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Nevada State Board of Pharmacy News

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Macdonald Honored Yet Again

Keith W. Macdonald, past executive secretary and member of the Nevada State Board of Pharmacy, has been named the 2012 Honorary President of the National Association of Boards of Pharmacy® (NABP®) for his exemplary service in protecting the public health and significant involvement with NABP. His stellar career ranges from beginning in his father's drugstore in Carson City, NV, to owning his own store, to deputy administrator for the Nevada Welfare Division, to executive secretary of the Nevada State Board of Pharmacy. Congratulations Keith for the much deserved recognition!

Marguerite Snyder-Kitts

Marguerite Snyder-Kitts became registered as a pharmacist in Nevada in 1947, after graduating from Capitol College of Pharmacy in Denver, CO, and may just be the first female pharmacist ever registered in our state! Ms Snyder-Kitts believes that there were only two or three female pharmacists in Nevada during this period. She was named in the 1970 edition of *Who's Who of American Women,* being the first female pharmacist in the Nevada State Hospital, establishing that pharmacy in 1963. A native Nevadan, she was raised on her father's eastern Nevada Cartetti Ranch, graduated from Reno High, and then nursing school at St Luke's Hospital School of Nursing in San Francisco, CA, prior to going to pharmacy school in Denver. Board President Beth Foster presented Ms Snyder-Kitts, now in her 90s, with a certificate of recognition to acknowledge her dedication to quality pharmaceutical health care over the years. Congratulations Marguerite!

Diversion of Controlled Substances Within a Pharmacy

Diversion is not a new problem to pharmacies, occasionally rearing its ugly head. Recently, there were two cases presented to the Board that involved thousands of narcotics being diverted from the pharmacy. In these cases, the guilty parties were both pharmacy technicians; in fact a majority of the cases in the past few years occurred because of pharmacy technicians diverting controlled substances. These technicians play an integral part of the pharmacy team, and there is often a three to one ratio of technicians to pharmacists. Supervision of these employees is the responsibility of the pharmacists. Nobody wants to work with someone continually watching over their shoulder, and asking one person to watch over three people's shoulders is problematic to say the least. By instituting various safeguards, there is the hope that we can reduce the amount of diversion that occurs in our pharmacies.

> **NAC 453.400 Security of controlled substances.** (NRS 453.221, 639.070) All applicants and registrants shall establish and maintain effective controls and procedures to prevent or guard against theft and misuse of controlled substances.

While NAC 453.400 may seem vague, there are some very important concepts to take from it. The first is the establishing of effective controls and procedures to prevent or guard against theft and misuse of controlled substances. The second concept is the maintenance of these controls and procedures. One must realize that as time progresses, current safeguards may no longer be effective. Doing the biannual inventory gives a good starting point, but losses can occur between the two years of the inventory dates. By making this an annual inventory, there is some ability to cut down on losses, but there still is room for improvement.

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FDA Warned Medical Practices About Counterfeits in US and Risks to Patients

In April 2012, Food and Drug Administration (FDA) sent letters to medical practices in several states requesting that they stop administering drugs purchased from any foreign or unlicensed source. FDA's letters were sent in response to the discovery that the medical practices purchased medications from foreign or unlicensed suppliers that sold illegal prescription medications. FDA has advised that these medical practices are putting patients at risk of exposure to medications that may be counterfeit, contaminated, improperly stored and transported, ineffective, and dangerous.

In an FDA statement, the agency urges the health care community "to examine their purchasing practices to ensure that they buy directly from the manufacturer or from licensed wholesale drug distributors in the United States." Further, FDA reminds health care providers, pharmacies, and wholesalers/distributors that they are valuable partners in protecting consumers from the threat of unsafe or ineffective products that may be stolen, counterfeit, contaminated, or improperly stored and transported. FDA advises that the receipt of suspicious or unsolicited offers from unknown suppliers should be questioned, and extra caution should be taken when considering such offers.

FDA notes that the "Verify Wholesale Drug Distributor Licenses" FDA Web page, available at *www.fda.gov/Drugs/DrugSafety/DrugIntegrityandSupplyChainSecurity/ucm281446.htm,* may be used to verify that a wholesale drug distributor is licensed in the state(s) where it is conducting business.

The FDA warning letters were sent following two incidences of counterfeit injectable cancer drugs found in US medical practices, one in February 2012, involving counterfeit Avastin® 400 mg/16 mL, and another in April 2012, involving a counterfeit version of Roche's Altuzan® 400 mg/16 ml (bevacizumab).

More information and a list of the medical practices that were sent warning letters are available on the FDA Web site at *www.fda.gov/Drugs/DrugSafety/DrugIntegrityandSupplyChainSecurity/ucm299920.htm.*

Rethink the Vial

This column was prepared by the Institute for Safe Medication Practices (ISMP). ISMP is an independent nonprofit agency 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 is a federally certified patient safety organization, providing legal protection and confidentiality for submitted patient safety data and error reports. ISMP is also an FDA MedWatch partner. Call 1-800/FAIL-SAF(E) to report medication errors to the ISMP Medication Errors Reporting Program or report online at* www.ismp.org. *ISMP address: 200 Lakeside Dr, Suite 200, Horsham, PA 19044. Phone: 215/947-7797. E-mail: ismpinfo@ismp.org.*

Recently, ISMP has been receiving many reports from consumers who report the pharmacy "shorted them" on a variety of opioid prescriptions. They report that when they call the pharmacy to complain about the missing number of tablets or capsules the pharmacy staff insists the proper quantity was dispensed. ISMP also receives reports from pharmacists reporting this same situation. The concern is that pharmacy personnel may be diverting the medication, the patient may be seeking more medication than what was prescribed, or some of the medication may be taken by someone else in the patient's home.

In the US, we dispense almost all oral solid drugs as loose tablets or capsules in a plastic vial that is labeled for the patient. This manner of dispensing makes diversion of a few tablets or capsules relatively easy. However, in many other countries, unit-dose and unit-of-use packaging is widely used.

It seems to reason that if unit-of-use, manufacturer-sealed containers or individual unit-dose packages of medications were used in the US for these drugs, diversion and/or speculation of diversion could be reduced. Manufacturers could produce unit-dose or unit-of-use packages, in numbered strips for ease of inventory and dispensing. Patients could be asked to sign for and agree to the amount dispensed at the point-of-sale. The numbered packaging would also help patients at home know if they had taken their medication or possibly alert them to diversion within their home. Of course, prescribers would need to prescribe quantities available in patient compliance packs or in multiples of that packaging, and insurance companies would have to pay for this specialized packaging.

Unit-of-use packs would provide other safety benefits. For example, patients would be able to verify the drug name on the label for each dose, which would add a redundancy in checking the pharmacy label to what was actually dispensed. Also, the manufacturer could print and attach the patient information sheet and/or medication guide to the package the patient receives, eliminating extra work in the pharmacy to print and supply these mandated education sheets to the patient.

It is evident that further steps must be taken to reduce and minimize abuse of prescription drugs. It is critical that education be provided to patients, caregivers, and health care providers to increase awareness about the dangers of prescription drug abuse and about ways to appropriately prescribe, dispense, store, and dispose of prescription medications. Development and deployment of consumer-friendly and environmentally responsible prescription drug disposal programs may also help to limit diversion (as well as reduce the risk of accidental ingestion) of drugs by family members and friends. FDA must continue its efforts to require new concepts for risk evaluation and mitigation strategies and provider education for opioid drugs. For more information on understanding prescription drug abuse, and to request *Parents' Guide to Understanding Prescription Drug Abuse* brochures for distribution to your patients, visit *www.SafeguardMyMeds.org.*

Counterfeit Vicodin ES Sold Via Rogue Internet Drug Outlet, Abbott Reports

In March 2012, Abbott warned consumers and health care providers about counterfeit Vicodin® ES purchased via the Internet. Abbott reports that the counterfeit product drug and package do not match that of Abbott's FDA-approved Vicodin ES (hydrocodone bitartrate and acetaminophen). Descriptions and images of the counterfeit product and authentic Vicodin ES are shown in a consumer alert posted on the Abbott Web site at *www.abbott.com/vicodin-consumer-alert.htm.* Abbott advises that anyone who has the counterfeit ver-

sion should stop taking the product. Further, consumers who suspect a product to be counterfeit or have questions about the legitimacy of Vicodin ES are encouraged to make a report to FDA Office of Criminal Investigations (OCI) by calling 800/551-3989 or by completing the online form on the OCI Web site at *www.accessdata.fda.gov/scripts/email/oc/oci/contact.cfm.*

PSM LEADER's Guide Offers Tips for Protecting Patients from Counterfeits

The Partnership for Safe Medicines (PSM) released a guide to assist health care providers in protecting patients from counterfeit drugs and recognizing the signs that may indicate use of counterfeits. Three versions of the *LEADER's Guide* – including one for nurses, one for doctors, and another specific to pharmacists – are available for download from the PSM Web site at *www.safemedicines.org/resources-for-healthcare-professionals.html*. Each guide provides tips specific to these health care provider roles and includes guidance for safe sourcing of medications, evaluating suspect medications, educating patients about counterfeit drugs and the risks of ordering drugs online, and reporting suspected counterfeit drugs.

FDA Urges Providers to Help Prevent Children's Accidental Exposure to Fentanyl Patches

FDA issued a safety alert reminding patients, caregivers, and health care providers to appropriately store, use, and dispose of fentanyl patches to prevent children's accidental exposure to the medication, which is potentially life-threatening. FDA recently evaluated a series of 26 cases of pediatric accidental exposures to fentanyl patches reported over the past 15 years, and determined that 10 of the cases resulted in death, and 12 in hospitalization. In addition, 16 of the 26 cases occurred in children two years old or younger.

FDA warns that young children may be at risk for accidental exposure when fentanyl patches are discarded in trash receptacles, or when children find lost or improperly stored patches. Young children can be harmed when they place the patches in their mouths or stick the patches to their skin. In addition, young children are at risk of exposure when being held by someone wearing a partially detached patch that can then transfer to the child. Exposure of young children to a fentanyl patch can lead to serious adverse events and even death, due to the amount of fentanyl present in the patches. FDA stresses that harm can even occur with used patches because they may still contain a considerable amount of fentanyl.

To prevent accidental exposure, FDA advises that patients securely store needed fentanyl patches out of children's reach and sight. When applying a patch, FDA also recommends that patients consider covering the fentanyl patch with an adhesive film to make sure the patch does not come off. Finally, FDA recommends checking throughout the day to make sure that the patch is still in place.

Further, FDA advises that used or unneeded patches are properly disposed. FDA recommends that the adhesive side of the patch should be folded together and then the patch should be flushed down the toilet. FDA notes that the agency "recognizes that there are environmental concerns about flushing medicines down the toilet. However, FDA believes that the risk associated with accidental exposure to this strong narcotic medicine outweighs any potential risk associated with disposal by flushing. When the patches are no longer needed, disposing by flushing completely eliminates the risk of harm to people in the home."

FDA urges health care providers to educate patients and their caregivers about the appropriate use and disposal of fentanyl patches. FDA's consumer Web page provides detailed information for patients and caregivers and is available at *www.fda.gov/ForConsumers/ConsumerUpdates/ucm300803.htm.* Providers, patients, and caregivers are also encouraged to review the fentanyl patch product label for instructions. The FDA safety alert is available at *www.fda.gov/Drugs/DrugSafety/ucm300747.htm.* Additional consumer information about safe medication use and storage, and the importance of proper disposal of unneeded medications, is available on the AWAR$_X$E® Web site at *www.awarerx.org/informedSiteMap.php.*

Providers Asked to Advise Patients of Acetaminophen Safe Use Steps

With a world of conditions and hundreds of medicines, the Acetaminophen Awareness Coalition asks pharmacists and other health care providers to educate patients and caregivers about the proper use of medications containing acetaminophen. As the most common drug ingredient in America, acetaminophen can be found in over 600 medicines, including many prescription and over-the-counter medicines. The coalition notes that when used as directed, acetaminophen is safe and effective. The coalition asks providers to advise patients that there is a daily dosage limit for acetaminophen and that taking more than directed is an overdose and can lead to liver damage.

The coalition calls on health care providers to participate in the Know Your Dose campaign, by reminding all patients and caregivers to (1) always read and follow the labels on their medicines; (2) know if a medicine contains acetaminophen; and (3) never take or administer two medicines that contain acetaminophen at the same time. Additional medication safety tips for consumers and more information about the Know Your Dose campaign are available on the "OTC Medication Use" page of the AWAR$_X$E Web site at *www.awarerx.org/OTCMedUse.php.* The AWAR$_X$E consumer protection program and the National Association of Boards of Pharmacy® (NABP®) are part of the Acetaminophen Awareness Coalition.

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With the mainstay of computers in the pharmacy, many have adopted the use of a perpetual inventory system to validate their current stock levels for ordering. This is also useful as a back count measure. This system fails usually along the lines of human error, where a drug was marked as received if it was not, or someone changing the current amount on hand.

Monitoring of the inventory can be done by a variety of different means. Some pharmacies have constant video surveillance, be it obvious or hidden. This is effective if you think there is diversion occurring, but can be costly to have the video reviewed constantly. Since most of the inventory ordering has been automated, or at least computer based, there are some programs that can be installed that compare the amount of drugs used to the amount ordered. These programs have set levels, usually based on a percentage before a warning goes off. The downside to this type of security is that that it is not proactive, and only comes into play after the fact.

More preventive measures can be addressed by limiting access to the inventory involved. One extreme of this would be to have a dedicated room, in which only certain staff members have access to. At the other end of the spectrum is that the inventory is on the general shelf, intermixed with non-narcotic medications. Depending on the physical location of the pharmacy in question will help determine where along this spectrum you may lie. In many community settings, as well as some institutional settings, it may not be possible to have a separate room. There may be a closet, cabinet, or drawer that can be locked to provide storage for the narcotics. Even just having back-stock in these areas can provide some inventory control.

'Medical Spas'

So what is a "medical spa"? Who runs them? Where do they get their drugs (Botox® and the like)? Who oversees or inspects them? Are they safe? These are all valid questions being explored by all of the health care boards. The Board of Pharmacy has investigated several consumer complaints involving such facilities, and the results have been quite troublesome. The Board has found illegal drugs purchased from foreign countries and other states, and some, if not most, are counterfeit. The Board has found dangerous drugs and controlled substances being purchased, administered, and dispensed by people with no authority or license to do so. The Board has found unlabeled single-dose vials and syringes as well as undated multidose vials. The Board even found one facility whose "doctor" lived in another state, yet was allegedly "seeing" patients and prescribing for them via a fax machine! Unfortunately, the Board has also found that many of these operations are buying drugs from local pharmacies. A word of caution: a pharmacy may only sell small quantities (unless they hold a wholesaler license) and only to a practitioner licensed to order and possess dangerous drugs and controlled substances (ie, a physician, advanced practice nurse, or physician assistant). Selling to a "nurse" who runs one of these spas is illegal and pharmacies that do so will undoubtedly be drawn into these cases as they develop. Secondly, if you are asked to compound for a medical spa, the product must be pursuant to a prescription, patient specific, and paid for by the patient (unless you hold a manufacturer's license with the Board).

The bottom line is that real horror stories are coming out of some of these places, one actually involving a death, and the consumer public is often being duped. If you are dealing with any such operation, please confirm proper licensure; know who you are doing business with; and be cautious!

The *Nevada State Board of Pharmacy News* is published by the Nevada State Board of Pharmacy and the National Association of Boards of Pharmacy Foundation, Inc, 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 the Foundation or the Board unless expressly so stated.

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