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Item 2336 – Bill Mixon Elected to Second Term as Board Member From the Western District

Please join the North Carolina Board of Pharmacy in congratulating Bill Mixon of Hickory, NC, for being elected by North Carolina pharmacists to a second five-year term on the Board from the Western District.

As reported in the July 2016 *Newsletter,* the Western District seat was the subject of a run-off election between Bill Mixon and Cathy Huie. The Western District election saw five total candidates. In addition to Mr Mixon and Dr Cathy Huie, the Board thanks Chip Etier, Tim Gentilcore, and David Landers for their candidacy.

Overall vote totals for the Western District run-off election were as follows.

Candidate Number	Candidate Name	Vote Count	Percentage of Total
1	Cathy Huie	807	46.2%
2	Bill Mixon	938	53.8%
	Total	**1,745**	**100%**

Item 2337 – Pharmacist-Manager Responsibilities for Technician Registration Applications

Board staff remind pharmacist-managers of their responsibility to oversee technician registration applications and to review those applications for completeness and accuracy prior to submission to the Board.

Board staff often receive calls from new-hire technicians who have no knowledge of the registration process and report that their supervising pharmacists have not provided any guidance. Board staff also receive applications in which technician applicants disclose serious (even disqualifying) criminal histories – or the Board's background check mechanisms uncover such histories – and, when questioned, the sponsoring pharmacist-manager claims no knowledge.

Pharmacy technicians are crucial to providing quality pharmacy care services to patients, and thousands of technicians do just that every day. Pharmacist-managers, in keeping with their overall responsibility for the lawful operation of a pharmacy and to the patients they serve, have a responsibility to ensure that their technicians are qualified, trained, and timely registered. Proactive assistance to technician registration applicants by pharmacist-managers on the registration process is essential; proper qualification screening of technician registration applicants is as well.

Item 2338 – FDA Issues Draft Compliance Policy Guidance on Compounding Issues

The United States Food and Drug Administration (FDA) continues to issue guidance documents concerning implementation of the Drug Quality and Security Act (DQSA) of 2013. On July 7, 2016, FDA issued for comment two draft guidance documents concerning compounding provisions of the DQSA:

- Compounded Drug Products That Are Essentially Copies of a Commercially Available Drug Product Under Section 503A of the Federal Food, Drug, and Cosmetic Act (found at *www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/UCM510154.pdf);* and
- Compounded Drug Products That Are Essentially Copies of Approved Drug Products Under Section 503B of the Federal Food, Drug, and Cosmetic Act (found at *www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/UCM510153.pdf).*

On August 3, 2016, FDA released for comment a draft guidance document titled "Insanitary Conditions at

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National Vaccine Safety Surveillance Program Available for Reporting Adverse Events

The Vaccine Adverse Event Reporting System (VAERS) eSubmitter program, a national vaccine safety surveillance program cosponsored by the Centers for Disease Control and Prevention (CDC) and Food and Drug Administration (FDA), is available for the reporting of any clinically significant adverse event that occurs after the administration of any vaccine licensed in the United States. VAERS information is analyzed by CDC and FDA to identify new safety concerns. VAERS reports can be filed by anyone, including health care providers, manufacturers, state immunization programs, and vaccine recipients. Vaccine recipients are encouraged to seek help from their health care provider when filling out the VAERS form. Health care providers can find information about submitting a report on the VAERS website at *https://vaers.hhs.gov/professionals/index*.

Improper and Unsafe Vaccine Storage

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.*

Few issues are more important than proper storage and handling of vaccines, because their ability to prevent disease is dependent on these factors. To maintain stability, most vaccines must be stored in a refrigerator or freezer, and many also require protection from light. Excessive heat or cold – even a single exposure in some instances – can reduce vaccine potency. These temperature excursions are often due to improper refrigeration or freezer units, inadequate thermostat controls, and refrigeration/freezer units with inadequate space to allow good air circulation and even temperatures.

Improper and unsafe storage can also result in serious errors caused by selecting the wrong vaccines, diluents, and other medications with look-alike names and/or labeling and packaging. Storing vaccines close to each other has led to dispensing and administering the wrong vaccine or wrong form of vaccine (eg, adult versus pediatric). Storing vaccines too close to non-biologic medications in a refrigerator or freezer has also led to serious adverse outcomes, particularly when the mix-up involved a vaccine and a high-alert medication. For example, vials of insulin have frequently been mistaken as influenza vaccine, and various neuromuscular blocking agents have been used to reconstitute vaccines or were mistaken as influenza or hepatitis B vaccines.

Store vaccines in their own dedicated refrigeration and freezer units. Regular temperature monitoring is necessary, and technology is available to assist with alarmed, continuous monitoring devices that can alert staff via email and pager if a unit is out of specified range. Separate vaccine vials and syringes into bins or other containers according to vaccine type and formulation, keeping diluents with the appropr iate vaccines. Never store different vaccines in the same containers. Do not store vaccines with similar labels, names, abbreviations, or overlapping components immediately next to each other or on the same shelf. Separate the storage areas of pediatric and adult formulations of vaccines. Label the specific locations where vaccines are stored to facilitate correct age-specific selection and to remind staff to combine the contents of vials. ISMP's March 26, 2015 newsletter[1] contains additional strategies, as does a Vaccine Storage & Handling Toolkit available from CDC.[2]

References

1. ISMP. Recommendations for practitioners to prevent vaccine errors. Part 2: analysis of ISMP vaccine errors reporting program (VERP). *ISMP Medication Safety Alert!* 2015;20(6):1-6.
2. CDC. Vaccine storage & handling toolkit. www.cdc.gov/vaccines/hcp/admin/storage/toolkit/storage-handling-toolkit.pdf. June 2016.

Coalition Reports Impact of Educational Efforts on Safe Acetaminophen Use

The Acetaminophen Awareness Coalition reports that progress has been made to increase consumer awareness about the safe use of acetaminophen. The coalition also notes a decline in unintentional overdoses. The National Poison Data System's 2015 report indicates unintentional acetaminophen exposures, including dosing errors and accidental misuse, have decreased through 2013 after a peak in 2009. In addition, a nationwide survey indicates the number of consumers who understand that exceeding the recommended daily dose of acetaminophen may lead to liver damage has increased to 87% in 2013 from 78% in 2010. The survey also reports the number of consumers who think it is important to check the medicine label for the maximum daily dose increased to 98% in 2013 from 93% in 2010.

Developed in 2011, the Know Your Dose campaign encourages pharmacists and other health care providers to talk to their patients about medicine safety and acetaminophen use. The Know Your Dose campaign offers a list of helpful health tips to share with patients, including the following:

(1) Read and follow the label.

(2) Know which medicines contain acetaminophen.

(3) Take only one medicine at a time that contains acetaminophen.
(4) Ask a health care provider or pharmacist about dosing instructions or medicines that contain acetaminophen.

Pharmacists may download or order free educational materials, including posters, flyers, and talking points, to give their patients on the Know Your Dose website, *www.knowyourdose.org*.

FDA Offers Webinars on Online Drug Information Resources for Students and Clinicians

FDA's Division of Drug Information in the Center for Drug Evaluation and Research presents a series of CE webinars targeted toward students and health care providers who wish to learn more about FDA and drug regulation. The webinars are presented by FDA staff and allow participants to interact with staff. Previous webinar topics have included an overview of FDA's expanded access program and the pregnancy and lactation labeling rule. The webinars and presentation slides can be accessed on FDA's website at *www.fda.gov/AboutFDA/WorkingatFDA/FellowshipInternshipGraduateFacultyPrograms/PharmacyStudentExperientialProgramCDER/ucm228391.htm*.

Fresenius Kabi Recalls Sensorcaine-MPF (Bupivacaine HCl) Injection, USP

In April 2016, Fresenius Kabi USA recalled a single lot of Sensorcaine®-MPF (bupivacaine HCl) injection, USP, 0.75%, 7.5 mg/mL, 30 mL fill in a 30 mL vial, because of visible particulate matter characterized as glass observed by the company during inspection of reserve samples. The recalled product was shipped in the US to wholesaler and distributor outlets between March 4, 2016, and March 21, 2016, and has an expiration date of September 2019. The recall affects lot number 6111504, product code 470237, and National Drug Code number 63323-472-37. The product is supplied as 0.75% strength in a 30 mL single-dose flint molded vial and is packaged in units of 25. To date, Fresenius Kabi has not received any reports of adverse events regarding this recall, indicates the press release posted to the FDA website.

Health care facilities that have the affected lot are instructed to immediately discontinue distributing, dispensing, or using the lot and return all units to Fresenius Kabi. Distributors are instructed to immediately notify their customers who have been shipped or may have been shipped the recalled product. Adverse reactions or quality problems may be reported to FDA's MedWatch Safety Information and Adverse Event Reporting program at *www.fda.gov/MedWatch*. Additional details are available on FDA's website at *www.fda.gov/Safety/Recalls/ucm497812.htm*.

Oral Liquid Docusate Sodium by PharmaTech Recalled Due to Contamination

In July 2016, FDA alerted health care providers that PharmaTech, LLC, of Davie, FL, voluntarily recalled all non-expired lots of Diocto Liquid, a docusate sodium solution distributed by Rugby Laboratories of Livonia, MI. The affected product was distributed nationwide in one-pint (473 mL) bottles with a Rugby label. FDA confirmed the product has been contaminated with *Burkholderia cepacia,* a bacteria linked to an outbreak in five states. The safety alert indicates FDA has received several adverse event reports of *B. cepacia* infections in patients, and some of these reports identify liquid docusate sodium products manufactured by companies other than PharmaTech. FDA and CDC continue to investigate the extent of this issue in order to identify other potentially contaminated liquid docusate sodium products. FDA joins CDC in recommending that clinicians not use any liquid docusate sodium product as a stool softener or for any other medical purpose. Adverse events or side effects may be reported to FDA's MedWatch Safety Information and Adverse Event Reporting Program at *www.fda.gov/MedWatch*. More information may be found in the safety alert on FDA's website at *www.fda.gov/Safety/MedWatch/SafetyInformation/SafetyAlertsforHumanMedicalProducts/ucm511528.htm*.

NABP Seeks Pharmacists From Districts 1, 5, and 7 to Serve as Volunteer Item Writers

The National Association of Boards of Pharmacy® (NABP®) is seeking pharmacists who reside in states in the following districts to serve as volunteer item writers:

- **District 1:** Connecticut, Maine, Massachusetts, New Hampshire, Rhode Island, and Vermont.
- **District 5:** Iowa, Minnesota, Nebraska, North Dakota, and South Dakota.
- **District 7:** Alaska, Idaho, Montana, Oregon, Washington, and Wyoming.

In an effort to secure more individuals representative of these areas of the country, NABP encourages pharmacists in all areas of practice as well as school and college of pharmacy faculty who reside in these states to apply.

NABP uses volunteer item writers to develop questions for the following examination programs: North American Pharmacist Licensure Examination® (NAPLEX®), Multistate Pharmacy Jurisprudence Examination® (MPJE®), Foreign Pharmacy Graduate Equivalency Examination® (FPGEE®), Pharmacy Curriculum Outcomes Assessment® (PCOA®), and Pharmacist Assessment for Remediation Evaluation® (PARE®).

Interested individuals should complete the online interest form available in the Meetings section of the NABP website. Individuals who are selected will receive further information on opportunities to attend and participate in NABP-hosted workshops.

For more information about NABP item writing, visit the Meetings section of the NABP website at *www.nabp.pharmacy*, or contact CompAssess@nabp.pharmacy.

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Compounding Facilities." Though the title might well cause the casual reader to think FDA had ventured into the mental health of compounding pharmacists and staff, in fact the draft guidance is intended to assist compounding facilities in identifying conditions that can lead to the adulteration of compounded products so that pharmacies can implement appropriate corrective actions. The draft guidance document is available at *www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/UCM514666.pdf.*

All draft guidance documents are open for either a 60-day or 90-day comment period after the date of issue. Instructions on how to submit comments are found at the beginning of each document.

Item 2339 – Guidance on CLIA-Waived Testing in Pharmacies

Board staff have received numerous questions about pharmacies' ability to perform "rapid diagnostic" and other "CLIA-waived" tests.

Some point-of-care tests for things like streptococcus infection, blood glucose levels, and cholesterol levels are approved by FDA as so-called "CLIA-waived" tests. The Clinical Laboratory Improvement Amendments Act (CLIA) is a federal statute that, as the name suggests, governs clinical laboratories.

When FDA approves an in vitro diagnostic device, it may designate the device as approved "for home use or that, as determined by the Secretary, are simple laboratory examinations and procedures that have an insignificant risk of an erroneous result, including those that employ methodologies that are so simple and accurate as to render the likelihood of erroneous results by the user negligible, or the Secretary has determined pose no unreasonable risk of harm to the patient if performed incorrectly" (42 USC § 263a(d)(3)). If so deemed by FDA, these tests may be performed in a laboratory that has applied for a waiver of CLIA requirements (Id. § 263a(d)(2)). CLIA-waived tests do not require as a condition of FDA approval any sort of "prescription" or medical order.

Unlike some states, North Carolina law does not impose a separate layer of regulations on top of CLIA. If a facility – including a pharmacy – meets the criteria to perform CLIA-waived tests, and obtains from the federal Centers for Medicare & Medicaid Services a CLIA waiver, then that facility may perform any CLIA-waived tests. More information about the CLIA waiver process may be found at *https://www2.ncdhhs.gov/DHSR/ahc/clia/cliafaq.html.*

Board staff are of the opinion that there is nothing in the law that would prevent a pharmacy that applies for and obtains a CLIA waiver from performing CLIA-waived tests. Of course, a pharmacy performing a CLIA-waived test cannot allow its pharmacists to use the results of a CLIA-waived test to prescribe drug therapy independently, or to do anything with the test results besides provide them to the patient and/or communicate them to the patient's provider of choice. (The exception would be a clinical pharmacist practitioner (CPP) whose agreement with the supervising physician authorizes the CPP to act on test results.)

Item 2340 – Statewide Standing Order for Naloxone in Effect

In late June, the North Carolina General Assembly passed and Governor Pat McCrory signed into law a bill allowing the state health director, Dr Randall Williams, to issue a statewide standing order for naloxone dispensing – a standing order that **any pharmacy in North Carolina may use.** This standing order will allow any licensed North Carolina pharmacist who chooses to participate to dispense naloxone to patients who are at risk of an opioid overdose or to their friends or family members or to people in a position to help them.

The North Carolina Department of Health and Human Services (DHHS) has set up a website to educate pharmacists and the public about the statewide standing order, which may be found at *www.naloxonesaves.org.* The website contains a copy of the standing order itself, educational materials, and other information about appropriate dispensing and administration of naloxone.

The website also includes instructions for pharmacies that wish to dispense under the standing order to notify DHHS that they intend to do so. Pharmacies dispensing under a standing order (whether through the state health director or through their own standing order) will be listed on the website after contact information is provided to DHHS.

If a pharmacist has any questions about the standing order that are not answered by the *www.naloxonesaves.org* website, please contact Board staff or Anna Stein, DHHS legal specialist, at anna.stein@dhhs.nc.gov.

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