

From: New Mexico Society of Health-System Pharmacists <nmsHP@nmsHP.org>
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To: Paul Davis
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NMSHP Pager

December 2, 2013

ON THIS DATE

*On **December 2, 1804**, Napoleon Bonaparte was crowned Napoleon I in Notre Dame Cathedral in Paris, the first Frenchman to hold the title of emperor in a thousand years. In **1859**, John Brown was executed in Charles Town, VA on charges of treason, murder and insurrection. In **1954**, the U.S. Senate voted 65-22 to condemn Joseph McCarthy for “conduct that tends to bring the Senate into dishonor and disrepute.” In **2001**, the Enron Corporation filed for Chapter 11 bankruptcy protection. Today’s Birthdays: Alexander Haig (1924-2010, American general and diplomat, U.S. Secretary of state); Edwin Meese (1931-, lawyer, author and U.S. Attorney General); Monica Seles (1973-, Yugoslavian-American tennis player; Britney Spears (1981 – singer/dancer and actress). Today’s Trivia: 1. What specific crime did John Brown commit that caused his arrest and execution? 2. Who was Chairman and CEO of Enron Corporation at the time it filed for bankruptcy? 3. Al Haig famously took the microphone to declare “I am in control here” during the follow-up to the assassination attempt on President Ronald Reagan in 1981. But in a previous assignment in the West Wing, he possibly held more control than being Secretary of State. What role did he serve under two consecutive Presidents?*

President's Corner

- Kim Neff, Pharm.D. Ph.C., NMSHP President

Hi Everyone!



One of my priorities this year is to find some way for each one of you to get more involved in organizational activities. Each of you has a unique skillset that not only makes you a wonderful pharmacist, but also an asset to NMSHP. Don't worry, chairing a committee is not the only way to be involved! Volunteering for a community service event, replying to an email with a recommendation about an activity, sending a pre-written letter to a legislator about a timely pharmacy issue, calling a friend or colleague to inform them of an upcoming activity or CE program; these are all ways you can contribute to NMSHP's success in enhancing the lives of our patients. Have an idea for a CE presenter? Let us know! Want to be a part of the Donut Dash? We can use your help!

I challenge each of you to find at least one way you can be more involved this year than you were last year. Remember, no matter how big or small it is, your efforts matter. We aim to make a difference and have a great time in the process! Over the next year you will hear about activities via in upcoming editions of the Pager, e-mails, word of mouth, facebook, flyers, and other modalities. Find something that you think you would enjoy and be a part of it!

As Mahatma Gandhi said, *"You must be the change you wish to see in the world."* Now it's your turn to make a difference!

Upcoming Dates:

December 14, 1 PM Ornament-making party for hospitalized children during the holidays
TBD Holiday Children's Toy Drive

Interested in any of the above? Contact me at kimbo1202@gmail.com for more details

NMSHP/ASHP

Don't Miss the Party! The **UNM/NMSHP Reception** at the **ASHP Mid-Year Clinical Meeting** will be held next **Tuesday, December 10** from **6:00 to 7:30 PM** in the **Challenger Rooms 38/39, International Tower, Mezzanine Level** of the **Hyatt Regency Orlando**. If you're attending the Midyear meeting, be sure to drop by and visit with friends and colleagues from across

the country.

STATE, NATIONAL & INTERNATIONAL

NM Hospitals Penalized by Medicare. Nineteen New Mexico hospitals were **penalized** with reduced payments **by Medicare** because they **failed to meet quality and performance measures**, according to the Henry J. Kaiser Family Foundation. The average penalty was a 0.42% reduction in Medicare reimbursement. The hospitals were assessed on 24 quality measures including patient satisfaction and death rates as well as readmissions. 1,451 hospitals in the U.S. were penalized. Presbyterian Hospital in Albuquerque received a 0.09% reduction while Lovelace Medical Center in Albuquerque saw a 0.49% decrease. The University of New Mexico Hospital in Albuquerque faces a 0.26% penalty, while CHRISTUS St. Vincent Hospital in Santa Fe received a 0.81% reduction. Lovelace Women's Hospital in Albuquerque did not receive a penalty or bonus. Three hospitals will receive **bonuses** in the form of higher reimbursement rates in 2014 including **Lovelace Regional Hospital** in Roswell (0.32%), **Mountain View Regional Medical Center** in Las Cruces (0.12%) and **Plains Regional Medical Center** in Clovis (0.35%).

Congress Passes Compounding Bill. The Senate passed **HR 3204**, the **Drug Quality and Security Act**, on November 18. The measure has already passed the House of Representatives and is now awaiting President Obama's signature to become law. The measure would create a **voluntary registration system** under FDA for "outsourcers" and create a system for **tracking drugs in the supply chain**. Traditional compounding pharmacies will continue to be regulated by state pharmacy boards, but those that expand into large scale compounding will be allowed to register with FDA and submit to federal inspections and manufacturer-type quality standards. Under the **"track and trace"** system incorporated in the bill, drug manufacturers would be required to **add unique serial numbers to all drug containers** within 4 years. After 10 years the industry will have to use **electronic tracking codes that can be used to trace medications from manufacturer to the pharmacy**. While the "outsourcer" registration with FDA is voluntary, lawmakers assume that hospitals will want to purchase from those firms approved by FDA, and there are indications that reimbursement models may move towards that requirement.

FDA Halts Marketing of 23andMe Genetic Tests. FDA has

ordered the **23andMe, Inc.** genetic testing company to **stop marketing its \$99 mail-order kit**, citing the risk that false results could cause consumers to undergo unnecessary health procedures, such as breast-cancer surgery. The warning to the company follows a debate that has grown into an international discussion as more consumers turn to direct-to-consumer genetic tests. FDA says that the company doesn't have proper clearance to market the DNA testing kit, and it has not worked with the agency to secure approval. The company says its **saliva-based test identifies more than 240 genetic traits that could offer clues to an individual's health or risk of disease.** The agency said that it could begin product seizures if the company doesn't take adequate steps in response to the FDA letter. The company announced that it would work with FDA to address its concerns. The agency says that it is concerned that genetic testing could produce a false positive which "could lead a patient to undergo prophylactic surgery, chemoprevention, intensive screening," while a false negative could miss an actual risk for the disease.

PRACTICE & PROFESSION

Veterans Latest Challenge – Medications. *The Wall Street Journal* recently detailed an apparent **high use of opioids** by the Veterans Administration when treating **patients suffering from PTSD.** Citing a study by the VA, the paper reports that veterans with PTSD were nearly **twice as likely to be prescribed opioids** as those without mental-health problems, and they were more likely to get multiple opioid drugs and receive the highest doses. Veterans with PTSD were also more than **twice as likely to suffer adverse outcomes such as injury and overdose** if they received opioids. Approximately **30% of Iraq and Afghanistan veterans** under VA care **have PTSD, and more than half suffer chronic pain.** At the same time, last year more than 50,000 veterans were treated by the VA for serious problems associated with opioid use, nearly double the number 10 years earlier. The total number of VA patients grew 30% over that time, with opioid prescriptions written by the VA rising 287% between 1999 and 2012. The report acknowledges that the VA struggles to treat a complex mixture of mental and physical problems in returning vets.

Pharmacists in Medical Homes in NC. Pharmacists have been involved in the Asheville, NC-based Mountain Area Health Education Center Family Health Center since 2001. The **patient-centered medical home** serves 16 counties in western North Carolina. Beginning with a solo pharmacist, the clinic's staff has now grown to 5 pharmacists, 2 residents and dozens of pharmacy students on rotations. The concept of the program is a physician-

led inter-professional group that coordinates patient care efficiently and in a cost-effective manner. The **most appropriate member of the team may assume management of any patient**, whether that is a nutritionist, nurse or pharmacist. Services are billed as part of annual wellness visits which, after the Initial Preventive Physical exam (which must be performed by a physician, nurse or PA), may be provided by a pharmacist or other licensed health care provider working under protocols. Required components of the visit include medication reconciliation, assessment of physical and cognitive functions and screening for depression and other health issues.

Telemedicine May Reduce Med Errors in Rural EDs.

According to a new study published in the *Annals of Internal Medicine*, **telemedicine may reduce errors in rural emergency departments.** University of California researchers found that **rural ED doctors made errors** in administering medications only **3% of the time** when they participated in a telemedicine consult. Med errors for patients were higher at about 10.8% for physicians who had consults by telephone and 12.5% for those receiving no consultation.

The **USC School of Pharmacy** will host a national conference in 2014 on **“Optimizing Medication Safety and Healthcare Quality.”** The conference emphasizes best practices in clinical pharmacy services. The 2-day event is slated for **February 20-21, 2014 in Los Angeles, CA.** A variety of national leaders have been retained as faculty and the targeted audience will include pharmacists who are already engaged in clinical pharmacy programs, senior leaders from medical groups, health plans and other payers and government officials. [Click here](#) for additional information.

NEW DRUGS & DEVICES

[Rosiglitazone Restrictions Loosened by FDA.](#) FDA has announced that recent data for **rosiglitazone-containing drugs**, such as **Avandia, Avandamet, Avandaryl**, and generics, **do not show an increased risk of heart attack** compared to the standard type 2 diabetes medicines metformin and sulfonylurea. As a result, FDA is requiring removal of the prescribing and dispensing restrictions for rosiglitazone medicines that were put in place in 2010. This decision is based on FDA's review of data from a large, long-term clinical trial and is supported by a comprehensive, outside, expert re-evaluation of the data conducted by the Duke Clinical Research Institute (DCRI). Previous data from a large, combined analysis of mostly short-term, randomized clinical trials

of rosiglitazone had suggested an elevated risk of heart attack, so FDA required a Risk Evaluation and Mitigation Strategy (REMS).

Although some scientific uncertainty about the cardiovascular safety of rosiglitazone medicines still remains, in light of the new re-evaluation of the Rosiglitazone Evaluated for Cardiovascular Outcomes and Regulation of Glycemia in Diabetes (RECORD) trial, **FDA's concern is substantially reduced** and the rosiglitazone REMS program requirements will be modified. FDA is also requiring **revisions to the rosiglitazone prescribing information** and the patient Medication Guide to include this new information. The agency suggests that patients with type 2 diabetes continue to work closely with their health care professionals to determine treatment options that are most appropriate. Health care professionals, pharmacies, and patients will no longer be required to enroll in the rosiglitazone REMS program to be able to prescribe, dispense, or receive rosiglitazone medicines. As part of the REMS, sponsors will ensure that health care professionals who are likely to prescribe rosiglitazone medicines are provided training based on the current state of knowledge concerning the cardiovascular risk of rosiglitazone medicines.

FDA Approves New H5N1 Vaccine. FDA has approved use of GlaxoSmithKline's H5N1 bird flu vaccine for people 18 and older who could be exposed to the virus. The vaccine is the **first with an adjuvant to be cleared in the U.S. for H5N1**. It will not be sold commercially, but rather kept in the national stockpile. FDA delayed approval of the vaccine earlier this year due to reports it might be linked to narcolepsy. There has been an outbreak this year of another avian influenza A, H7N9. CDC reported that since the outbreak began in April in China, the virus has **infected 139 people and killed 45**.

Hepatitis C Drug OK'd by FDA. Johnson & Johnson and Medivir's **Olysio (simeprevir)**, in **combination** with **interferon** and **ribavirin**, has been approved by FDA as a treatment for **chronic hepatitis C infection**. Data from clinical trials show that the virus could not be detected in about 80% of patients after treatment with Olysio. The labeling suggests **patients be screened for a genetic mutation called Q80K polymorphism** that renders the drug ineffective. In clinical trials the mutation showed up in about 48% of U.S. patients with genotype 1a infection, the more common subtype in the U.S. compared with genotype 1b, which is more prevalent in Europe and Asia and isn't typically associated with the mutation.

New Dosage Form Approved. FDA has approved a new **tablet**

formulation of Noxafil (posaconazole). The 100-mg delayed release tablets will be added to the oral suspension formulation. The new tablets are designed to be taken in two 300-mg doses on the first day, followed by a 300 mg dose once daily. The drug is approved for preventing invasive Aspergillus and Candida fungus infections in patients ages 13 and older who are at high risk of developing them due to depressed immune function resulting from hematopoietic stem cell transplants and low white blood cell counts caused by chemotherapy.

FDA Gives Breakthrough Status to Factor Xa Inhibitor Antidote. Portola Pharmaceuticals' experimental **Factor Xa inhibitor antidote andexanet alfa** has received breakthrough therapy designation from FDA. The drug is designed for patients who need emergency surgery or who experience uncontrolled bleeding after taking Factor Xa inhibitors such as apixaban and rivaroxaban. The company will seek a fast track designation for the drug and could start registration-enabling trials next year.

FDA OK's Epilepsy Device. FDA has granted **NeuroPace** approval for its **RNS System**, an implantable device designed to **minimize seizures in epilepsy patients** who have failed to respond to medications. The device is implanted in the skull beneath the scalp and attaches to one or two wires that send an electrical current to parts of the brain thought to cause seizures. About 3 million people in the U.S. have epilepsy and 40 percent of them continue to experience symptoms despite drug treatment, according to the Epilepsy Foundation.

Morquio A Syndrome Drug Passes Committee. An experimental drug to treat Morquio A Syndrome has been **recommended for approval by an FDA advisory panel.** The condition is a rare genetic disorder that causes **skeletal malformation** and a variety of related **lung, eye, ear and heart problems.** According to the committee, the benefits of **Vimizim (elosulfase alfa)**, made by BioMarin Pharmaceutical Inc. outweighs its risks. Morquio A Syndrome is characterized by a deficiency of N-acetylgalactosamine-6-sulfatase, which causes excessive storage in the body of long chains of glycosaminoglycans. This build-up can lead to short stature and joint abnormalities that limit mobility and endurance. Symptoms often appear before the age of 5.

RECALLS, WARNINGS & SHORTAGES

Meridian Medical Technologies Auto-Injections – Expiration

Date Extensions. FDA is aware of a **disruption in supply** to health care providers and emergency response personnel of **Atropen** (atropine), **DuoDote** (atropine/pralidoxime chloride), **morphine sulfate, pralidoxime chloride, and diazepam auto-injectors** manufactured by **Meridian Medical Technologies**, a Pfizer Inc. company. FDA and Meridian are working together to resolve the disruption as quickly as possible, but it is unclear how long this disruption may persist.

FDA concluded that it was scientifically supported that certain lots of **DuoDote** can be used for an **additional year beyond the manufacturer’s original labeled expiration date**. FDA is continuing to assess whether these identified lots of DuoDote can receive further expiration date extensions if needed, and whether additional lots of DuoDote that were not listed in FDA’s September 5, 2013, memo can have their expiration date extended.

FDA is currently reviewing data for the potential use of Atropen (atropine), DuoDote (atropine/pralidoxime chloride), morphine sulfate, pralidoxime chloride, and diazepam auto-injectors beyond their labeled expiration dates in order to mitigate any potential shortages of these medically necessary drugs.

FDA will provide additional information about use of these products beyond the labeled expiration date in the coming weeks. Until FDA provides additional information, these **expired auto-injectors may be used for patient care under emergency situations** when no other product is available.

INDUSTRY MATTERS

Johnson & Johnson is experiencing a “really bad hair day” in the judicial system. The company has agreed to pay about **\$2.5 billion** to resolve thousands of lawsuits filed by patients who allege they were harmed by some of the company’s artificial hips. The deal would require J&J to pay \$250,000 for each surgery to replace the implants in an estimated 8,000 patients. An additional \$475 million fund will be established to cover the costs of **certain injuries sustained by hip-replacement patients**. J&J will also pay off liens costing around \$60,000 to \$75,000 for each patient that were taken by government and private health plans while covering the medical costs of the patients, which could total an additional \$600 million. Additionally, the company faces non-U.S. lawsuits over the hip-replacement products. The company also still faces more than 23,000 lawsuits related to the **surgical-mesh products** implanted in women to relieve severe pelvic discomfort

after childbirth. Most recently, a Philadelphia jury awarded \$11 million to a patient whose son was born with a cleft palate after the pregnant mother took Topamax. It's the second case over a **Topamax-related birth defect** to go to trial. A jury awarded \$4 million to another mother last month who alleged that J&J's subsidiary Janssen didn't do enough to publicize the drug's links to cleft lip and palate. Janssen says it will appeal both verdicts. Overall, J&J faces more than 130 cases linking Topamax to birth defects, now consolidated in the Philadelphia court.

ACE Inhibitors May Lead to Oral Reactions. According to a poster presentation at the **American College of Allergy, Asthma and Immunology** meeting, two patients developed **severe oral allergy syndrome after receiving ACE inhibitors**. One patient on lisinopril for a decade went into anaphylaxis after eating an apple while a second on the same drug for a year developed tongue angioedema three times after eating jackfruit and cashews. "The cases suggest that concomitant use of ACE inhibitors in patients with oral allergy syndrome might represent a priming effect, thereby increasing the severity of oral allergy syndrome symptoms," according to the authors. In both cases, patients had seasonal allergies and were found to have immunoglobulin E (IgE) sensitization to birch.

Sanofi Ditches Bone Marrow Cancer Drug. Sanofi has stopped all clinical trials and **cancelled plans to obtain regulatory approval of fedratinib**. The **JAK2 inhibitor** was in late-stage development for treatment of **myelofibrosis**. The decision followed reports of cases consistent with Wernicke's encephalopathy in patients receiving fedratinib in the trials.

Just Stay Inside for the Next 16 years. An updated **Malaria Vaccine Technology Roadmap** presented at the 2013 American Society of Tropical Medicine and Hygiene meeting calls for the development of vaccines that can **eliminate malaria by 2030**. The goal will be to create new vaccines that show at least 75% efficacy against clinical malaria for use in all malaria-endemic areas. The 2013 roadmap focuses on developing safe and effective vaccines against *Plasmodium falciparum* and *P. vivax* parasites. According to WHO, there are 219 million cases of infection with malaria each year, including 660,000 deaths. There has been a **26% reduction in the global mortality rate in the past decade** as a result of malaria control measures.

DNA Patch Spurs Bone Growth. A small patch that delivers **DNA-loaded nanoparticles** may be the **next step in bone regeneration**. A [report](#) on animal tests at the University of Iowa, shows the patch delivered material that codes for the **platelet-**

derived growth factor PDGF-B, which stimulates cell production, and it regrew enough bone to cover skull wounds. The patch itself is composed of a **collagen scaffold loaded with synthetically created plasmids with the DNA**. By placing the patch on a small area of skull, the plasmids are able to infiltrate surrounding bone cells and spur growth to replace what had been broken or missing.

ANSWER TO TODAY'S TRIVIA

1. John Brown became a militant in the mid-1850's when as a leader of the Free State forces in Kansas he fought pro-slavery settlers in the territory. In 1859 he gathered a group of racially mixed followers and set out to Harpers Ferry in present-day West Virginia intending to seize the Federal arsenal of weapons and retreat to the Appalachian Mountains where they would establish an abolitionist republic of liberated slaves and abolitionist whites. Interestingly, after initial success at Harpers Ferry, he and his followers were repelled by a troop of U.S. Marines commanded by (U.S.) Colonel Robert E. Lee and Lieutenant J.E. B. Stuart. Brown was arrested, found guilty and sentenced to death by hanging. 2. Kenneth Lay was Enron's chief executive, who oversaw a dramatic rise in the energy-trading company's assets, and the subsequent fall. Ultimately "Enron" became synonymous with large-scale corporate fraud and corruption. 3. Alexander Haig had a notable career, beginning as a staff officer under General Douglas MacArthur in Korea. He soon moved to Pentagon assignments and a tour as a battalion commander in Vietnam during that war. He became involved in White House activities by being named Security Adviser, but ultimately became White House Chief of Staff, while still retaining his Army commission, during the height of the Watergate affair from May 1973 to August 1974, when President Nixon resigned. He took over the position from H.R. Haldeman who resigned on April 20, 1973. He was largely credited with keeping the government running while President Nixon was preoccupied with Watergate, and was essentially seen as the "acting president" during Nixon's last few months in office. He remained as Chief of Staff under President Gerald Ford for about a month and was ultimately replaced by Donald Rumsfeld.

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Contact email: Paul.Davis@nmshp.org



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