmacy burglary or robbery.

Pharmacies must maintain adequate security to deter theft of drugs by personnel or the public. Security requirements for new or remodeled pharmacies must meet the requirements of Chapter 2 of the Wyoming Pharmacy Act Rules. This may include installing security cameras, hold-up/duress buttons, door and window bars, pull-down gates, and reinforced heavy-duty doors and frames. Signage should be posted alerting customers and potential criminals that they are being recorded. It is also important to be aware of customers and acknowledge those coming into your pharmacy, especially customers who seem to be wandering around and not shopping. This may discourage robbers, as they will know you are aware of their presence, making it difficult for them to scope out the pharmacy. For example, in one of the burglaries in Wyoming, the criminals were in and out of the pharmacy within 92 seconds; they knew exactly where to go to get the medications they were seeking. Also, **always** take precautions to keep yourself and your coworkers safe. These precautions include staffing at least two employees during opening and closing hours, walking in pairs to the parking lot, and always being aware of your surroundings.

If and when a burglary should occur, the safety of employees and customers is the primary concern. It is crucial to remain calm, comply with the robbers' demands, and follow their instructions. Do not resist or make any sudden movements. Something you should do is make mental notes about the criminals. What are they wearing? What is their size, build, and hair length? Do they have any scars, tattoos, or other distinguishing characteristics? Try to remember as much information as possible to report to the police. Finally, do **not** try to apprehend the criminal – keep yourself and your coworkers safe! Medication can be replaced, but you cannot!

After a robbery, the first thing to do is make sure all the employees and customers are safe and get any medical attention that may be needed. Call the police first, then the pharmacy supervisor. Lock the doors to prevent re-entry of the suspect(s) and keep them closed until police arrive. Protect the crime scene. Keep customers and employees away from anything that the suspect(s) touched. Write down all the mental notes you took of the suspect(s). Also, make a list of everything that was taken. Write as much down as soon as possible, as short-term memory can be fleeting, especially during an adrenaline rush.

Whenever there is a pharmacy break-in, the pharmacist-in-charge must notify and submit a complete inventory to the Wyoming State Board of Pharmacy (Wyoming Controlled Substances Act Rules, Chapter 3, Section 28(c)). The pharmacy must also notify DEA if thefts of controlled substances (CS) are involved. Completion of DEA Form 106 (Report of Theft or Loss of Controlled Substances) is required, and a copy must be sent to the Board office. The form is available at *https://apps.deadiversion.usdoj.gov/webforms/dtlLogin.jsp.*

A great resource for information regarding pharmacy robberies is the Rx Pattern Analysis Tracking Robberies & Other Losses (RxPATROL) website: *www.rxpatrol.com/pdf/A7957-draft.pdf.* In an ongoing effort to combat the abuse and diversion of prescription drugs, Purdue Pharma L.P. has developed and funded an information clearinghouse for data related to pharmacy robberies, burglaries, and thefts that involve the loss of CS. RxPATROL is an

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National Pharmacy Compliance News

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The applicability of articles in the *National Pharmacy Compliance News* to a particular state or jurisdiction can only be ascertained by examining the law of such state or jurisdiction.

FDA Draft Guidance Addresses Delayed Enforcement of DSCSA Requirements for Product Identifiers

Food and Drug Administration (FDA) issued a draft guidance for industry that informs manufacturers and other supply chain stakeholders that although manufacturers are to begin including a product identifier on prescription drug packages and cases on November 27, 2017, FDA is delaying enforcement of those requirements until November 2018 to provide manufacturers additional time and avoid supply disruptions. The compliance policy outlined in the June 2017 draft guidance, *Product Identifier Requirements Under the Drug Supply Chain Security Act – Compliance Policy,* applies solely to products without a product identifier that are introduced into commerce by a manufacturer between November 27, 2017, and November 26, 2018. While manufacturers work to meet product identifier requirements, they must comply with other Drug Supply Chain Security Act (DSCSA) requirements. The draft guidance can be accessed from FDA's website at *www.fda.gov/Drugs/DrugSafety/DrugIntegrityandSupplyChainSecurity/DrugSupplyChainSecurityAct/ucm565358.htm.*

Amount of Prescribed Opioids Remains High, Reports CDC

The amount of opioids prescribed remains approximately three times as high as in 1999, despite reductions in each year after 2010 through 2015. Centers for Disease Control and Prevention (CDC) researchers analyzed retail prescription data to assess opioid prescribing in the United States from 2006 to 2015 and county-level prescribing patterns in 2010 and 2015. According to a CDC report, results of the study showed higher amounts of opioids were prescribed in counties that had a greater percentage of non-Hispanic white residents, a higher prevalence of diabetes and arthritis, micropolitan status (ie, town/city; nonmetro), and higher unemployment and Medicaid enrollment rates. The researchers conclude that health care providers should carefully weigh the benefits and risks when prescribing opioids outside of end-of-life care, follow evidence-based guidelines (eg, CDC's *Guideline for Prescribing Opioids for Chronic Pain*), and consider non-opioid therapy for chronic pain treatment.

Additionally, the researchers conclude that state and local jurisdictions can use these findings along with prescription drug monitoring program (PDMP) data to identify prescribing patterns that place patients at risk for opioid use disorder and overdose and to target interventions with prescribers based on opioid prescribing guidelines. The July 7, 2017 *Morbidity and Mortality Weekly Report,* "Vital Signs: Changes in Opioid Prescribing in the United States, 2006–2015," can be accessed on the CDC website at *www.cdc.gov/mmwr/index.html* in the Weekly Report section.

AMA Opioid Task Force Encourages Co-Prescribing Naloxone to At-Risk Patients

The American Medical Association (AMA) Opioid Task Force encourages physicians to consider co-prescribing naloxone when it is clinically appropriate to do so. The AMA Opioid Task Force offers several questions for determining whether to co-prescribe naloxone to a patient or a patient's family member or close friend, which may be found in the August 2017 document, "AMA Opioid Task Force naloxone recommendations," available on the AMA opioid microsite at *https://www.end-opioid-epidemic.org.*

The Naloxone section of the AMA opioid microsite also offers physicians multiple resources on co-prescribing naloxone in their practice and community. To help end the opioid epidemic, the AMA Opioid Task Force made several recommendations for physicians, including registering and using state PDMPs, training and education on evidence-based treatment, and promoting safe storage and disposal of opioids and medications.

Opioid Addiction Medications Should Not Be Withheld From Patients Taking Benzodiazepines or CNS Depressants

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 in an FDA Drug Safety Communication announcement at *www.fda.gov/Drugs/DrugSafety/ucm575307.htm.*

New Study Shows Substantial Variation in the Availability of Pharmacies Across the Country

Despite the rising number of US pharmacies from 2007 to 2015, the availability of pharmacies varied significantly across local areas, indicates a new study. The study, *The availability of pharmacies in the United States: 2007–2015,* found that the number of community pharmacies increased 6.3% from 63,752 to 67,753 between 2007 and 2015. Although the number of pharmacies per capita remained at 2.11 per 10,000 individuals between 2007 and 2015, the researchers found substantial variation across counties. "Some counties have 13 pharmacies per capita, while others have none," said Dima Qato, lead study author and assistant professor of pharmacy systems, outcomes and policy, in a University of Illinois at Chicago (UIC) news release.

In 2015, counties in the highest quintile had nearly three-fold more pharmacies than those in the lowest quintile. Counties in the lowest quintile are located in the Pacific West, Southwest, and Great Lakes regions, while counties with the highest tend to be located in the Northeast, Southeast, Northern Appalachia, and Plains states. The researchers conclude that future programs and policies should address the availability of pharmacies and ensure that pharmacy characteristics, including accommodations such as multilingual staffing and home delivery, align with local population needs.

To view the study, visit *https://doi.org/10.1371/journal.pone.0183172.* The UIC news release is available at *https://today.uic.edu/access-to-pharmacies-limited-to-some-patients.*

Consent Decree Entered Against Outsourcing Facility Isomeric Pharmacy Solutions

Under a consent decree of permanent injunction entered in August 2017, Isomeric Pharmacy Solutions of Salt Lake City, UT, its owners, and chief operating officer are prohibited from manufacturing, processing, packing, holding, or distributing drugs until they comply with the Federal Food, Drug, and Cosmetic Act (FD&C Act) and its regulations, in addition to other requirements. Isomeric manufactured and distributed purportedly sterile drug products, including injectable and ophthalmic drugs, that were adulterated because the drugs were made under insanitary conditions and in violation of current good manufacturing practice requirements under the FD&C Act, according to the complaint for permanent injunction. The complaint also alleges that Isomeric manufactured and distributed unapproved drugs and drugs that were misbranded because their labeling did not bear adequate directions for use. Isomeric initially registered as an outsourcing facility in July 2015 and reregistered in December 2015 and January 2017. Additional information is available in an FDA news release at *www.fda.gov/NewsEvents/Newsroom/PressAnnouncements/ucm570130.htm.*

FDA Issues Warning on Alcohol Pads or Benzalkonium Chloride Antiseptic Towelettes Made by Foshan

In September 2017, FDA alerted health care providers and patients to not use alcohol pads or benzalkonium chloride antiseptic towelettes made by Foshan Flying Medical Products Co, Ltd, located in China, due to lack of sterility assurance and other quality issues. These products are distributed by Total Resources International, of Walnut, CA, and Simple Diagnostics, Inc, of Williston Park, NY. The use of these alcohol pads and antiseptic towelettes could cause infections.

FDA placed all drug products made by Foshan on import alert on May 23, 2017, to stop these products from entering the US. However, FDA is concerned these products might still be in distribution in the US. FDA also sent Foshan a warning letter on August 1, 2017, for violations of current good manufacturing practice regulations. FDA initially contacted Foshan regarding a recall on May 25, 2017, and had several follow-up meetings with the company. Foshan has not taken action to remove its alcohol pads or antiseptic towelettes from the market. The safety alert posted to FDA's website may be found at *www.fda.gov/Safety/MedWatch/SafetyInformation/SafetyAlertsforHumanMedicalProducts/ucm574576.htm.*

Pharmacies and health care facilities that have alcohol pads and antiseptic towelettes labeled by Total Resources or Simple Diagnostics should immediately stop using them and discard the products. Adverse events or side effects related to the use of these products may be reported to FDA's MedWatch Safety Information and Adverse Event Reporting Program at *www.fda.gov/MedWatch/report.*

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initiative designed to collect, collate, analyze, and disseminate pharmacy theft intelligence to law enforcement throughout the nation. If your pharmacy experiences a robbery or burglary, the information can be reported on the RxPATROL website. The website also includes training videos and an incident search database that is useful for seeing if there have been other robberies or burglaries in your area. A checklist is also available for pharmacies to evaluate their security system.

To recap, a pharmacy robbery can happen anywhere, anytime, and to anyone. It is essential to take preventative measures to reduce the risk of a robbery or burglary happening in your pharmacy. Know what you should and should not do. Remain calm and comply with the suspect to keep yourself and others safe. After the event, attend to those who may have been harmed and notify the local police department as soon as possible. Report any loss of CS to DEA and the Board. Remember: no medication is worth your life, give the suspects what they want, and keep yourself safe.

Board Meeting Schedule for 2018

- ♦ March 14-15 at 130 Hobbs Ave, Cheyenne, WY 82009
- ♦ June 20-21 in Sheridan, WY
- ♦ September 12-13 in Laramie, WY
- ♦ December 5-6 in Casper, WY

Meetings begin at 1 PM on the first day.

Recent Disciplinary Actions

M.M., Pharmacist License #3102: Administrative penalty of $500 for failing to renew licensure for 2017 and continuing to work as a pharmacist. Five additional hours of continuing education (CE) on pharmacy law required, plus a plan to prevent unlicensed practice in the future.

A.O., Pharmacy Technician License #T2336: Administrative penalty of $500 for failing to renew licensure for 2017 and continuing to perform pharmacy functions. Two additional CE hours pertaining to pharmacy law required.

Compliance Corner: Focus of Inspections in 2018

By Lisa Hunt and Matt Martineau, Board Compliance Officers

The focus of inspections in 2018 includes the following:

- ♦ Perpetual inventory reconciliation;
- ♦ Demonstration of the ability to access the Wyoming Immunization Registry and the Wyoming Online Prescription Database (WORx);
- ♦ Written agreements between pharmacies and long-term care facilities;
- ♦ Labeling of unit-dose packaging (bubble packs);
- ♦ Documentation of training and compounding competencies for compounding staff (sterile and nonsterile);
- ♦ Review of the master compounding record for nonsterile compounding, including reconciliation of ingredients for any compounding;
- ♦ Current CPR certification for immunizing pharmacists; and
- ♦ Any other issue identified during the previous inspection.

Sterile compounding pharmacies may remember that last year's inspections required more time to complete. To prepare for the inspection, be sure to review and complete a self-inspection using the National Association of Boards of Pharmacy® Universal Inspection Form – Sterile Compounding Module in advance. The compliance officers will garb and enter the cleanroom to observe sterile compounding and inspect the facility for compliance with United States Pharmacopeia (USP) Chapter <797>. While implementation of USP Chapter <800> has been delayed until December 1, 2019, the compliance officers will review the requirements for compliance with USP <800> and your preparation. In light of the recent pharmacy robberies, the compliance officers will also look at pharmacy security.

Gabapentin WORx Reporting

By Anna Shaw, PharmD and MBA Candidate 2018

As of July 2017, Wyoming now requires all prescriptions for gabapentin, naloxone, and cyclobenzaprine dispensed within the state to be reported to WORx, the prescription drug monitoring program (PDMP). Speaking to the inclusion of gabapentin specifically, the following outlines some of the pertinent discussion points in the ongoing dialogue.

Gabapentin is a GABA mimetic that inhibits excitatory neurotransmitters such as glutamate, substance P, and noradrenaline by blocking voltage-gated calcium channels. Questions remain of its action on dopaminergic pathways and resulting addiction potential. It is approved for use in the US for post-herpetic neuralgia and partial epileptic seizures, but is widely used off label for a plethora of conditions, including hot flashes, neuropathic and non-neuropathic pain, bipolar disorder, alcohol and narcotic withdrawal, restless leg syndrome, attention deficit hyperactivity disorder, and social anxiety disorder.

With 64 million prescriptions in 2016, prescriptions for gabapentin have nearly doubled since 2012, and it is currently one of the top 10 most frequently prescribed medications within the US. Illicit use has increased, especially in users with current or previous substance use disorder. In this population, gabapentin is often used at higher than

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recommended doses and as part of a cocktail that includes other central nervous system-altering drugs, such as narcotics, alcohol, LSD, and marijuana. Illicit users report inclusion of gabapentin as a means to potentiate the high from other medications, a method to alleviate withdrawal symptoms from other substances, or as a means to get high in and of itself. They report side effects similar to the high from marijuana with dissociative euphoric elements. Currently, accessibility is not a deterrent. As previously mentioned, it is a common prescription for humans, but is also frequently prescribed for pets. This poses an interesting access point, as not all veterinarians report to PDMPs and pet medications are sold online.

The addictive potential of gabapentin is minimal for individuals not prone to illicit drug use and has not been definitively proven even for those who do have a history. The question then remains of whether or not access should be limited via scheduling of gabapentin at a state level and if it even qualifies.

Wyoming has started to monitor gabapentin prescriptions through WORx to evaluate its pattern of use, which has already revealed a number of likely "doctor shoppers" previously unknown. These same steps were taken in Wyoming for tramadol and carisoprodol, leading to a state-level scheduling of the medications, which were later scheduled federally. Although the conclusion of the matter is not yet known for gabapentin, prescribers and pharmacists are encouraged to be vigilant for signs of abuse in patients with use of this medication and to be educated in offering the most appropriate treatment options for them.

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® (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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