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Oregon State Board of Pharmacy News

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No. 594 Board Member News

The Oregon State Board of Pharmacy welcomes Public Members Sue Richardson and Tim Logan as the Board's newest members. They were appointed by Governor Kate Brown and confirmed by the Legislative Senate Rules Committee in February this year.

Sue's appointment began February 14, 2018, and runs through September 30, 2018, finishing out Christine Chute's remaining term. It is expected that Sue will be reappointed in the fall. Now retired, Sue worked for 33 years in federal service. For 25 of those years, she worked for the Small Business Administration, primarily as a customer service representative for various programs. Sue received a number of special achievement awards throughout her federal career. She has been actively engaged in community service since 2011, including serving as a board member for the Milwaukie Public Safety Foundation for five years. She looks forward to being a public member of the Board, and believes she brings a good background of service to contribute to the Board and that it will be a very interesting and educational experience.

Tim's appointment began February 14, 2018, and runs through May 31, 2021. Tim currently has his own business, SoValTi, where he is a group facilitator, counselor, and agency administrator. He performs contract services for couples, families, and individuals in conflict, in addition to leading culturally specific batterer intervention groups for court-referred offenders from Multnomah County and facilitating violence prevention groups and cultural sensitivity groups for juvenile and adult men. Tim also works with Multnomah County Probation Services as a temporary probation officer/counselor. Tim has a bachelor of arts degree in psychology with minors in sociology and communications from Eastern Washington University. He currently is on the Board of Directors for Albina Head Start. When researching the Board of Pharmacy's public member position, he was impressed with the similarities between the Board and his work-life experience, as standards of accountability and integrity are an integral part of the Board's responsibility. He feels that his own personal values and special talents might be of benefit to the Board.

Welcome, Sue and Tim!

No. 595 Policy Statement – Sterile Syringe Access and Harm Reduction

By Nicole LoGiudice, PharmD Candidate 2018, Pacific University School of Pharmacy

The Board recently adopted a position statement, as follows, related to sterile syringe access in Oregon pharmacies.

There is an opioid, heroin, and methamphetamine crisis occurring across Oregon and the United States. Evidence shows that access to sterile syringes and naloxone are effective strategies to reduce negative health outcomes and the spread of disease related to injection drug use, including HIV, hepatitis B and C, and overdose. Reuse of syringes is common when new syringes are unavailable; this increases the risk of infections and communicable diseases for intravenous drug users (IDUs).

Oregon was the first state to squarely face the question of syringe access as a public health measure. Prior to 1987, syringe sales were not regulated. In that year, the Oregon State Legislature passed a paraphernalia law based on the model statute, but heeded the advice of state health officials to explicitly exclude syringes from the definition of paraphernalia (Oregon Revised Statute (ORS) 475.525(3)). In Oregon, it is therefore legal to sell syringes not only in pharmacies but also in other retail outlets and to distribute them free through syringe exchange programs or other mechanisms. Of note, the sale of syringes in Oregon does not require a prescription. However, a pharmacist must use good professional judgment when selling syringes to minors (individuals under 18 years of age) (see ORS 475.744).

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National Pharmacy Compliance News

May 2018

NABPF
National Association of Boards of Pharmacy Foundation

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 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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The Oregon approach has minimized the legal barriers to syringe access.

Public health studies have proven that legal syringe access reduces syringe reuse and sharing, does not promote injection drug use, and does not increase criminal activity in surrounding areas. When pharmacies or pharmacists choose to directly or indirectly restrict syringe sales to IDUs or to not carry naloxone, the opportunity to decrease or prevent individual and community harm from addiction and injection drug use is lost.

The Board recommends and encourages pharmacies and pharmacists to increase access of sterile syringes and naloxone to the public. Pharmacies are important public health partners for infectious disease and drug overdose prevention. Existing laws in Oregon have positioned pharmacies and pharmacists to support public health efforts to increase community member access to sterile syringes and naloxone, deliver health education, and refer IDUs to local health care and recovery services. Removing the stigma of selling sterile syringes and prescribing and dispensing naloxone will improve patient care in the short and long term.

The purpose of this position statement is to highlight the impact that pharmacists can have on the care of IDUs. It can be challenging to offer new services at a pharmacy without interrupting the current workflow. However, the time required to sell sterile syringes or offer naloxone to a patient is minimal when one looks at the benefits these items provide. IDUs are **patients** who require pharmacy assistance the same as a patient coming in to pick up a prescription. Changing one's perspective of IDUs will ensure all community members are receiving the same quality of care.

To access this and other Board position statements, please visit *www.oregon.gov/pharmacy/Pages/Position_Statements.aspx.*

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