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News

North Carolina Board of Pharmacy

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Item 2300 – Voting for Board Member Election for Southeastern District Opens April 15, 2015

As reported in the January 2015 *Newsletter,* the next North Carolina Board of Pharmacy election will take place in April and May 2015. One position on the Board will be filled: the Southeastern District seat presently held by Robert (Joey) McLaughlin. Mr McLaughlin will complete his second consecutive five-year term on April 30, 2016, and as a result, is term-limited.

Nominations were open through March 15, 2015. Please monitor the Board's website for candidates' names and biographies, which will be posted in early April.

Voting will run from April 15 through May 15. All pharmacists living in North Carolina and actively licensed as of March 15, 2015, will be eligible to vote. Just as in years past, eligible voters will log into the Board's secure site using their license number and personal identification number to cast their vote.

Voting closes on May 15, and votes will be tallied immediately following. Provided that a run-off election is not needed, results will be certified at the Board's June 16 meeting. Any necessary run-off election will be held in late May/early June 2015.

Please contact Jack W. "Jay" Campbell IV or Kristin Moore at the Board office if you have questions about the election process.

Item 2301 – Proper Identification of Compounding Risk Levels and Notification to the Board

Pharmacies that hold a permit from the Board and that engage in any type of compounding are required to notify the Board. Such pharmacies must report (both on an initial permit application and as part of each annual renewal): (1) whether the pharmacy compounds; (2) a good-faith estimate of the percentage of the pharmacy's dispensing that involves compounded products; (3) whether the pharmacy engages in nonsterile compounding; (4) whether the pharmacy engages in sterile compounding; and if so, (5) what risk level of sterile compounding, as defined by United States Pharmacopeia Chapter <797>, the pharmacy performs.

Accurate reporting of this information is crucial for at least two reasons. First, failure to provide accurate information in connection with seeking or renewing a permit is grounds to revoke or void a pharmacy permit (NCGS §90-85.38). Second, the Board's risk-based inspection intervals are driven by the scope and type of service provided at a pharmacy, particularly compounding services.

In at least one recent case, a pharmacy reported that it was only engaged in low-risk sterile compounding. An inspection showed that the pharmacy was, in fact, engaged in high-risk sterile compounding. Such misreporting is a serious issue, and will be treated as such.

In an effort to reduce any confusion concerning this reporting requirement, Board staff has developed a guidance document, which may be found at *www.ncbop.org/PDF/CompoundingRiskLevelsandCategoriesMar2015.pdf.*

Item 2302 – Voting for Election for Rehabilitation Technology Supplier Seat on the Device and Medical Equipment Subcommittee Opens in June

In June 2015, the Board's Device and Medical Equipment (DME) Subcommittee will hold an election for the Rehabilitation Technician Supplier representative seat. This seat is presently held by DME Subcommittee Member Edward Dressen, who is eligible to run for a second term.

continued on page 4

FDA's New Database Simplifies Searching for Guidance Documents

Food and Drug Administration (FDA) has released a new database that houses most FDA guidance documents for regulatory professionals. The guidance documents for nearly all FDA-regulated professions and industries are available in a searchable database that allows users to enter keywords that update automatically as they are typed. Search results may also be narrowed by product, date, document type, and other terms. The database also indicates whether there is an open comment period and the deadline for submitting comments.

The database can be accessed at *www.fda.gov/RegulatoryInformation/Guidances/default.htm.*

2014-2015 Targeted Medication Safety Best Practices for Hospitals

This column was prepared by the Institute for Safe Medication Practices (ISMP). ISMP is an independent nonprofit agency and federally certified patient safety organization 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 provides legal protection and confidentiality for submitted patient safety data and error reports. Help others by reporting actual and potential medication errors to the ISMP National Medication Errors Reporting Program Report online at* www.ismp.org. *Email: ismpinfo@ismp.org.*

The purpose of the Targeted Medication Safety Best Practices (TMSBP) for Hospitals is to identify, inspire, and mobilize widespread, national adoption of consensus-based best practices on specific medication safety issues that continue to cause fatal and harmful errors in patients despite repeated warnings in ISMP publications. These best practices are realistic practices, already adopted by many organizations, upon which hospitals can focus their medication safety efforts. The best practices are applicable to all types of hospitals including, but not limited to, critical access hospitals, cancer hospitals, and children's hospitals. They may also be applicable to other health care settings, as well as non-inpatient areas of hospitals and hospital systems. These best practices have been reviewed by an external expert advisory panel and approved by the ISMP Board of Trustees. Related issues of the *ISMP Medication Safety Alert!* are referenced after each best practice.

Recurrent Issue of Serious Harm

Oral methotrexate for non-oncological indications administered daily instead of weekly or twice weekly is a recurrent issue and one of the six TMSBPs.

ISMP has published this error in seven *ISMP Medication Safety Alert!* issues from 1996 to 2013. Although dosed daily for oncology purposes, it is used weekly or twice weekly to treat a variety of autoimmune diseases (eg, psoriasis, severe rheumatoid arthritis). Error reports point to inadvertent ordering and/or entering as daily instead of weekly or twice weekly, and lack of patient education/understanding of medication dosing schedule. To minimize the risk of error, **Best Practice 2** calls for hospitals to:

a) Use a weekly dosage regimen default for oral methotrexate. If overridden to daily, require a hard stop verification of an appropriate oncologic indication.

b) Provide patient education by a pharmacist for all weekly oral methotrexate discharge orders.

Question: Does the best practice of a weekly frequency default for oral methotrexate apply to a specialty cancer hospital?

Answer: The intent of this best practice is to reduce errors when methotrexate is prescribed as a weekly regimen for non-oncologic or oncologic indications. Even when used for oncologic purposes, oral methotrexate is sometimes prescribed as a weekly regimen, not daily. Thus, this best practice applies to all patient care settings, including specialty cancer hospitals.

Teaching Points (Both Verbal and Written)

- Explain the weekly dosing schedule.
- Explain that taking extra doses is dangerous.
- Have the patient repeat back the instructions.
- Provide the patient with the free ISMP high-alert medication consumer leaflet on methotrexate (found at *www.ismp.org/AHRQ/default.asp).*

To read all of the best practices, visit *www.ismp.org/Tools/BestPractices/default.asp.*

ACPE Releases Updated Definition of CPE and Guidance on CPD

The Accreditation Council for Pharmacy Education (ACPE) has released two documents that provide guidance and support for continuing pharmacy education (CPE) and continuing professional development (CPD). The two documents, approved by the ACPE board of directors, are described below.

- The revised *Definition of Continuing Education for the Profession of Pharmacy* defines the quality of CPE required by ACPE and the competencies required for CPE activity content. The *Definition* document will assist providers of CPE in planning activities that will be applicable to the professional development of pharmacists and certified pharmacy technicians.
- The *Guidance on Continuing Professional Development (CPD) for the Profession of Pharmacy* incorporates feedback from a broad survey of the pharmacy profession that was conducted in July 2014. The *Guidance* document provides details on the learning activities that may contribute to the professional development of both pharmacists and pharmacy technicians beyond CPE, and also "provides a process for pharmacists and pharmacy technicians to meet and maintain defined competencies in areas relevant to their respective professional responsibilities."

Additional information, including links to the documents, is available in a press release on the ACPE website at *www.acpe-accredit.org/pdf/ACPEAdvancesCPE-CPDforPharmacists.pdf.*

Hospira Issues Recall for Multiple Lots of Ketorolac Tromethamine Injection Due to Potential Contamination

Hospira, Inc, of Lake Forest, IL, has issued a voluntary recall of ketorolac tromethamine injection, USP in the United States and Singapore due to potential particulate matter. The presence of particulate was confirmed through a customer report of visible floating particulate that was identified as calcium-ketorolac crystals. If in-

jected, medications contaminated with particulate matter may cause localized inflammation, allergic reaction, granuloma formation, or microembolic effects. Multiple lots are impacted by this recall and are listed in a press release posted to the FDA website at *www.fda.gov/Safety/Recalls/ucm433857.htm*. The lots were distributed from February 2013 to December 2014 in the US. To date, there have been no cases of adverse events associated with this medication. Adverse reactions may be reported to FDA's MedWatch Safety Information and Adverse Event Reporting Program.

FDA Warns of Counterfeit Cialis Tablets Entering the US

Potentially dangerous, counterfeit versions of Cialis® 20 mg tablets were intercepted in the mail before reaching a US consumer, warns FDA. Laboratory analysis of the counterfeit product showed that it contained multiple active ingredients that could lead to adverse effects or harm if used, indicates an FDA Drug Safety Announcement. The agency reminds US consumers to only buy prescription medications from state-licensed pharmacies located in the US. FDA notes that it cannot confirm that the manufacturing, quality, storage, and handling of products ordered from unlicensed websites follow US standards because the products are from an unknown source.

To help consumers identify these counterfeit medications, FDA provides guidelines in the safety announcement. For example, these counterfeits list "AUSTR81137" on the front of the bottle and lack a National Drug Code number. Other possible identifiers include misspellings and unusual colors on the label, and a manufacturer listed as "112 Wharf Road, WEST RYDE, NSW 2114" on the side of the bottle.

To date, FDA is not aware of any adverse events associated with these counterfeit medications; however, consumers are encouraged to talk to a health care provider about their condition and options for treatment if a counterfeit product was received.

The National Association of Boards of Pharmacy® (NABP®) has reviewed more than 10,900 websites selling prescription drugs to patients in the US and found that nearly 97% are operating out of compliance with pharmacy laws and practice standards established to protect the public health. To help consumers in the US find the safest sources for purchasing medications online, NABP developed the Verified Internet Pharmacy Practice Sites® (VIPPS®) program. NABP encourages consumers to look for the VIPPS Seal and to check NABP's list of accredited sites on the AWAR$_x$E® Prescription Drug Safety Program website. In addition, consumers may soon watch for pharmacy sites using the newly launched .pharmacy Top-Level Domain; sites in the domain (with a website address ending in .pharmacy) will be reviewed by NABP and approved only if they are legitimate online pharmacies or pharmacy resources adhering to applicable pharmacy laws and best practices.

Additional details on the counterfeit Cialis are available in a Drug Safety Announcement posted to the FDA website at *www.fda.gov/Drugs/DrugSafety/ucm431071.htm*. More information on VIPPS and other NABP programs is available in the Programs section of the NABP website, *www.nabp.net*.

New FDA Drug Info Rounds Training Videos Review Drug Disposal and REMS

FDA Drug Info Rounds, a series of online videos, provides important and timely drug information to practicing clinical and community pharmacists so they can help patients make better decisions. The latest Drug Info Rounds videos are as follows.

- In "Disposal of Unused Medicines," pharmacists discuss how consumers can safely dispose of expired or unused medications to prevent abuse or misuse and accidental poisoning.
- In "REMS," pharmacists discuss the many components of Risk Evaluation and Mitigation Strategies (REMS) and how they can help manage a drug product with known or potential serious risks.

Drug Info Rounds is developed with contributions from pharmacists in FDA's Center for Drug Evaluation and Research, Office of Communications, Division of Drug Information. These videos and previous Drug Info Rounds resources are available on the FDA website at *www.fda.gov/Drugs/ResourcesForYou/HealthProfessionals/ucm211957.htm*.

FDA Issues New Drug Labeling Rules to Benefit Pregnant, Breastfeeding Women

FDA announced new prescription drug labeling requirements that will clarify how medications might affect women who are pregnant or breastfeeding and men and women of reproductive potential. The final "Content and Format of Labeling for Human Prescription Drug and Biological Products; Requirements for Pregnancy and Lactation Labeling Rule" removes the previously used pregnancy letter categories – A, B, C, D, and X – and places information into three main categories:

- **Pregnancy:** Labor and delivery guidelines now fall under this category, which also now includes information for pregnancy exposure registries. Such registries track data on the effects of certain approved medications on pregnant and breastfeeding women.
- **Lactation:** Previously labeled "Nursing Mothers," this category provides information such as how much drug is secreted through breast milk and the potential effects on a breastfed infant.
- **Females and Males of Reproductive Potential:** This is a new category that includes information on how a certain medication might affect pregnancy testing, contraception, and infertility.

The new labeling changes go into effect on June 30, 2015. Over-the-counter medication labels will not be affected. The new rules are available for download through the *Federal Register* at *https://s3.amazonaws.com/public-inspection.federalregister.gov/2014-28241.pdf*.

FDA Approves Zohydro ER With Abuse-Deterrent Properties

In February 2015, FDA approved a new formulation of Zohydro® ER with abuse-deterrent properties. The new formulation uses a technology that allows the drug to maintain its release properties when used as intended, according to a press release from Zogenix. The abuse-deterrent system, known as BeadTek, incorporates "pharmaceutical excipients" that create a viscous gel when the medication is crushed and dissolved in a liquid or solvent, thus making the product more difficult to abuse through methods that involve crushing, breaking, or dissolving the drug. In early 2014, Zohydro ER became the first extended-release, single-ingredient hydrocodone product to receive approval for use in the US. Approval of the drug came under criticism, with some organizations arguing that the potential for addiction, abuse, and misuse could outweigh therapeutic benefits, in part because the drug lacked abuse-deterrent properties. Zogenix indicates that transition to the new abuse-deterrent formulation will take place in second quarter 2015.

Additional information on the new formulation is provided in a press release available on the Zogenix website at *http://ir.zogenix.com/phoenix.zhtml?c=220862&p=irol-newsArticle&cat=news&id=2012326*.

continued from page 1

The Rehabilitation Technician Supplier representative must practice in the particular area for which he or she is nominated, but need not practice exclusively in that area. As of this writing, the nomination period (which runs through April 1, 2015) is open.

All North Carolina DME permit holders residing in the state as of March 15, 2015, are eligible to vote. As in past years, voting will be electronic; a DME person-in-charge will log into his or her individual Board account to cast an electronic ballot. More details, including instructions for requesting a paper ballot if preferred, will follow in the coming weeks.

Item 2303 – Guidance on the Federal Drug Quality and Security Act

North Carolina pharmacists are aware that in November 2013, the federal Drug Quality and Security Act (DQSA) became effective. Board staff periodically receives questions about DQSA's operation. To assist, a guidance document is available at *www.ncbop.org/faqs/Pharmacist/faq_DQSA.htm*. This guidance document will be updated periodically.

Item 2304 – Public Hearing on Proposed Amendments to Rule 21 NCAC 46.3301 Governing Technician Registration Scheduled for Tuesday, May 12, 2015

The Board has published proposed amendments to the technician registration rule (21 NCAC 46.3301) to improve conformity to the statutory requirements of NCGS 90-85.15A, as well as address technician registration requirements at free and charitable pharmacies. A public hearing will be held on May 12, 2015, at 9 AM at the North Carolina Board of Pharmacy Office, located at 6015 Farrington Road, Suite 201, Chapel Hill, NC 27517.

The Board welcomes comment on the proposed amendment. Any person may comment on the proposed amendment by attending the public hearing on May 12, 2015, and/or by submitting a written comment by 9 AM on May 12, 2015, to Jay Campbell, executive director, North Carolina Board of Pharmacy, 6015 Farrington Road, Suite 201, Chapel Hill, NC 27517; by fax to 919/246-1056; or by email to jcampbell@ncbop.org.

More information, including the text of the proposed amendments, is found at *www.ncbop.org/rulemakings.htm*.

Item 2305 – Substitution of Extended Release Methylphenidate Products

Pharmacists are aware that Food and Drug Administration (FDA) changed the "Orange Book" equivalency rating of extended release methylphenidate products manufactured by Mallinckrodt and Kudco from "AB" to "BX" due to concerns about bioequivalence with Janssen Pharmaceuticals' Concerta® product. More details concerning FDA's action, the reasons for it, and the consequences are found at *www.fda.gov/drugs/drugsafety/ucm422569.htm*.

Note further that Janssen Pharmaceuticals manufactures an "authorized generic" of Concerta, which is marketed by Actavis under a licensing agreement. Actavis' product is not marketed under the Concerta name, but it is identical to Janssen's Concerta. FDA's "Orange Book" rating change does not apply to the Actavis product.

Board staff has received questions as a result of the FDA action. A guidance document is available at *www.ncbop.org/PDF/CONCERTA_METHYLPHENIDATE_FAQ.pdf*.

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