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No. 562: Introducing Oregon's Two New Technician Board Members!

During the 2015 Oregon Legislative Session, the Oregon Legislative Assembly voted Senate Bill 148 into law. It amended Oregon Revised Statute 689.115, adding two voting pharmacy technician members to the Oregon State Board of Pharmacy. The law requires each pharmacy technician member to be licensed and in good standing, have at least three years of experience performing the duties of a technician, and be actively engaged in the duties of a pharmacy technician in Oregon.

The Board welcomes Pharmacy Technician Cyndi Vipperman to the Board. Cyndi was appointed by Governor Kate Brown and confirmed by the Legislative Senate Rules Committee. Her appointment began February 17, 2016, and runs until February 16, 2020. Cyndi received her bachelor of science degree in liberal studies at Eastern Oregon University in 2005. Cyndi has been a pharmacy technician since 1998 at Fred Meyer in The Dalles, OR, and obtained her national certification in 2008. Cyndi has been active in a leadership role with the American Cancer Society's Relay for Life for 18 years and is an advocate for cancer research, early detection, and education. She is also involved in many of her local community's volunteer opportunities. Cyndi also loves to travel and spend time with her five children and eight grandchildren whenever she can.

The Board welcomes Pharmacy Technician Dianne Armstrong to the Board. Dianne was appointed by Governor Brown and confirmed by the Legislative Senate Rules Committee. Her appointment began February 17, 2016, and runs until February 16, 2020. Dianne worked for Wells Fargo Bank, Technology Information Group for over 25 years in a management capacity. She chose to change the second half of her life and return to school for an encore career. She attended Clark College to obtain her pharmacy technician certificate of proficiency, graduated with merit in 2007, and was nationally certified and licensed the same year. Dianne currently works at Kaiser Sunnyside Medical Center in Clackamas, OR. Dianne has mentored many employees throughout her management career, provided volunteer technical training for seniors at the national OASIS Institute, and volunteered with the Oregon SMART (Start Making A Reader Today) program, assisting second graders to gain reading skills.

No. 563: Counseling and Providing Drug Education to Meet the Needs of Your Patients

Oregon Administrative Rule (OAR) 855-019-0230(1)(f) states:

> For each patient, the pharmacist or intern shall determine the amount of counseling that is reasonable and necessary under the circumstance to promote safe and effective use or administration of the drug or device, and to facilitate an appropriate therapeutic outcome for that patient.

Each patient interaction is an opportunity for a pharmacist to engage in a dialogue about medications, disease management, and overall health-related issues that can help promote positive health outcomes. As the rule requires, the determination of the amount of counseling a patient receives must be assessed by the pharmacist. The pharmacist is the professional whose judgment comes from years of educational training in school plus experience and licensure, whereas a patient may not even know enough about a medication or therapy plan to know what to ask. In other words, counseling is more than asking a patient if he or she has questions. The Board expects pharmacists to be consistently exercising this professional judgment, as it relates directly to the safety of each patient.

Special considerations should be made when providing patient education and medication counseling to **all** patients. For example, taking opiates and certain other drugs induces drowsiness and may impair one's ability to drive or perform other functions. It is not prudent to simply assume that patients are aware of the short-term and long-term effects of these drugs. It is critical to tailor the advice given to a person receiving a prescription for an acute pain situation, to include the message that the goal should be to reduce or prevent his or her pain, and also to taper off of the medication when possible. Pharmacists should regularly check in with their chronic pain patients, asking questions such as, "Has the patient been able to successfully reduce his or her daily morphine equivalent dose, perhaps by seeking alternative therapies such as acupuncture, massage, or exercise? Is he or she regularly checking in and discussing the pain management plan with a primary care provider or pain specialist?"

Efforts at the local, state, and national level are being introduced and enforced to increase awareness of the challenges society is facing related to opiates, and pharmacists certainly have a critical professional role to play in the well-being of patients. In fact, the National Transportation Safety Board recently published guidelines that include Safety Recommendation I-14-001, which recommends "that health care providers discuss with patients the effect their medical condition and medication use may have on their ability to safely operate a vehicle in any mode of transportation." Pharmacists have tools, which include a patient's profile and the Oregon Prescription Drug Monitoring Program database, as well as their in-depth knowledge of drugs to work in partnership with patients and providers to create safe and effective strategies to address pain management.

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FDA Approves Naloxone Nasal Spray to Prevent Opioid Overdose Deaths

Food and Drug Administration (FDA) has approved Narcan® Nasal Spray (also known as naloxone), a life-saving medication that can stop or reverse the effects of an opioid overdose. Prior to this approval, naloxone was only approved in injectable forms, most commonly delivered by syringe or auto-injector, explains FDA in a news release.

Narcan Nasal Spray does not require assembly and delivers a consistent, measured dose when used as directed. This prescription product can be used on adults or children and is easily administered by anyone, even those without medical training. The drug is sprayed into one nostril while the patient is lying on his or her back, which can be repeated if necessary. However, it is important to note that it is not a substitute for immediate medical care, and the person administering Narcan Nasal Spray should seek further immediate medical attention on the patient's behalf. The use of Narcan Nasal Spray in patients who are opioid dependent may result in severe opioid withdrawal characterized by body aches, diarrhea, increased heart rate (tachycardia), fever, runny nose, sneezing, goose bumps (piloerection), sweating, yawning, nausea or vomiting, nervousness, restlessness or irritability, shivering or trembling, abdominal cramps, weakness, and increased blood pressure. Narcan Nasal Spray is distributed by Adapt Pharma, Inc, of Radnor, PA. The FDA news release is available at *www.fda.gov/NewsEvents/Newsroom/PressAnnouncements/ucm473505.htm.*

Selected Medication Safety Risks to Manage in 2016

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.*

It is a nearly impossible task to list all the risks associated with medication use that could lead to harmful medication errors. So where do health care professionals start to improve medication safety? Most people frequently resort to playing "whack-a-mole," addressing risks only after they pop up and become visible after an adverse event.

Listed below are two serious medication safety risks that might fall off the radar screen unless an adverse event happens to draw attention to them. Additional serious risks will be published in future issues of the National Association of Boards of Pharmacy® *National Pharmacy Compliance News.*

Patient Information – Placing Orders on the Wrong Patient's Electronic Health Record

A potentially hidden vulnerability that can lead to serious errors is placing orders on the wrong patient's electronic health record. A recent study published in the *Journal of the American Medical Informatics Association* identified and quantified close calls that would have resulted in wrong-patient errors. According to this study, about 14 wrong-patient electronic orders are placed every day in a large hospital system with approximately 1,500 beds, or about 68 wrong-patient errors per 100,000 medication orders. By this measure, one in 37 hospitalized patients will have an order placed for them that was intended for another patient.[1]

These errors are sometimes due to juxtaposition but more often caused by interruptions and having more than one patient's electronic health record open.

Multiple studies have demonstrated ways to reduce these events. Requiring verification of the patient's identity has reduced errors by 16% to 30%, and requiring re-entry of the patient's identification has reduced errors by 41%.[1,2] Prompting clinicians for an indication when certain medications are ordered without an indication on the patient's problem list has intercepted errors at a rate of 0.25 per 1,000 alerts.[3] In one study, most emergency department (ED) staff (81%) felt a room number watermark on the patient's electronic health record would eliminate most wrong-patient orders in the ED.[4]

Communication About Drug Therapy – Confusing the Available Concentration as the Patient's Dose on Electronic Records

Another risk deals with how home medications appear on computer screens. For example, a physician accidentally ordered 100 units of Lantus® (insulin glargine) instead of the correct dose of six units because the list of medications used at home displayed the concentration right next to the drug name on the first line, and the patient's dose below it on the second line: "Insulin glargine (Lantus) 100 units/mL," followed on the next line with "6 units subcutaneous daily every evening."

Now that insulin is available in 100 units/mL, 200 units/mL, 300 units/mL, and 500 units/mL concentrations, the risk

of receiving an overdose of insulin is high if the presentation of the order lists the product's concentration before the patient's dose. ISMP's recommendation is to list the drug name, patient-specific dose, and directions for use on the first line of the electronic medication administration record and patient medication lists, and the available concentration and any directions on how to measure the patient's dose below it.

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4. Yamamoto LG. Reducing emergency department charting and ordering errors with a room number watermark on the electronic medical record display. *Hawaii J Med Public Health*. 2014; 73(10):322-328.

FDA Provides Training Videos on MedWatch Resources and Breakthrough Therapy

FDA Drug Info Rounds, a series of online videos, provides important and timely drug information to practicing clinical and community pharmacists so they can help patients make better decisions. In the January 2016 Drug Info Rounds video, "MedWatch Tips and Tools," pharmacists discuss reporting adverse events to FDA's MedWatch Safety Information and Adverse Event Reporting Program and the resources available for health care professionals to report safety information. In the December 2015 Drug Info Rounds video, "Breakthrough Therapy," pharmacists discuss the breakthrough therapy designation program, which is intended to expedite the development and review of drugs for serious or life-threatening conditions. Drug Info Rounds is developed with contributions from pharmacists in FDA's Center for Drug Evaluation and Research (CDER), Office of Communications, Division of Drug Information. All Drug Info Rounds videos can be viewed on the FDA website at *www.fda.gov/Drugs/ResourcesForYou/HealthProfessionals/ucm211957.htm.*

Reading Medicine Labels Helps Reduce Acetaminophen Overdoses

The Acetaminophen Awareness Coalition (AAC) reminds pharmacists and other health care providers to encourage patients to properly read medicine labels to avoid unintentional acetaminophen overdoses. The coalition also encourages pharmacists and other health care providers to talk to their patients about medicine safety and acetaminophen use.

AAC's "Know Your Dose" campaign reminds patients to take these four steps to avoid acetaminophen overdose:

(1) Always read and follow the medicine label.
(2) Know if their medicines contain acetaminophen.
(3) Take only one medicine at a time that contains acetaminophen.
(4) Ask their health care provider about any questions.

Additionally, pharmacists may download or order free educational materials, including posters, flyers, and talking points, to give their patients on the Know Your Dose website at *www.knowyourdose.org.*

Over-the-Counter Children's Medicine Recalled Due to Incorrect Dose Markings

In January 2016, Perrigo Company voluntarily recalled two lots of children's guaifenesin grape liquid cough medicine (100 mg/5 mL) and three lots of children's guaifenesin DM cherry liquid cough medicine (100 mg guaifenesin and 5 mg dextromethorphan HBr/5 mL) sold in 4 oz bottles. The recall was initiated because some packages contain an oral dosing cup with incorrect dose markings. The affected products were sold by distributors nationwide and distributed through retail stores. The recalled lots and store brands are available in the Perrigo press release posted on the company's website, *www.perrigo.com,* under "Investors." To date, the company has not received reports of overdose. Distributors and retailers that have the affected lots should stop distribution and return the product using the information provided in the press release.

Adverse reactions or quality problems may be reported to FDA's MedWatch Safety Information and Adverse Event Reporting Program at *www.fda.gov/MedWatch.*

FDA Offers Webinars on Online Drug Information Resources for Students and Clinicians

FDA's Division of Drug Information, CDER, presents a series of continuing education webinars targeted toward students and health care providers who wish to learn more about FDA and drug regulation. The webinars are presented by FDA staff and allow participants to interact with staff. Past topics have included "Introduction to FDA's MedWatch Adverse Reporting Program" and "An Overview of the FDA's Breakthrough Therapy Designation Program." Upcoming webinars, previous webinars, and presentation slides can be accessed on FDA's website at *www.fda.gov/AboutFDA/WorkingatFDA/FellowshipInternshipGraduateFacultyPrograms/PharmacyStudentExperientialProgramCDER/ucm228391.htm*.

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Pharmacists have the unique opportunity to have direct and ongoing conversations with patients, as they regularly check in for questions and refill pickups. Prioritizing counseling in order to provide education to patients is one of the single most important duties that a pharmacist can perform, ultimately seeking positive health outcomes for the citizens of Oregon. Not only is patient education in the form of counseling required by state and federal law, but it is also paramount in maximizing patient understanding and safety.

No. 564: FDA Issues New Labeling Requirement for the Entire Class of Opioid Pain Medicines

Summarized by Phuoc Doan, 2016 PharmD Candidate

Food and Drug Administration (FDA) is deeply concerned about the growing epidemic of opioid abuse, dependence, and overdose in the United States. In response to this crisis, the agency has developed a comprehensive action plan to take concrete steps toward reducing the impact of opioid abuse on American families and communities. On March 22, 2016, FDA announced that it is requiring several safety labeling changes for all opioid pain medications in its continuing effort to educate prescribers and patients about the potential risks related to opioid use. "Opioid addiction and overdose have reached epidemic levels over the past decade, and the FDA remains steadfast in our commitment to do our part to help reverse the devastating impact of the misuse and abuse of prescription opioids," said Robert Califf, MD, FDA commissioner. Drug overdose deaths, driven largely by overdose from prescription opioids and illicit drugs like heroin and illegally made fentanyl, are now the leading cause of injury death in the US, surpassing motor vehicle crashes. "Things are getting worse, not better, with the epidemic of opioid misuse, abuse and dependence," added Califf. "It's time we all took a step back to look at what is working and what we need to change to impact this crisis."

Safety Labeling for IR Products

FDA is requiring a new boxed warning about the serious risks of misuse, abuse, addiction, overdose, and death. The updated indication clarifies that because of these risks, immediate-release (IR) opioids should be reserved for pain severe enough to require opioid treatment and for which alternative treatment options are inadequate or not tolerated. The dosing information also provides clearer instructions regarding patient monitoring and drug administration, including initial dosage, dosage changes during therapy, and a warning not to abruptly stop treatment in a physically dependent patient.

FDA also requires a precaution that chronic maternal use of opioids during pregnancy can result in neonatal opioid withdrawal syndrome (NOWS), which may be life-threatening if not recognized and treated using protocols developed by neonatology experts. NOWS may occur in a newborn exposed to opioid drugs for a prolonged period while in utero.

Safety Labeling for All Opioids (Both Extended-Release/Long-Acting and IR Products)

FDA is requiring updated labeling to include safety information about potentially harmful drug interactions with antidepressants and migraine medications that can result in serotonin syndrome. Updated labeling will also include information about opioid effects on the endocrine system, such as adrenal insufficiency and androgen deficiency. These labeling changes will also make it clear that these negative outcomes can occur whether a patient is taking an opioid to treat pain or if the product is being used for medication-assisted treatment, which combines behavioral therapy and medications to treat substance use disorders.

Pharmacists play a crucial role in the fight against the misuse and abuse of prescription opioids. Per Drug Enforcement Administration (DEA) Regulation Title 21 Code of Federal Regulations §1306.04, the pharmacist filling a controlled substance prescription has a corresponding responsibility to make sure the prescription was "issued for a legitimate medical purpose by an individual practitioner acting in the usual course of his professional practice." A pharmacist who knowingly fills a fraudulent prescription shall be subject to disciplinary action by the Board, as well as DEA. Oregon pharmacists must utilize professional judgment to dispense only pursuant to a valid prescription issued within a valid patient-practitioner relationship (OAR 855-019-0210). As health care providers, pharmacists dispensing opioid medications have a due diligence to ensure that their patients are receiving appropriate, safe, and effective therapies. Familiarize yourself with these new guidelines set forth by FDA. Additional information is available at *www.fda.gov/NewsEvents/Newsroom/PressAnnouncements/ucm491739.htm.*

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