August 2012

Oregon State Board of Pharmacy News

Published to promote compliance of pharmacy and drug law

800 NE Oregon St, Suite 150 • Portland, OR 97232

No. 506: Drug Disposal Sites

Drug disposal sites for consumers sponsored by the various law enforcement agencies are springing up around the state. The list was updated in June 2012 and is updated periodically as new sites are added and existing sites closed. You can find the most current updated list on the Oregon State Board of Pharmacy Web site at *www.pharmacy.state.or.us* under *Topics of Interest: Law Enforcement Drug Disposal Sites* or go directly to *www.pharmacy.state.or.us/Pharmacy/Imports/ORUnwantedDrugDropOffSites.pdf.*

Pharmacies should be familiar with this list. Keep it handy and be prepared to provide the list or information on how to access the list to patients and customers when appropriate.

No. 507: New Board Members

Two new Board members have been appointed by Governor John Kitzhaber. **Roberto Linares** is a pharmacist and is on the faculty at the Oregon State University (OSU) College of Pharmacy. He has extensive experience in community retail pharmacy practice. Having graduated with a bachelor of science degree in pharmacy from OSU in 1991, Mr Linares has worked for Bi-Mart in Cottage Grove, OR, and in Monmouth, OR. In 2004 he accepted the position of pharmacy practice instructor at his alma mater. He has continued his community practice part-time doing relief staffing for several community pharmacies and medical clinics. Mr Linares is a member of the American Pharmacists Association and the American Association of Colleges of Pharmacy where he served as OSU College of Pharmacy's delegate to last year's annual conference. His term on the Board began July 1, 2012.

Brad Fujisaki is a pharmacist on the faculty at Pacific University College of Health Professions School of Pharmacy. He is a graduate of the 1999 OSU College of Pharmacy with a bachelor of science degree in pharmacy and received his PharmD degree from the University of Colorado – Denver Health Sciences Center in 2008. Dr Fujisaki completed a general residency at the Portland VA Medical Center in 2001 and a specialty residency at the Oregon Health and Science University (OHSU) Hospitals and Clinics in 2002. He held the position of information systems pharmacist at OHSU prior to taking his current full-time position as assistant professor at Pacific University in 2006. His term also began July 1, 2012.

These new appointees are assigned to serve four-year terms on the Board and are eligible for reappointment at the end of this term. They replace the very active and now outgoing pharmacist Board members Ann Zweber of OSU and Larry Cartier of Wellpartner, both of whom finished their terms June 30, 2012.

No. 508: Pharmaceutical Manufacturer and Wholesaler Registration Fee

As most pharmacists and technicians will remember, the Board raised license fees in 2011 for pharmacists, technicians, and pharmacies with its operating budget. At that time, the Board's budget presentation included a two-part fee increase, which would raise certain fees in 2011 and certain others in 2013. As the staff prepares for the 2013 budget presentation, the second phase of the fee increase is being put into motion. That is, fees for the pharmaceutical manufacturing and wholesale drug outlets will be proposed for increase in 2013.

Organizations representing the manufacturers and wholesalers were recently notified of the Board's intent. A memo was sent to these organizations on June 18, 2012, with the following message:

> . . . The Oregon Board of Pharmacy established the present registration fees in 2001. The fee increase is needed as a result of recent modernization of administrative rules, increased compliance matters over the past several years required to ensure the integrity, security and safety of drugs and prescription devices distributed into or within Oregon and eleven years of inflation.
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> Costs associated with the investigations and staffing for the regulation of manufacturing and wholesale drug outlets continue to increase. In order to continue to maintain the same level of oversight, protection and regulation, a registration fee increase is included with the Board's 2013-2015 proposed budget, to be considered by 2013 Legislature. If authorized, the annual, registration fee for manufacturing and wholesale drug outlets will increase from $400 to $800. If the proposed budget is approved,

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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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the formal public rulemaking process to implement the fee increase will be conducted following the legislative session.

Please note that fee increases for all other categories were implemented in 2011. It was determined at that time that increases for manufacturers and wholesalers, also necessary to ensure sustainability for the agency, would be delayed until the 2013 budget cycle.

If you have questions about this notice, contact the Board by e-mail at: pharmacy.board@state.or.us.

No. 509: Veterinary Prescriptions

By Terese DeManuelle, DVM. Dr DeManuelle is a board-certified veterinary dermatologist and is the owner of Allergy & Dermatology Veterinary Referral Center in Milwaukie, OR.

An increasing number of veterinarians have serious concerns that some community pharmacists have changed veterinary prescriptions: directing the veterinary client to a different drug, changing the prescribed dosage, or advising the client to lower a drug's dosage.

The community pharmacists lowering the dosage of thyroid medications is perhaps the most common problem we have encountered. But we also have learned of a community pharmacist who counseled a client to lower the dosage of phenobarbital for an epileptic dog and another who switched insulin for a diabetic cat even though the prescribed insulin and the redirected insulin were not interchangeable. When instances like this occur, several things happen:

1. The veterinary patient receives a drug not indicated for the animal's condition or sub-therapeutic treatment for the condition, very possibly jeopardizing – and at times seriously compromising – the animal patient's health.
2. Because an animal may receive sub-therapeutic treatment due to a community pharmacist's decision, the dog or cat might have to be on the medication for an additional period of time – all at extra cost to the veterinary client.
3. The community pharmacist's message to the veterinary client is that the veterinarian does not know what he or she is doing (ie, often overmedicating the patient – when, in fact, it is the community pharmacist who lacks the sufficient clinical knowledge and understanding of an animal's physiological reaction to drugs to determine which drug and/or dosage is most appropriate for the patient).

It is important for community pharmacists to understand that cats and dogs are not little people. I know, this sounds so simple – and reasonable. But our experience as veterinarians tells otherwise – that some community pharmacists are not making the connection that most animal patients are able to accept a higher dosage of a drug than human patients.

If you have a concern about a drug prescribed by a veterinarian, please call the prescribing veterinarian and ask for clarification about the prescription. We are available to discuss any concerns with you, as we want to ensure that our patients receive the best and most appropriate treatment they need and deserve. You should only change drugs and/or the medication's dosage after fully discussing the issue with the veterinarian and obtaining his or her authorization. This is best for the veterinary patient and best for the animal's owner.

Editorial Comment: *Board of Pharmacy staff has been in contact with the Oregon Veterinary Medical Association, the American Veterinary Medical Association, and the Oregon Veterinary Medical Examining Board to discuss this issue. So far, no formal complaint has been received by the Board against an Oregon pharmacist for inappropriately changing a veterinary prescription or advising a veterinary client.*

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