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Item 2306 – Board Member Election for Southeastern District

At the time of this writing, the election for the Southeastern District North Carolina Board of Pharmacy membership was in a run-off between Andy Bowman and Jennifer Buxton. By the time of the *Newsletter's* publication, either Dr Bowman or Dr Buxton will have been certified as the Board's Southeastern District member-elect, with a five-year term to commence on May 1, 2016.

The general election for the Southeastern District membership seat took place between April 15 and May 15, 2015. Six candidates vied for election. Board members and staff thank each of the candidates for their interest and commitment to protection of the public health and safety. In addition to Drs Bowman and Buxton, the candidates were Ashley Abode, Lisa Ashworth, Henry Herring, and Mark Lyons.

During the general election, 2,162 votes were cast as follows.

Candidate Name	Vote Count	Percentage of Total
Ashley Abode	392	18.1%
Lisa C. Ashworth	293	13.6%
J. Andrew Bowman	558	25.8%
Jennifer Askew Buxton	406	18.8%
Henry Herring	400	18.5%
Mark Lyons	111	5.1%
None	2	0.1%
Total*	**2,162**	**100.0%**

Because no candidate garnered a substantial plurality (>40%) of the vote total, a run-off election among the two top vote recipients was available at the request of the second highest vote recipient. Dr Buxton requested a run-off. Voting in the run-off was scheduled to close on June 23, 2015, with the Board convening shortly afterward to review and certify the election results.

The next Board member elections are scheduled for spring 2016. Two district seats will be up for election: (1) the Western District, which consists of Alexander, Alleghany, Ashe, Avery, Buncombe, Burke, Caldwell, Catawba, Cherokee, Clay, Cleveland, Gaston, Graham, Haywood, Henderson, Jackson, Lincoln, Macon, Madison, McDowell, Mitchell, Polk, Rutherford, Swain, Transylvania, Watauga, Wilkes, and Yancey counties; and (2) the Northern District, which consists of Alamance, Caswell, Forsyth, Guilford, Orange, Person, Rockingham, Stokes, Surry, and Yadkin counties. These two seats are presently held by Board members Bill Mixon and Carol Yates Day, respectively.

Pharmacists interested in running for either the Western District or Northern District seats should feel free to contact Board staff. To be eligible, the candidate must be a licensed pharmacist residing in one of the counties that compose the district at the time of election. Board staff will host question-and-answer sessions in each district in early 2016. More information will follow on the Board's website in the coming months.

Item 2307 – Board Welcomes New Public Member Robert Graves

Governor Pat McCrory appointed Robert Graves to serve a five-year term as the public member of the Board beginning May 1, 2015. Mr Graves graduated from the North Carolina State Highway Patrol 68th Basic Patrol School in 1980, and served until his retirement in 2009 at the rank of lieutenant. During his career with the Patrol, he served in Orange, Forsyth, Cumberland, Randolph, and Guilford counties. His last assignment prior to retirement was Troop executive officer for Troop D Headquarters, Greensboro, NC. He was awarded The Order of the Long Leaf Pine in 2009, the Colonel's Certificate of Achievement, and the Advanced Law Enforcement Certificate.

After retiring from the Patrol, Mr Graves joined Randolph Community College as the director of safety and emergency preparedness.

Mr Graves is active in numerous church and community organizations and activities. He is a member of First Baptist Church in Asheboro, NC, where he serves as a deacon (past chairperson) and is a member of the Executive Council and the Adult Worship Choir. He is a member of the Randolph Rotary Club, where he is a past president (2012-2013), a Paul Harris Fellow, a Paul Harris Society member, and a

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Counterfeit Botox Found in the United States, FDA Warns

On April 16, 2015, Food and Drug Administration (FDA) alerted health care providers that a counterfeit version of Botox® was found in the United States and may have been sold to doctors' offices and clinics throughout the country. The counterfeit products may be identified by a missing lot number on the vial, missing information on the carton (next to LOT, MFG, and EXP), and a displayed active ingredient as "Botulinum Toxin Type A" instead of "OnabotulinumtoxinA." The counterfeit products were sold by an unlicensed supplier who is not authorized to ship or distribute drug products in the US, according to an FDA Drug Safety Alert. The agency advises health care providers to confirm that the distributor from which they purchase Botox is authorized by Allergan, the drug's manufacturer. No adverse events related to this product have been reported to FDA.

Medical practices that purchase and administer counterfeit, illegal, and unapproved medications from unlicensed or foreign sources are putting patients' health at risk, as patients may not be getting proper treatment, warns FDA. Wholesale drug distributors must be licensed in the states where they conduct business. Suspicious Botox products may be reported to FDA's Office of Criminal Investigations. More information is available on the FDA website at *www.fda.gov/Drugs/DrugSafety/ucm443217.htm*.

One way pharmacies can be assured of the legitimacy of a wholesale distributor is to look for the National Association of Boards of Pharmacy® (NABP®) Verified-Accredited Wholesale Distributors® (VAWD®) Seal. Wholesale distributors that achieve VAWD accreditation are in compliance with state and federal laws, as well as NABP's VAWD criteria. Wholesale distributors that display the VAWD Seal as part of their accreditation have undergone a criteria compliance review, including a rigorous review of their operating policies and procedures, licensure verification, survey of facility and operations, background checks, and screening through the NABP Clearinghouse. Accredited facilities are reviewed annually and undergo an on-site survey every three years. Created in 2004, the accreditation program plays a pivotal role in preventing counterfeit drugs from entering the US drug supply.

Seven Persistent Safety Gaffes in Community/Ambulatory Settings That Need to Be Resolved!

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.*

ISMP has been reflecting on the strength and resolve of many across the nation who have demonstrated an unparalleled commitment to keeping patients safe. Despite the many safety accomplishments in 2014, ISMP cannot help but mull over persistent medication safety gaffes that continue to be unresolved. ISMP would like to share seven persistent safety gaffes of 2014, in three parts, with NABP *National Pharmacy Compliance News* readers with the hope that they will join ISMP in bringing attention to these crucial issues and the compelling need for their resolution. Part one of the three-part series is below.

1) Patient Counseling: Still Only a Veiled "Offer" in Many States

The effectiveness of patient counseling in a community pharmacy to detect and prevent medication errors, and its link to improved medication adherence and positive clinical outcomes have been well documented in the literature. Yet, studies have placed patient counseling rates at only eight percent to 42%. An increase in the frequency and quality of patient counseling has been linked to state-specific regulations that require patient counseling for new prescriptions coupled with strict enforcement surveillance. States that require an "offer" to counsel have very low patient counseling rates. Patients often fail to recognize an offer to counsel when simply asked, "Do you have any questions?" or told to "Please sign here." They may not even know what to ask. This means that, with few exceptions, pharmacies in states that require only an offer to counsel will likely dispense a powerful opioid such as fentanyl transdermal patches and allow the patient or caregiver to walk out of the pharmacy without even a brief discussion about safe use and disposal. ISMP has long promoted mandatory patient counseling in community pharmacies for prescriptions for targeted high-alert medications.

For a list of high alert community medications, please visit *www.ismp.org/communityRx/tools/ambulatoryhighalert.asp.* ISMP hopes you will use this list to determine which medications require mandatory patient education in order to reduce the risk of errors and minimize harm.

2) Patients Impacted by Dispensing Errors: Callous Response From Pharmacists

When patients report dispensing errors to ISMP, they are usually more upset about the response they received when contacting the pharmacist or pharmacy manager than the actual error itself. All too often, consumers tell ISMP that pharmacy staff have responded in a callous manner when confronted with the possibility of a dispensing error, demonstrating a lack of empathy and concern for the adverse effects the patient might have experienced. While pharmacy staff may want to be more responsive to patients who report errors, they are often following corporate policies that are focused on legal concerns. As patients are continually encouraged to be active participants in their health care, they want and deserve honest disclosure of errors, and knowledge that there is an action plan to reduce the risk of it happening again.

Flurbiprofen-Containing Topical Medication May Be Dangerous to Pets, Cautions FDA

People who use topical medications containing flurbiprofen, a nonsteroidal anti-inflammatory drug (NSAID), should take care to prevent their pets from being exposed to the drug, recommended FDA in an April 2015 Safety Alert. The warning is in response to reports of cats in two separate households that became ill or died after their owners used topical medications containing flurbiprofen to treat

muscle, joint, or other pain. Two cats in one household developed kidney failure and recovered with veterinary care. Two cats in a second household developed symptoms that included reluctance to eat, lethargy, vomiting, melena, anemia, and dilute urine, and subsequently died despite veterinary care. A third cat in the second household also died after the owner stopped using the medication. Necropsies on the three cats found evidence that were consistent with NSAID toxicity. The pet owners had applied the drug to their own neck or feet, and not directly to the pet, and it is not known exactly how the cats became exposed to the medication, the Safety Alert notes.

Health care providers who prescribe or dispense topical pain medications containing flurbiprofen should advise patients with pets to take steps to prevent exposure of the pets to the medication. Additional information is available in the FDA Safety Alert available at *www.fda.gov/Safety/MedWatch/SafetyInformation/SafetyAlertsforHumanMedicalProducts/ucm443386.htm*.

New FDA Drug Info Rounds Videos Available

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 "NDC Directory," pharmacists demonstrate how to use this quick, easy, online resource.
- In "FAERS," pharmacists discuss the FDA Adverse Event Reporting System (FAERS) and review three ways FAERS data is made available to the public.

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*.

Mucinex Cold, Sinus, and Flu Medications Recalled Due to Possible Labeling Error

In April 2015, RB (formerly Reckitt Benckiser) of Parsippany, NJ, issued a voluntary recall of certain lots of liquid Mucinex® due to a potential error involving the over-the-counter medications' drug facts labels. While the front label of the recalled lots correctly lists the name of the product as well as the active ingredients, some bottles may not have the correct corresponding drug facts label on the back. The recall was initiated after a confirmed report from a retailer. The recalled medications include:

- MUCINEX FAST-MAX Night-Time Cold & Flu;
- MUCINEX FAST-MAX Cold & Sinus;
- MUCINEX FAST-MAX Severe Congestion & Cough; and
- MUCINEX FAST-MAX Cold, Flu & Sore Throat.

If mislabeled, consumers who purchase these products may be unaware of the side effects and potential risks associated with active ingredients such as acetaminophen, dextromethorphan, guaifenesin, phenylephrine, and/or diphenhydramine. RB is recalling these products as a precautionary measure to ensure consumers have all relevant facts and warnings; the company asks consumers to dispose of any unused product.

Additional information about the recall, including the lot numbers and expiration dates for the recalled medications and guidelines for safe disposal, is available on the FDA website at *www.fda.gov/Safety/Recalls/ucm444028.htm*.

Pharmacists Are Performing More Patient Care Activities, National Survey Indicates

Pharmacists are performing more patient care activities in a variety of health care settings and are spending less time in traditional dispensing roles, indicates the *2014 National Pharmacist Workforce Survey*. Specifically, the report found that 60% of pharmacists provided medication therapy management, and 53% performed immunizations in 2014, indicates a press release from the American Association of Colleges of Pharmacy (AACP). The survey was created using a random sample of 5,200 individuals selected from a list of 7,000 licensed pharmacists in the US. Response rate to the survey was 48%.

Additional details, including the full results of the survey and an executive summary, are available through the Resources section of the AACP website, *www.aacp.org*.

Potentially Lethal Drug Sold Globally as Diet Supplement, Warns INTERPOL

INTERPOL has issued a global alert for a drug known as 2.4-dinitrophenol (DNP), an illicit and potentially lethal drug sold as a dieting and body building aid. The "Orange Notice" warning about DNP was published in May 2015, following the death of a woman in the United Kingdom and the serious illness of a man in France. In the 1930s, DNP was used to boost metabolism and encourage weight loss, but it was taken out of circulation due to several deaths. Sold as a plain yellow powder, capsules, or cream, DNP is often illegally manufactured and sold via the Internet; unsafe manufacturing of the drug and potential contamination may be magnifying the dangers of taking the drug, notes INTERPOL.

Additional information is available on the INTERPOL website at *www.interpol.int/News-and-media/News/2015/N2015-050*.

HHS Announces New Interactive Training on Safe Opioid Use

The Department of Health and Human Services (HHS) has announced a new, interactive training course that teaches health care providers how to talk to patients about safely using opioids to manage chronic pain. The course, "Pathways to Safer Opioid Use," also teaches implementation strategies for meeting the opioid-related recommendations from the National Action Plan for Adverse Drug Event Prevention. Adverse drug events (ADEs) are the largest contributor to hospital-related complications and account for more than 3.5 million physician office visits each year, according to HHS. The training, which is offered at no cost, includes self-guided interactive videos with decision points to help users learn how to apply health literacy strategies to help patients understand and act on information to prevent opioid-related ADEs; identify individual risk factors, opioid medications, and interactions that place individuals with chronic pain at increased risk for opioid-related ADEs; recognize the importance of a multidisciplinary team-based approach to treating patients with chronic pain; and demonstrate the ability to combine the principles of the Health Literate Care Model and the biopsychosocial model.

Additional information, including a link to the National Action Plan for Adverse Drug Event Prevention, is available on the course website at *http://health.gov/hcq/training.asp#pathways*.

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benefactor. Mr Graves served as the Rotary Foundation District 7690 Foundation Advocate for Area 8 in 2013-2015, and received the Rotary Foundation District Service Award in 2015. He is currently serving as the assistant governor for Area 8. He is also a member of Asheboro Masonic Lodge #699 (past Lodge Master), where he served as secretary and is a member of the Oasis Shrine. A member of the Asheboro/Randolph Chamber of Commerce, Mr Graves serves as chairperson of the Government Committee, and is a 2002 graduate of Leadership Randolph.

In 2013, he was appointed to the North Carolina Criminal Justice Information Network Governing Board by the Honorable Thom Tillis, then-Speaker of the North Carolina House of Representatives.

Mr Graves resides in Asheboro with his wife, Donna. They have two adult children, who are both married, and two wonderful grandchildren.

With Mr Graves' appointment, Dr Parker Chesson concludes 10 years of superlative service to the Board and the people of North Carolina, emblematic of his deep commitment to public service throughout a long and distinguished career. Board members and staff are grateful for Dr Chesson's service, guidance, and mentoring. His was always a quick mind and steady hand.

Item 2308 – Board Members and Staff Thank Lazelle Marks for Five Years' Service

On April 30, 2015, Lazelle Marks concluded five years' service as the Board's Central District member. Mr Marks owns and has operated Medical Center Pharmacy in Rockingham, NC, since 1997. His service on the Board is emblematic of a career filled with service to the profession above and beyond the call of duty. He has served on the North Carolina Mutual Wholesale Drug Company Board of Directors since 1993, and previously served as a board member for the North Carolina Association of Pharmacists and the Pharmacy Foundation of North Carolina. Mr Marks also serves on the Dean's Board of Advisors for both the South Carolina College of Pharmacy and the Campbell University College of Pharmacy & Health Sciences, as well as on the Wingate University Board of Trustees.

Board staff and members thank Mr Marks for his steady leadership and commitment to the protection of the public health and safety.

Item 2309 – Fraudulent Activity Involving Compounded Topical Prescription Products

North Carolina pharmacists are likely aware of recent national news coverage of instances in which some compounding pharmacies – typically using salespeople or "runners" – market topical "pain" creams to patients. News reports have detailed instances in which patients receive these topical compounds despite no recollection of having authorized them and no interaction whatsoever with the prescribing physician. These patients often later find that their insurance policies have been billed tens (or even hundreds) of thousands of dollars for these "pain" creams.

Unscrupulous pharmacies have particularly (though not, by any means, exclusively) targeted beneficiaries of various federal payer programs (such as TRICARE) – especially military veterans – in these schemes. A few news stories detailing these activities may be found at the following links.

- *www.cbsnews.com/news/investigation-insurance-billed-18000-for-unwanted-pain-meds*
- *www.militarytimes.com/story/military/benefits/health-care/2015/04/10/tricare-compound-medications-tactics/25535291*
- *http://wtop.com/national/2015/05/report-military-vets-getting-dubious-pain-drugs-astronomical-taxpayer-expense*

Board staff are monitoring these developments and, where appropriate, working with federal authorities to identify and take proper action against pharmacies engaged in fraudulent activities of this nature. Board staff urge any pharmacy aware of such practices and any members of the public concerned that they have been subjected to them to contact Board staff. Board staff will receive complaints or concerns through any communications medium – phone, fax, email, and in person. More information about filing complaints with the Board may be found at *www.ncbop.org/complaint.htm*.

Item 2310 – Public Hearing on Proposed Amendments to Rule 21 NCAC 46.2612 Governing Storage of Devices and Medical Equipment Scheduled for Tuesday, September 15, 2015

The Board proposes amending the rule regarding delivery of devices and medical equipment from a device and medical equipment facility to permit holders to provide that those items may be delivered from allowed storage sites without first taking those items to permitted locations if delivery is performed by a bona fide employee of a permitted location. A public hearing will be held on September 15, 2015, at 9 AM at the North Carolina Board of Pharmacy office, 6015 Farrington Road, Suite 201, Chapel Hill, NC 27517.

Any person may object to the proposed amendment by attending the public hearing on September 15, 2015, and/or by submitting a written objection by 9 AM on September 15, 2015, to Jack W. "Jay" Campbell IV, 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. The Board is interested in all comments pertaining to the proposed rule. All persons interested and potentially affected by the proposal are strongly encouraged to read the entire notice on the Board's website and make comments on the proposed rule.

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

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