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News

North Carolina Board of Pharmacy

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Item 2311 – Andy Bowman Elected to the Board From the Southeastern District

Congratulations to J. Andrew "Andy" Bowman, who was selected by the pharmacists of the state as the Southeastern District North Carolina Board of Pharmacy member-elect. Andy will begin a five-year term of service beginning May 1, 2016.

Andy is director of continuing education and a clinical assistant professor of pharmacy practice at the Campbell University College of Pharmacy & Health Sciences (CPHS). Andy is also a Campbell University CPHS alumnus, the first elected to Board membership.

During the run-off election, 2,571 votes were cast as follows.

Candidate Name	Vote Count	Percentage of Total
Andy Bowman	1,467	57.1%
Jennifer Askew Buxton	1,104	42.9%
Total	**2,571**	**100.0%**

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 comprise 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 2312 – Biosimilars and Interchangeable Biosimilars

The Federal Food, Drug, and Cosmetic Act now provides a pathway whereby biological products may be classified as "biosimilars" or "interchangeable biological products." Food and Drug Administration (FDA) maintains the "Purple Book," which lists biological products, including any biosimilar and interchangeable biological products licensed by FDA under the Public Health Service Act (PHS Act).

The lists include the date a biological product was licensed under section 351(a) of the PHS Act and whether FDA evaluated the biological product for reference product exclusivity under section 351(k)(7) of the PHS Act. The "Purple Book" will also enable a user to see whether a biological product licensed under section 351(k) of the PHS Act has been determined by FDA to be biosimilar to or interchangeable with a reference biological product (an already licensed FDA biological product). Biosimilar and interchangeable biological products licensed under section 351(k) of the PHS Act will be listed under the reference product to which biosimilarity or interchangeability was demonstrated.

The "Purple Book" may be accessed at *www.fda.gov/Drugs/DevelopmentApprovalProcess/HowDrugsareDevelopedandApproved/ApprovalApplications/TherapeuticBiologicApplications/Biosimilars/ucm411418.htm*. Note that, as of this writing, FDA has not approved any interchangeable biological product for marketing.

During the 2015 legislative session, the North Carolina General Assembly amended the Pharmacy Practice Act to clarify that, when authorized by the prescriber, an interchangeable biologic product may be substituted by a pharmacist. The statute goes on to say that:

> Within a reasonable time following the dispensing of a biological product requiring a prescription, the

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FDA Issues Warning About Name Confusion for Brintellix and Brilinta

Due to similar brand names, there have been incidents where the antidepressant Brintellix® (vortioxetine) and the anti-blood clotting medication Brilinta® (ticagrelor) have been confused, resulting in prescribing and dispensing errors, warns Food and Drug Administration (FDA). The agency notes that no reports indicate that a patient has ingested the wrong medication; however, reports of prescribing and dispensing errors continue. FDA recommends that health care providers include the generic name of the medication in addition to the brand name, as well as the indication for use when prescribing these medications. Patients are advised to check their prescriptions to ensure that the correct medication was dispensed. More information is available in an FDA safety alert at *www.fda.gov/Safety/MedWatch/SafetyInformation/SafetyAlertsforHumanMedicalProducts/ucm456569.htm.*

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.*

This is part two of a three-part series on seven persistent safety gaffes of 2014.

3) Vaccine Errors: Repetitive Errors Reported in the Last Decade

How often do DTaP (diphtheria and tetanus toxoids, and acellular pertussis) and Tdap (tetanus toxoid, reduced diphtheria toxoid, and acellular pertussis) vaccine mix-ups need to occur before regulatory action is taken to prevent confusion? Whatever the number, we can say that health care providers have probably met that threshold! Yet, vaccine errors like this continue to occur at an alarming rate (based on those reported to ISMP alone). Vaccine mix-ups occur often because of age-dependent formulations of the same vaccine, similar vaccine abbreviations, similar vaccine containers and labels, and storage near each other. Confusion between the diluent and vaccine has led to administration of the diluent alone or use of the wrong diluent. With an unfortunate rise in parents choosing not to vaccinate their children or themselves, health care providers cannot continue to make errors when vaccinating those who choose to be immunized; the impact on both individual and community immunity may be far-reaching.

4) Wrong Patient Errors: Not Opening the Bag at the Point of Sale

Community pharmacies are vulnerable to dispensing correctly filled prescriptions to the wrong patient at the point of sale, a risk that is well substantiated in the literature. This error is not influenced by the attributes of a specific medication; thus, dispensing any prescription medication to the wrong patient at the point of sale carries a similar level of risk. Based on an ISMP study, the error happens frequently at an estimated rate of 1.22 per 1,000 prescriptions. Among approximately 56,000 community pharmacies in the United States, this error rate suggests that 332,755 prescriptions will be dispensed to the wrong patient each month, or about six every month per pharmacy. One of the most effective ways to prevent this error is to open the bag of filled prescriptions at the point of sale to verify that the medications are for the correct patient. According to the ISMP study, this simple step reduces the risk of error by 56%, yet few pharmacies follow this practice.

5) Disrespectful Behavior: A History of Tolerance in Health Care

Bullying, incivility, and other forms of disrespectful behavior are still rampant in health care and allowed to exist. Health care providers tolerate the behavior, remain silent, or make excuses in an attempt to minimize the profound devastation that disrespectful behavior causes. An ISMP survey conducted in 2003 clearly demonstrated the scope of disrespectful behavior among many levels of interdisciplinary staff, and an ISMP survey conducted a decade later demonstrates little progress. Disrespect diminishes a person's ability to think clearly, make sound judgments, speak up regarding questions, or avoid at-risk behaviors. Disrespectful behaviors also underlie a resistance to collaborate with others, follow procedures that promote safe practices, or implement new safety practices. While a culture of disrespect is harmful on many levels, its effect on patient safety makes it a matter of national urgency.

FDA Advises Caution Against Codeine for Treating Colds in Young Patients

FDA is evaluating the safety of using medicines containing codeine to treat patients under 18 years old for coughs and colds because of the possibility of severe side effects. Codeine, an opioid, may cause slowed or difficult breathing in children, especially for those who already suffer from breathing problems, the agency notes. FDA recommends that health care providers use caution when prescribing or recommending codeine for patients under 18 years old, and that parents and caregivers be alert for signs of shallow or noisy breathing, confusion, or unusual sleepiness. FDA is also considering a European Medicines Agency recommendation made in April to not give children under 12 codeine for coughs and colds, and to not use codeine for patients 12 to 18 years old who have asthma or other chronic breathing problems. More information is provided in an FDA safety alert available at *www.fda.govSafety/MedWatch/SafetyInformation/SafetyAlertsforHumanMedicalProducts/ucm453379.htm.*

Daytrana Patch May Cause Permanent Skin Color Changes, FDA Warns

In June 2015, FDA warned health care providers and consumers that Daytrana®, a methylphenidate transdermal system prescribed for treating attention deficit hyperactivity disorder, may cause permanent loss of skin color in the affected area. FDA has added a new warning to the drug label to describe this skin condition, known as chemical leukoderma. Chemical leukoderma is a skin condition that causes the skin to lose color as a result of repeated exposure to specific chemical compounds, according to an FDA safety alert. The condition is not physically harmful, but it is disfiguring.

FDA advises patients and caregivers to watch for new areas of lighter skin, especially under the drug patch, and to immediately report any changes to their health care providers. Patients should not stop using the Daytrana patch without consulting a health care provider. FDA also recommends that providers for patients who experience these skin color changes consider alternative treatments. More details are included in the FDA safety alert available at *www.fda.gov/Safety/MedWatch/SafetyInformation/SafetyAlertsforHumanMedicalProducts/ucm452595.htm.*

FDA Expands NSAID Warning Labels Regarding Risks of Heart Attack, Stroke

The labels of certain non-steroidal anti-inflammatory drugs (NSAIDs) will soon contain more detailed information about the risk that the drugs may contribute to heart attack and stroke, reports FDA. Such warnings have been on prescription and over-the-counter NSAIDs since 2005, but the new requirements take into account new data showing that the risk of heart attack and stroke occurs even during the first few weeks of taking an NSAID. People who have cardiovascular and other heart problems are at even greater risk of adverse effects. An FDA alert available at *www.fda.gov/ForConsumers/ConsumerUpdates/ucm453610.htm* provides more details.

Baxter International, Inc, Recalls Three Lots of IV Solutions Due to Particulate Matter

In July 2015, Baxter International, Inc, voluntarily recalled two lots of intravenous (IV) solutions distributed to hospitals and other health offices because of the presence of particulate matter identified as an insect. The problem was identified before patient administration and no adverse health effects have been reported. The recall affects 0.9% sodium chloride injection, USP 50 mL and 100 mL, lot numbers P319921 and P327635, which were distributed to US customers between October 7, 2014, and July 14, 2015. Additional information is available in an FDA press release at *www.fda.gov/Safety/MedWatch/SafetyInformation/SafetyAlertsforHumanMedicalProducts/ucm455421.htm.*

Baxter also voluntarily recalled one lot of IV solution to the hospital/user level because of the potential for leaking containers, particulate matter, and missing port protectors. This recall affects 0.9% sodium chloride injection, USP (AUTO-C) with lot number C964601 (National Drug Code 0338-0049-03; expiration date: April 30, 2016). This recalled lot was distributed to customers and distributors nationwide between January 22, 2015, and February 12, 2015. Leaking containers, particulate matter, and missing port protectors could result in contamination of the solution and, if not detected, could lead to a bloodstream infection or other serious adverse health consequences, explains FDA. The agency notes further that "injecting a product containing particulate matter, in the absence of in-line filtration, may result in blockage of blood vessels, which can result in stroke, heart attack or damage to other organs such as the kidney or liver. There is also the possibility of allergic reactions, local irritation and inflammation in tissues and organs." More information about this recall is available in an FDA safety alert at *www.fda.gov/Safety/MedWatch/SafetyInformation/SafetyAlertsforHumanMedicalProducts/ucm456793.htm.*

FDA Warns Against Unapproved Prescription Ear Drops

FDA has ordered the manufacturers of certain prescription ear drops to stop making and distributing the products because they are not FDA-approved. The product labels do not disclose that they lack FDA approval, and health care providers may not be aware of the unapproved status, notes FDA. The agency took action against unapproved prescription otic drug products containing these ingredients:

- benzocaine;
- benzocaine and antipyrine;
- benzocaine, antipyrine, and zinc acetate;
- benzocaine, chloroxylenol, and hydrocortisone;
- chloroxylenol and pramoxine; and
- chloroxylenol, pramoxine, and hydrocortisone.

These drugs are frequently given to relieve ear swelling and pain in young children, and FDA took this action to protect patients from the risks of taking unapproved drugs with no proven safety or effectiveness information. Further, such drugs may be contaminated or manufactured incorrectly, notes the agency. More information is provided in an FDA news release available at *www.fda.gov/NewsEvents/Newsroom/PressAnnouncements/ucm453348.htm.*

Acino Products in New Jersey Ordered to Stop Selling Rectacort-HC and GRx HiCort 25

Under the direction of FDA, a federal judge for the District of New Jersey has ordered Acino Products, LLC, of Hamilton, NJ, to stop selling and destroy certain unapproved and misbranded prescription drugs in its possession.

According to FDA, Acino has marketed unapproved hydrocortisone acetate 25 mg suppositories, under the brand names Rectacort-HC and GRx HiCort 25, for treatment of medical conditions including inflamed hemorrhoids, chronic ulcerative colitis, and other inflammatory conditions. The drugs have not been FDA-approved and also fail to carry adequate directions for use on their labels. Acino continued to market and sell the products despite several warnings from FDA investigators. The FDA news release is available at *www.fda.gov/NewsEvents/Newsroom/PressAnnouncements/ucm453466.htm.*

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> pharmacist or a designee shall communicate to the prescriber the product name and manufacturer of the specific biological product dispensed to the patient. This required communication shall be conveyed by making an entry into an interoperable electronic medical records system, or electronic prescribing technology, or a pharmacy benefit management system, or a pharmacy record that can be electronically accessible by the prescriber. Entry into one of the above referenced methods of communication is presumed to provide the required communication. Otherwise, the pharmacist or a designee shall provide the required communication to the prescriber by facsimile, telephone, electronic transmission, or other prevailing means . . .

No notification is required if "[t]here is no [FDA]-approved interchangeable biological product for the product prescribed" or "[a] refill prescription is not changed from the product dispensed on the prior filling of the prescription."

The Board is required to maintain a link on its website to the "current list of biological products determined by the [FDA] to be interchangeable with a specific biological product." As previously noted, that list is found in FDA's "Purple Book," and the Board will maintain a link to the "Purple Book" on its website.

Item 2313 – Registration of Free Clinic Pharmacy Technicians

Amendments to Board Rule .3301, which speaks to pharmacy technician registration, went into effect on July 1, 2015. Among other things, amended Rule .3301 clarifies that pharmacy technicians who provide services solely at a free clinic (as defined in NCGS 90-85.44) are required to register as technicians, but are exempt from the registration fee.

Implementation of a fee-exempt registration required a programming change to the Board's online registration system for technicians. That programming change was completed in August.

Accordingly, technicians practicing solely at free clinics should now complete the online registration application, found at *https://www.ncbop1.org/techapp/TechnicianApp.aspx*. The registration fee will be waived upon verification of the free clinic site.

Pharmacist managers are welcome to call or email Board staff with any questions. Thank you to pharmacists and technicians who each day provide terrific service to North Carolina citizens at free and charitable clinics.

Item 2314 – Impersonating a Board Inspector/Investigator

In August, a person presented himself at a Raleigh, NC pharmacy claiming to be a Board inspector/investigator. This person demanded access to certain pharmacy records. Pharmacy staff were rightly suspicious and requested identification. This person refused to show any and left the pharmacy, but then returned and hung around the pharmacy waiting area for several minutes before leaving.

Pharmacists should be aware that a Board inspector/investigator will always identify himself or herself as such and will gladly provide credentials. If you have concerns about the true identity of someone claiming to be a Board investigator, please call the Board office immediately.

Item 2315 – Reminder of the DQSA's Prohibition on 'Office Use' Compounding, Except by Section 503B Outsourcing Facilities

Pharmacies are reminded once again that in November 2013, the federal Drug Quality and Security Act (DQSA) became effective. That statute prohibits a pharmacy from compounding and dispensing human drug products except pursuant to individual patient prescriptions. Only "outsourcing facilities" registered with FDA under Section 503B of the DQSA may compound drugs for "office use." Board staff assembled an FAQs document that discusses the DQSA's prohibitions and operation. It may be found at *www.ncbop.org/faqs/FAQsDQSA030615.pdf.*

Item 2316 – Donation and Dispensing of Prescription Drugs, Devices, and Medical Supplies

Board staff has seen an uptick in questions about the permissibility of donating prescription drugs to free and charitable clinics. Several years ago, the General Assembly passed a statute describing the circumstances under which prescription drugs, devices, and medical supplies may be donated for redispensing. Board staff assembled an FAQs document explaining the circumstances under which donation may occur. It may be found at *www.ncbop.org/faqs/Pharmacist/FAQDrugSuppliesMedicalDeviceRespositoryProgr.pdf.*

Board staff encourages all pharmacists to familiarize themselves with the donation process and find opportunities to contribute to free and charitable clinics.

Item 2317 – Board Inspection Forms Available on the Board Website

Inspections by Board field staff are unannounced. But the standards and items that field staff inspect in a pharmacy are certainly no mystery. In fact, each and every one of the Board's inspection forms is readily available on the Board website, *www.ncbop.org/resourcesfornewpermitholders.htm*.

Board staff encourages pharmacists to download these forms and use them as a sort of self-check-up to ensure that pharmacy operations are compliant with state law and federal law.

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™ (NABPF™) 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 NABPF or the Board unless expressly so stated.

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