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South Dakota State Board of Pharmacy News

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New Registered Pharmacists

The following candidates recently met licensure requirements and were registered as pharmacists in South Dakota: Robert Brower; Courtney Conaster; Erin Weyer; Casey Williams; Brenda Marks; Jenna Kucera; Crystal Huntrods; Suzanne Kopp; Jenifer Long; Katie Gregory; Ann Konechne; and Andrew Willuweit.

New Pharmacies

Pharmacy licenses have been issued recently to Lewis Family Drug #72 – Mitchell, SD, Bill Ladwig, pharmacist-in-charge (PIC); Avera Compounding Pharmacy – Sioux Falls, SD, Darrel Mutchler, PIC; and SD Human Services Center Pharmacy – Pierre, SD, Jeffrey Herron, PIC.

Board Staff

The office has overcome some staffing shortages and is presently operating at full tilt. Jony Bruns began employment on April 16, 2012, as the Prescription Drug Monitoring Program (PDMP) assistant. Jony comes to the South Dakota State Board of Pharmacy from the Sanford Network and has an extensive background in medical transcription. This makes Jony a good fit as the Board can toss medical terminology right at her and she does not blink. The Board welcomes her to the staff and she has proved to be a valuable asset to the program as well as support for the entire office.

As stated, the Board is "presently" operating at full staff; however, this will be a temporary situation. PDMP Director Ron Huether has announced his resignation from the Board staff. Ron's official date of retirement is July 16, 2012. Over the past seven-plus years Ron has been an inspector, executive secretary, and PDMP director. His guidance, wisdom, and vision have proved invaluable to the Board and staff as well as pharmacists across the state. He will certainly be missed. The Board is in the process of looking for Ron's replacement.

From the DEA

The next Drug Enforcement Administration (DEA) National Prescription Drug Take-Back Day is scheduled for September 29, 2012.

During the last take-back day held on April 28, 2012, DEA's partners and law enforcement agencies collected 552,161 pounds (276 tons) of unwanted or expired medications at more than 5,600 take-back sites nationwide. This take-back day and the DEA's three other take-back events have added up to more than 1.5 million pounds of medication that have been removed from circulation.

"While a uniform system for prescription drug disposal is being finalized, we will continue to sponsor these important take-back opportunities as a service to our communities," said DEA Administrator Michele M. Leonhart. National Prescription Drug Take-Back Day is important, according to DEA, because a majority of abused prescription drugs are obtained from family and friends, often from medicine cabinets at home.

Notes From Inspectors

Below are scenarios that have been repeatedly noticed by Board inspectors. If you have questions, please contact your inspector or the Board office.

1. Carisoprodol: most everyone is aware that this is a controlled substance (C-IV), but not everyone has conducted a baseline inventory. This should have been done on January 11, 2012.
2. Combat Meth Certificate: remember to check the expiration date.
3. If there is a change of PIC, remember to complete a count of controlled substances and have both (former and new) PICs sign off.
4. Reverse Distributor: if you are using a reverse distributor for processing returns, remember they need to be licensed with the Board of Pharmacy.
5. Sterile Compounding Practices: remember that hoods should be inspected every six months now. Also, your multiple dose vial outdate policy should be 28 days.
6. Random controlled substance inventory audits should be conducted at more frequent intervals. Starting inventory points can be estimated for containers with less than 1,000 tablets; however, if a variance is recognized, accurate starting inventory counts from the last random audit or the biennial inventory should provide better results.
7. It has been noticed that the technician to pharmacist ratio (2:1) in some locations is not being complied with. A 3:1 ratio can be considered under ARSD 20:51:29.02 as long as your pharmacy meets the requirements stated in the rule. This request must be presented and approved by the Board prior to implementation.

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.

Prescription Drug Monitoring Program Update

South Dakota pharmacies and nonresident pharmacies licensed by the Board have been very responsive in complying with the requirement to submit prescription information to the South Dakota PDMP. Indian Health Service pharmacies in South Dakota are also submitting data. As of May 30, 2012, there are over 800,000 prescriptions in the database (2011 – 407,868; 2012 – 415,351). Many pharmacists have helped Board staff reach out to prescribers and encourage them to request online access. Currently 308 pharmacists and 333 prescribers have been approved to access the South Dakota PDMP database.

Top 10 Controlled Substances in South Dakota by Number of Doses Dispensed: January 1, 2012 to May 25, 2012

2012 Most Prescribed Drugs	No. of Prescriptions	Doses Dispensed	Average Doses/ Rx
Hydrocodone/ APAP	91,708	5,089,150	55
Clonazepam	23,638	1,459,284	62
Lorazepam	26,873	1,265,055	47
Oxycodone	13,464	1,117,253	83
Alprazolam	18,419	1,064,999	58
Zolpidem	32,744	1,037,898	32
Oxycodone/APAP	14,261	859,028	60
Methylphenidate	16,900	759,869	45
Amphetamine Salts	15,070	667,521	44
APAP/Codeine	12,536	481,743	38

Pharmacists are encouraged to use information from the South Dakota PDMP to assist in making well informed decisions when dispensing controlled drug prescriptions to patients. You may register for online access by visiting the following Web site: *www.hidinc.com/sdpmp.*

Please call the Board office if you have any questions about this very important program.

Board Meeting Dates

Please check the Board Web site for the time, location, and agenda for future Board meetings.

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Please read all *Newsletters* and keep them for future reference. The *Newsletters* will be used in hearings as proof of notification. Please contact the Board office at 605/362-2737 if you have questions about any article in the *Newsletter.* Past *Newsletters* are also available on the Board's Web site.

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