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News

Idaho State Board of Pharmacy

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Farewell, Kitty Gurnsey

The Idaho State Board of Pharmacy is deeply saddened by the passing of Ms Kitty Gurnsey. Ms Gurnsey was first elected to the State of Idaho House of Representatives in 1974, and won 10 elections before she retired in 1996. She made her mark in the State of Idaho Legislature as co-chair of the Joint Finance-Appropriations Committee (JFAC), which is the state budget-writing committee. She was appointed to JFAC in 1976 and became co-chair in 1980, holding that position for 16 years.

She was appointed by then-Governor Phil Batt on January 1, 1999, as the public member replacing Jack Jones on the Board. Ms Gurnsey had a love for public service that was evident to all who knew her. A collection of her legislative letters is housed at Boise State University *(http://digital.boisestate.edu/cdm/landingpage/collection/p15948coll12)*. She served terms as a Board member as well as chairperson until she again retired on December 31, 2010. Kitty Gurnsey will be fondly remembered and sorely missed by those who knew her.

Reporting Thefts and Losses of CS

Thefts and/or losses of controlled substances (CS) must be reported to the Board office, as well as to Drug Enforcement Administration (DEA) per the following rules and statutes.

IDAPA 27.01.01.208. Controlled Substances – Theft or Loss Reporting. A registrant must report to the Board on the same day reported to the DEA a theft or loss of a controlled substance that includes the information required by federal law. (3-21-12)

Title 21 Code of Federal Regulations §1301.74 Other security controls for non-practitioners; narcotic treatment programs and compounders for narcotic treatment programs.

(c) The registrant shall notify the Field Division Office of the Administration in his area, in writing, of any theft or significant loss of any controlled substances within one business day of discovery of the theft or loss. The supplier is responsible for reporting all in-transit losses of controlled substances by the common or contract carrier selected pursuant to paragraph (e) of this section, within one business day of discovery of such theft or loss. The registrant shall also complete, and submit to the Field Division Office in his area, DEA Form 106 regarding the theft or loss. Thefts and significant losses must be reported whether or not the controlled substances are subsequently recovered or the responsible parties are identified and action taken against them. When determining whether a loss is significant, a registrant should consider, among others, the following factors:

(1) The actual quantity of controlled substances lost in relation to the type of business;
(2) The specific controlled substances lost;
(3) Whether the loss of the controlled substances can be associated with access to those controlled substances by specific individuals, or whether the loss can be attributed to unique activities that may take place involving the controlled substances;
(4) A pattern of losses over a specific time period, whether the losses appear to be random, and the results of efforts taken to resolve the losses; and, if known,
(5) Whether the specific controlled substances are likely candidates for diversion;
(6) Local trends and other indicators of the diversion potential of the missing controlled substance.

Mark Johnston Departs as Executive Director of the Board

Mark D. Johnston, RPh, has resigned as the executive director of the Board, effective July 1, 2015, as he accepted a position with CVS Health as director of pharmacy regulatory affairs. Mark was hired by the Board to run day-to-day operations in 2007. In addition to many other victories during Mark's tenure at the Board, pharmacists received limited prescriptive authority, all Board rules were rewritten, online prescription monitoring program (PMP) access was established, and the Pharmacist Recovery Network and license/registration online renewal were developed. Fortunately, Mark remains an Idaho resident. The Board wishes Mark well in his new endeavors. He made a difference!

Alex Adams, New Board Executive Director

The Board began the hiring process for the vacated executive director position back in June when Mark Johnston made the Board aware of his pending departure. After a couple of solicitations for applications and the interviewing of qualified candidates, the Board has made a selection that it is very excited about. Alex Adams, PharmD, has accepted the position. Alex comes to the Board from his position as vice president of pharmacy programs at the National Association of Chain Drug Stores (NACDS) Foundation. Alex is a fourth-generation pharmacist who obtained his doctor of pharmacy degree from the University of Toledo College of Pharmacy, and has recently received his master of public health from Johns Hopkins University Bloomberg School of Public Health. Through his position at NACDS, he has worked extensively on pharmacy practice issues and with a large variety of organizations, including universities, chain pharmacies, associations, boards of pharmacy, and other state and federal agencies. Beyond this experience, Alex displays a deep understanding of policy, and has a genuine zeal for what the Board

continued on page 4

Counterfeit Botox Found in the United States, FDA Warns

On April 16, 2015, Food and Drug Administration (FDA) alerted health care providers that a counterfeit version of Botox® was found in the United States and may have been sold to doctors' offices and clinics throughout the country. The counterfeit products may be identified by a missing lot number on the vial, missing information on the carton (next to LOT, MFG, and EXP), and a displayed active ingredient as "Botulinum Toxin Type A" instead of "OnabotulinumtoxinA." The counterfeit products were sold by an unlicensed supplier who is not authorized to ship or distribute drug products in the US, according to an FDA Drug Safety Alert. The agency advises health care providers to confirm that the distributor from which they purchase Botox is authorized by Allergan, the drug's manufacturer. No adverse events related to this product have been reported to FDA.

Medical practices that purchase and administer counterfeit, illegal, and unapproved medications from unlicensed or foreign sources are putting patients' health at risk, as patients may not be getting proper treatment, warns FDA. Wholesale drug distributors must be licensed in the states where they conduct business. Suspicious Botox products may be reported to FDA's Office of Criminal Investigations. More information is available on the FDA website at *www.fda.gov/Drugs/DrugSafety/ucm443217.htm*.

One way pharmacies can be assured of the legitimacy of a wholesale distributor is to look for the National Association of Boards of Pharmacy® (NABP®) Verified-Accredited Wholesale Distributors® (VAWD®) Seal. Wholesale distributors that achieve VAWD accreditation are in compliance with state and federal laws, as well as NABP's VAWD criteria. Wholesale distributors that display the VAWD Seal as part of their accreditation have undergone a criteria compliance review, including a rigorous review of their operating policies and procedures, licensure verification, survey of facility and operations, background checks, and screening through the NABP Clearinghouse. Accredited facilities are reviewed annually and undergo an on-site survey every three years. Created in 2004, the accreditation program plays a pivotal role in preventing counterfeit drugs from entering the US drug supply.

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.*

ISMP has been reflecting on the strength and resolve of many across the nation who have demonstrated an unparalleled commitment to keeping patients safe. Despite the many safety accomplishments in 2014, ISMP cannot help but mull over persistent medication safety gaffes that continue to be unresolved. ISMP would like to share seven persistent safety gaffes of 2014, in three parts, with NABP *National Pharmacy Compliance News* readers with the hope that they will join ISMP in bringing attention to these crucial issues and the compelling need for their resolution. Part one of the three-part series is below.

1) Patient Counseling: Still Only a Veiled "Offer" in Many States

The effectiveness of patient counseling in a community pharmacy to detect and prevent medication errors, and its link to improved medication adherence and positive clinical outcomes have been well documented in the literature. Yet, studies have placed patient counseling rates at only eight percent to 42%. An increase in the frequency and quality of patient counseling has been linked to state-specific regulations that require patient counseling for new prescriptions coupled with strict enforcement surveillance. States that require an "offer" to counsel have very low patient counseling rates. Patients often fail to recognize an offer to counsel when simply asked, "Do you have any questions?" or told to "Please sign here." They may not even know what to ask. This means that, with few exceptions, pharmacies in states that require only an offer to counsel will likely dispense a powerful opioid such as fentanyl transdermal patches and allow the patient or caregiver to walk out of the pharmacy without even a brief discussion about safe use and disposal. ISMP has long promoted mandatory patient counseling in community pharmacies for prescriptions for targeted high-alert medications.

For a list of high alert community medications, please visit *www.ismp.org/communityRx/tools/ambulatoryhighalert.asp.* ISMP hopes you will use this list to determine which medications require mandatory patient education in order to reduce the risk of errors and minimize harm.

2) Patients Impacted by Dispensing Errors: Callous Response From Pharmacists

When patients report dispensing errors to ISMP, they are usually more upset about the response they received when contacting the pharmacist or pharmacy manager than the actual error itself. All too often, consumers tell ISMP that pharmacy staff have responded in a callous manner when confronted with the possibility of a dispensing error, demonstrating a lack of empathy and concern for the adverse effects the patient might have experienced. While pharmacy staff may want to be more responsive to patients who report errors, they are often following corporate policies that are focused on legal concerns. As patients are continually encouraged to be active participants in their health care, they want and deserve honest disclosure of errors, and knowledge that there is an action plan to reduce the risk of it happening again.

Flurbiprofen-Containing Topical Medication May Be Dangerous to Pets, Cautions FDA

People who use topical medications containing flurbiprofen, a nonsteroidal anti-inflammatory drug (NSAID), should take care to prevent their pets from being exposed to the drug, recommended FDA in an April 2015 Safety Alert. The warning is in response to reports of cats in two separate households that became ill or died after their owners used topical medications containing flurbiprofen to treat

muscle, joint, or other pain. Two cats in one household developed kidney failure and recovered with veterinary care. Two cats in a second household developed symptoms that included reluctance to eat, lethargy, vomiting, melena, anemia, and dilute urine, and subsequently died despite veterinary care. A third cat in the second household also died after the owner stopped using the medication. Necropsies on the three cats found evidence that were consistent with NSAID toxicity. The pet owners had applied the drug to their own neck or feet, and not directly to the pet, and it is not known exactly how the cats became exposed to the medication, the Safety Alert notes.

Health care providers who prescribe or dispense topical pain medications containing flurbiprofen should advise patients with pets to take steps to prevent exposure of the pets to the medication. Additional information is available in the FDA Safety Alert available at *www.fda.gov/Safety/MedWatch/SafetyInformation/SafetyAlertsforHumanMedicalProducts/ucm443386.htm*.

New FDA Drug Info Rounds Videos Available

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. The latest Drug Info Rounds videos are as follows.

- In "NDC Directory," pharmacists demonstrate how to use this quick, easy, online resource.
- In "FAERS," pharmacists discuss the FDA Adverse Event Reporting System (FAERS) and review three ways FAERS data is made available to the public.

Drug Info Rounds is developed with contributions from pharmacists in FDA's Center for Drug Evaluation and Research, Office of Communications, Division of Drug Information. These videos and previous Drug Info Rounds resources are available on the FDA website at *www.fda.gov/Drugs/ResourcesForYou/HealthProfessionals/ucm211957.htm*.

Mucinex Cold, Sinus, and Flu Medications Recalled Due to Possible Labeling Error

In April 2015, RB (formerly Reckitt Benckiser) of Parsippany, NJ, issued a voluntary recall of certain lots of liquid Mucinex® due to a potential error involving the over-the-counter medications' drug facts labels. While the front label of the recalled lots correctly lists the name of the product as well as the active ingredients, some bottles may not have the correct corresponding drug facts label on the back. The recall was initiated after a confirmed report from a retailer. The recalled medications include:

- MUCINEX FAST-MAX Night-Time Cold & Flu;
- MUCINEX FAST-MAX Cold & Sinus;
- MUCINEX FAST-MAX Severe Congestion & Cough; and
- MUCINEX FAST-MAX Cold, Flu & Sore Throat.

If mislabeled, consumers who purchase these products may be unaware of the side effects and potential risks associated with active ingredients such as acetaminophen, dextromethorphan, guaifenesin, phenylephrine, and/or diphenhydramine. RB is recalling these products as a precautionary measure to ensure consumers have all relevant facts and warnings; the company asks consumers to dispose of any unused product.

Additional information about the recall, including the lot numbers and expiration dates for the recalled medications and guidelines for safe disposal, is available on the FDA website at *www.fda.gov/Safety/Recalls/ucm444028.htm*.

Pharmacists Are Performing More Patient Care Activities, National Survey Indicates

Pharmacists are performing more patient care activities in a variety of health care settings and are spending less time in traditional dispensing roles, indicates the *2014 National Pharmacist Workforce Survey*. Specifically, the report found that 60% of pharmacists provided medication therapy management, and 53% performed immunizations in 2014, indicates a press release from the American Association of Colleges of Pharmacy (AACP). The survey was created using a random sample of 5,200 individuals selected from a list of 7,000 licensed pharmacists in the US. Response rate to the survey was 48%.

Additional details, including the full results of the survey and an executive summary, are available through the Resources section of the AACP website, *www.aacp.org*.

Potentially Lethal Drug Sold Globally as Diet Supplement, Warns INTERPOL

INTERPOL has issued a global alert for a drug known as 2.4-dinitrophenol (DNP), an illicit and potentially lethal drug sold as a dieting and body building aid. The "Orange Notice" warning about DNP was published in May 2015, following the death of a woman in the United Kingdom and the serious illness of a man in France. In the 1930s, DNP was used to boost metabolism and encourage weight loss, but it was taken out of circulation due to several deaths. Sold as a plain yellow powder, capsules, or cream, DNP is often illegally manufactured and sold via the Internet; unsafe manufacturing of the drug and potential contamination may be magnifying the dangers of taking the drug, notes INTERPOL.

Additional information is available on the INTERPOL website at *www.interpol.int/News-and-media/News/2015/N2015-050*.

HHS Announces New Interactive Training on Safe Opioid Use

The Department of Health and Human Services (HHS) has announced a new, interactive training course that teaches health care providers how to talk to patients about safely using opioids to manage chronic pain. The course, "Pathways to Safer Opioid Use," also teaches implementation strategies for meeting the opioid-related recommendations from the National Action Plan for Adverse Drug Event Prevention. Adverse drug events (ADEs) are the largest contributor to hospital-related complications and account for more than 3.5 million physician office visits each year, according to HHS. The training, which is offered at no cost, includes self-guided interactive videos with decision points to help users learn how to apply health literacy strategies to help patients understand and act on information to prevent opioid-related ADEs; identify individual risk factors, opioid medications, and interactions that place individuals with chronic pain at increased risk for opioid-related ADEs; recognize the importance of a multidisciplinary team-based approach to treating patients with chronic pain; and demonstrate the ability to combine the principles of the Health Literate Care Model and the biopsychosocial model.

Additional information, including a link to the National Action Plan for Adverse Drug Event Prevention, is available on the course website at *http://health.gov/hcq/training.asp#pathways*.

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continued from page 1

does. Through his wife, who is from Idaho, Alex already has connections in the state. He has been licensed in Idaho since 2011. Alex joined the Board permanently on September 1, 2015. Please join all of us at the Board in welcoming Alex to the position.

Idaho PMP Daily Reporting Requirement

The Idaho PMP tracks over 2.6 million CS dispensed every year. As of January 1, 2015, community pharmacies and out-of-state mail service pharmacies are required to report any dispensed CS prescriptions in Schedules II-V on a **daily** basis. Zero reports will continue with weekly reporting.

Personnel Changes Must Be Reported to Board

Board Rule 017 requires any changes to information provided on an initial or renewal application to be reported to the Board within 10 days. Information includes, but is not limited to, name change, any address changes, and employment changes.

Board Rule 302 requires both the incoming and outgoing pharmacists-in-charge (PICs) to notify the Board within 10 days of the change in PIC designation. Rule 622 also requires both an incoming and outgoing director to report to the Board a change in the institutional pharmacy director within 10 days of the change.

For veterinary drug technicians (VDTs), Rule 673 requires notification of personnel changes to be provided to the Board within 10 days of the change, and must include the names and addresses of both the resigning and the newly hired VDTs.

Changes Pharmacists May Make to Schedule II Prescription Drug Orders

The Board supports a DEA statement whereby a pharmacist may use his or her professional judgment in addressing a prescription drug order for a Schedule II CS that is incomplete or deemed incorrect, pursuant to the following updated Board policy. A pharmacist may change or add the dosage form, drug strength, drug quantity, and directions for use only after consultation with and agreement of the prescriber. After consultation with and agreement of the prescriber, a pharmacist may also add a missing date or change an obvious prescriber's error when writing the date, such as the prior year when a new year has just begun, but a date may never be changed to circumvent an expiration date or to provide a dispensing earlier than a prescriber has authorized when issuing multiple Schedule II prescription drug orders. Additionally, to satisfy the requirements of Idaho Code Section 37-2725(6), which requires an alpha and numeric quantity on Schedule II prescription drug orders, after consultation and agreement with the prescriber, a pharmacist may add or change the alpha and/or numeric quantity. Also, a patient's address and a prescriber's DEA registration number may be added to a prescription drug order or corrected without consulting the prescriber after verifying with another reliable source. Finally, the patient's name may be corrected, such as changing a maiden name to a married name or correcting a misspelled name, but the patient's name, the physician's name, and the drug name may otherwise never be added or changed.

Board License and Registrant Statistics

The Board has the following active licenses or registrations: Certified Technician – 1,380; Technician-in-Training – 592; Pharmacy Technician – 414; Pharmacist – 2,399; Pharmacist CS Registration – 1,688; Extern Pharmacist – 345; Intern Pharmacist – 14; Nonresident Pharmacist – 509; Practitioner CS – 7,461; Researcher CS – 18; Prescriber Drug Outlet – 224; Durable Medical Equipment – 386; Outsourcing Facility – 10; Manufacturer – 227; Retail Pharmacy – 287; Hospital Pharmacy – 60; Limited Service Pharmacy – 30; Mail Service Pharmacy – 577; Narcotic Treatment Center – 3; Institutional Drug Outlet – 52; Non-Pharmacy Drug Outlet – 1,133; Nonresident Central Drug Outlet – 30; Veterinarian Drug Outlet – 8; VDT – 28; Wholesaler – 544; Wholesaler Legend Medical Devices/Over-the-Counter – 208. **Grand Total – 11,180.**

Recent Board Discipline

L. M., PharmD: 18 credit hours of continuing pharmacy education for failing to follow the instructions of a prescriber.

D. G., Certified Technician: $250 for failing to maintain certification.

A.N., Certified Technician: Revocation of certified technician registration, diversion.

Special Notice

The *Idaho State Board of Pharmacy Newsletter* is considered an official method of notification to pharmacies, pharmacists, pharmacy interns/externs, and pharmacy technicians registered by the Board. Please read them carefully. The Board encourages you to keep them filed in your pharmacy, preferably in your *Idaho Pharmacy Law Book,* for future reference.

The *Idaho State Board of Pharmacy News* is published by the Idaho 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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