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Proper Medication Disposal

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In 2010, Montana ranked third in the nation for teen abuse of prescription pain medication. In response, the state started a program known as Operation Medicine Cabinet. This program provides information to the public on prescription drug abuse, statistics on who is using these medications and where they are getting them, and where people can dispose of expired or unwanted prescription drugs. It established a drop box system at local law enforcement agencies where people can dispose of their medications in a no-questions-asked setting during normal business hours.

The National Association of Boards of Pharmacy Foundation® (NABPF®) has developed a consumer protection program called AWARxE® to fight back against national prescription drug abuse and the increase in fake drugs available on Web sites. They provide medication safety information and news on prescription drug abuse and prevention, as well as news about recalls, drug shortages, and counterfeit drugs. They provide a list of online drugstores that have been accredited by the Verified Internet Pharmacy Practice Sites℠ (VIPPS®) program to document authenticity and help eliminate risks associated with shopping online for medications. According to the AWARxE Web site, approximately one in five teens has used prescription medication that was not theirs to help them "get high or deal with problems." Many surveys over the past decade have shown the general feeling among young people to be that prescription drugs are safer than street drugs because a doctor legally prescribed them. Unfortunately, emergency room visits for misuse and abuse of pharmaceuticals increased by 98.4% from 2004 to 2009.

On October 12, 2010, President Obama signed the Secure and Responsible Drug Disposal Act (S 3397) into law. This act allowed for the promulgation of new rules that will allow for the return of controlled substances. In Montana, pharmacies and other places people want to return medication to, such as drop boxes that have been set up at a number of police departments, are not allowed to accept returned medication, especially controlled substances. By law, a take-back program for these medications must be authorized by the Attorney General and have a member of law enforcement present if any controlled medications are present. Shortly after this act was passed, Drug Enforcement Administration (DEA) launched the National Take-Back Initiative and the SMARxT Disposal program was developed through a partnership between the United States Fish and Wildlife Service, the American Pharmacists Association, and the Pharmaceutical Research and Manufacturers of America. These two programs are designed to promote awareness and provide an opportunity for people to fight back against the prescription drug epidemic and properly dispose of their medications. At the fourth take-back day held on April 28, a record-breaking 276 tons of unwanted or expired medication was disposed of, which brings the combined total of all four take-back days to 774 tons. This emphasizes the sheer amount of medications sitting in homes across the country and the need for education and a continuation of current disposal programs. The next DEA national take-back day is scheduled for September 29, 2012. For more information visit *www.deadiversion.usdoj.gov/drug_disposal/takeback/*.

Many patients refer to their daily medications by its appearance, such as "the little blue round one," rather than the medication name or what it is used for. These same patients, when questioned during counseling, may not know why they are taking it. This blind acceptance of medications is troubling. If patients do not know what medications they are currently taking and what is sitting at home unused in their medicine cabinets, they do not understand the risks. In 2008 and 2009, approximately 50% of people who abused prescription medications obtained them from friends and family according to the AWARxE Web site. With prescription drug abuse at an all-time high, awareness is starting to increase about abuse, but there is a great need for patient education on the importance of taking responsibility for those medications sitting at home, whether leftover or part of a current regimen. It is important to continue to emphasize that patients should keep the medication sitting at home safe and locked away under proper storage conditions so they will not freeze or overheat.

How can people safely dispose of the medications leftover in their medicine cabinets? There are several resources available with this information. The following is a summary of information from these sources:

- There are local medication disposal programs in the state of Montana. Areas with higher populations have drop boxes set up at local law enforcement offices/buildings. For example, Gallatin County has a drop box in the Gallatin County Justice Department. A comprehensive list of these locations is available on the Montana Department of Justice's Operation Medicine Cabinet Web site: *https://doj.mt.gov/prescriptiondrugabuse/operation-medicine-cabinet/*.
- Food and Drug Administration (FDA) provides information to consumers on procedures to safely and properly dispose of their medications. The following steps are a summary of their instructions for "home disposal":
  1. Check the label or package insert for the medication for specific directions on safe disposal.
  2. Do not flush down the toilet unless it is clearly marked safe to do so. A list of medications that can be flushed is available on the FDA Web site.
  3. If there are not any specific directions, take the medication out of its original container. Mix it with an undesirable substance,

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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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most often coffee grounds or cat litter, then seal the container and place in the garbage.

- The Environmental Protection Agency both warns and encourages people to check with their local waste management to verify that disposal of their medications in the garbage is legal in their area. Some state laws are much stricter and more specific on home medication disposal guidelines.

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Montana Prescription Drug Registry Update

The Montana Prescription Drug Registry (MPDR) began accepting prescription data from pharmacies on March 12, 2012. As of June 1, the MPDR has over 650,000 prescriptions in its database, and more are being added every day. MPDR software developers have worked hard to get the bugs out of its new system, and have also worked closely with those pharmacies that had trouble getting their data into the ASAP 4.1 format. The Montana Board of Pharmacy is happy to say that this process was fairly complete by late June and wants to say, "thank you!" to each of the pharmacy staff people and software vendors who have been so patient with the sometimes-bumpy system implementation.

As soon as the last few kinks in the data submission system have been resolved, MPDR software developers will be able to finalize the next phase of the MPDR. These features will include:

- Online application for permission to search the database. Prescribers, pharmacists, and representatives of approved government agencies, such as Medicare, Medicaid, and Indian Health Service (IHS), will be able to apply for online access to the MPDR database.
- Online searching of patients' controlled substance prescription history. This powerful tool will be available to those individuals whose online access application is approved. The MPDR's search screen can help you identify patients who may be receiving controlled substances prescriptions from other practitioners.
- Prescribers will also be able to search their own prescribing history. Providers in several states whose drug registries offer this feature have successfully identified prescription forgeries simply by reviewing their own history.
- The MPDR will be able to accept data from unlicensed pharmacies such as those affiliated with IHS or the Veterans Administration. While these facilities are not required to report to the MPDR, they are eager to share their valuable information with other health care providers who may treat their patients.

The Board anticipates that these features should be available for use early this fall. Everyone who is eligible for online search access will be notified by mail when the database is ready for you to register. Educational material will be included with the mailing, and all applicants will be required to complete a brief online training program before registering.

Other features the Board hopes to implement during the late fall or early winter include:

- The ability for MPDR staff to generate reports for law enforcement and licensing boards' compliance programs. These individuals will be required to submit a paper application and supporting documentation to the MPDR before receiving a report.
- Administrative and statistical reporting capabilities for MPDR staff.
- Provide prescribers and dispensers with an online portal that allows them to pay the required $15 annual fee. This fee is not tied in to your license renewal, and must be paid separately. The Board will notify everyone by mail when it is time to pay this fee, and the Board expects to begin that process in the late months of 2012.

Additional features of the MPDR that will be implemented in 2013 include:

- Unsolicited reporting. These reports, generated by the MPDR, will identify patients who have received an unusual number of controlled substances, and will be delivered to all prescribers and pharmacists who have been involved in that patient's care.
- Sharing data with prescription drug registries in other states. Montana and its neighboring states have a population that often crosses state borders to obtain medical care. Once this feature is implemented, you will be able to see whether your patient has obtained a controlled substance from a provider in another state.

As you can see, the MPDR is a work in progress. Please check the Board's Web site to obtain the most current status at *www.Pharmacy.mt.gov* and click on the Drug Registry tab.

New Board Member

Governor Brian Schweitzer has appointed Marian Jensen of Butte, MT, as the new public member of the Board. Ms Jensen replaces Susan Hagen, whose term expires on July 1, 2012. Her term on the Board is July 1, 2012 to July 1, 2017.

Bio – Marian Jensen

A former college dean of students, Marian Jensen came to Montana in 1999. Following a 30-year career as an educator, she has served in numerous volunteer capacities in Butte, most recently as a volunteer coordinator for the Montana Folk Festival and as a member of the State Executive Board of the Montana Democratic Party. She is a former member of the board of the Butte Education Foundation, and the Montana Standard editorial board.

She holds a doctorate in education from West Virginia University, a master's in counseling from the University of Cincinnati, and a bachelor's degree in English from Centre College of Kentucky.

She has worked as a teacher, a counselor, and an administrator. While in Butte, she has taught as an adjunct at Montana Tech of the University of Montana. In her spare time, she has written four mystery novels, as yet unpublished.

Her husband is a faculty member at Montana Tech of the University of Montana in occupational safety and industrial hygiene, and her daughter, a former pharmacy technician, is an industrial hygienist in Portland, OR.

The *Montana Board of Pharmacy News* is published by the Montana 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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