

July 2012



North Carolina Board of Pharmacy

News

Published to promote compliance of pharmacy and drug law

6015 Farrington Rd, Suite 201 • Chapel Hill, NC 27517 • Tel: 919/246-1050
Fax: 919/246-1056 • www.ncbop.org

Item 2241 – Board Welcomes New Members Carol Day and Bill Mixon, Bids Farewell to Betty Dennis and Rebecca Chater

This May saw significant transition at the North Carolina Board of Pharmacy. The Board welcomed new members Carol Yates Day of Carrboro, NC, and William A. “Bill” Mixon of Hickory, NC. As reported in Item 2223 of the July 2011 *Newsletter*, pharmacists in the state elected Mrs Day and Mr Mixon last spring as the Board representatives from the Northern and Western Districts, respectively. After a year of learning more about the Board and their roles as Board members, Mrs Day and Mr Mixon were commissioned by Governor Bev Perdue on May 1, 2012.

Simultaneously, Betty Dennis and Rebecca Chater completed their 10 years of superlative service to the Board and the citizens of North Carolina. Board members and staff bid Dr Dennis and Mrs Chater a fond farewell, with tremendous gratitude for their service.

The next Board elections will take place in spring 2014.

Item 2242 – Gene Minton to Serve as Board President for 2012-2013; Lazelle Marks to Serve as Board Vice President

At the Board’s May 2012 meeting, the members selected Gene Minton to serve as Board president and Lazelle Marks to serve as Board vice president. Messrs Minton and Marks will serve in these capacities until May 2013.

Item 2243 – Updates on the Board of Pharmacy Web Site

Pharmacists are reminded that Board staff frequently post alerts, frequently asked questions guidance, and other information on the Board Web site at www.ncbop.org.

The Web site’s Frequently Asked Questions section was recently revised and reorganized. All Board Web site

content is searchable by keyword, and keyword searches can be channeled to specific categories such as Board agendas, *Newsletters*, disciplinary actions, and rules/laws. Finally, the Board Web site is RSS feed enabled, so pharmacists have the ability to receive notices each time new content is added to the site.

As always, Board staff welcomes your suggestions for Web site content.

Item 2244 – Reminder Concerning Payment of Board Fees

Effective May 1, 2012, the Board ceased accepting checks and American Express as forms of payment. All holders of licenses, permits, and registrations (or applicants for them) should make any necessary adjustments.

Item 2245 – Donation and Redispensing of Certain Prescription Drugs

In certain circumstances, North Carolina law (N.C.G.S. §90-85.44) and Board rule (21 N.C.A.C. 46.2513) permit the donation and redispensing of some prescription drugs. In response to questions about the scope and operation of drug donation programs in North Carolina, Board staff developed a Frequently Asked Questions document, which may be found at www.ncbop.org/faqs/Pharmacist/FAQDrugSuppliesMedicalDeviceRespositoryProgr.pdf.

Pharmacists are encouraged to familiarize themselves with the opportunities and requirements for drug donation. The North Carolina Association of Free Clinics can provide assistance to pharmacies seeking a free or charitable clinic with whom to partner.

Item 2246 – Update on Electronic Controlled Substance Prescribing Systems

Board staff have seen an uptick in the number of inquiries about the status of electronic prescribing for

continued on page 4



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 pre-

scriptions. 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-

Compliance News

Compliance News to a particular state or jurisdiction should not be assumed as representing the law of such state or jurisdiction.)



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 AWARE_xE[®] 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 AWARE_xE Web site at www.awarerx.org/OTCMedUse.php. The AWARE_xE consumer protection program and the National Association of Boards of Pharmacy[®] (NABP[®]) are part of the Acetaminophen Awareness Coalition.



Pharmacists & Technicians:
Don't Miss Out on Valuable CPE Credit.
Set Up Your NABP e-Profile and Register for CPE Monitor Today!

CPE Monitor™ integration is underway. Soon all Accreditation Council for Pharmacy Education (ACPE)-accredited providers will require you to submit your NABP e-Profile ID, assigned when you set up your NABP e-Profile, along with your date of birth (MMDD), in order to obtain continuing pharmacy education (CPE) credit for any ACPE-accredited activity. Many have already begun to do so.

Visit www.MyCPEmonitor.net to set up your e-Profile and register for CPE Monitor and avoid possible delays in your CPE reporting.

CPE Monitor is a national collaborative service from NABP, ACPE, and ACPE providers that will allow licensees to track their completed CPE credit electronically.

continued from page 1

controlled substances. As a refresher, Drug Enforcement Administration (DEA) promulgated a rule in June 2010 that would allow the prescribing of all schedules of controlled substances electronically. That rule also provided, however, that any system for the **transmission or receipt** of electronic controlled substance prescriptions must be certified by DEA or a DEA-authorized entity as meeting the significant security requirements in that rule. Surescripts recently provided information to boards of pharmacy indicating that several transmitting and receiving systems for electronic controlled substance prescriptions have now been certified as compliant with the DEA rule. Visit www.ncbop.org/PDF/SurescriptsEPCSUpdate051712REVISED.pdf for more information.

Pharmacies are strongly advised to continue checking with their software vendors to determine whether and when your system is certified as DEA-rule compliant.

Page 4 – July 2012

The *North Carolina Board of Pharmacy News* is published by the North Carolina 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.

Jack W. “Jay” Campbell IV, JD, RPh - State News Editor
Carmen A. Catizone, MS, RPh, DPh - National News Editor
& Executive Editor

Larissa Doucette - Communications Manager
