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To: Paul Davis
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NMSHP Pager

November 4, 2013

ON THIS DATE

On November 4, 1956, a spontaneous national rebellion that began 12 days before in Hungary was crushed by Soviet tanks and troops. In 1979, Iranian students stormed the U.S. embassy in Tehran, taking more than 60 American hostages and leading to an embargo of Iranian oil ordered by U.S. President Jimmy Carter. In 1990, “Dances with Wolves” debuted. In 1994, the first conference to focus exclusively on the subject of the commercial potential of the World Wide Web opened in San Francisco.

Today’s Birthdays: Will Rogers (1879-1935, cowboy philosopher and humorist); Art Carney (1918-2003, actor); Today’s Trivia: 1. Who was the Director of “Dances with Wolves?” 2. Art Carney had a long entertainment career, in film, stage, radio and TV. He is best known for what early TV role?

NMSHP/ASHP

President Calls for growth and change in NMSHP. Newly installed NMSHP President **Kim Neff** called on members to become more involved and reach out to others to continue the vital role that pharmacists play in healthcare in New Mexico during her incoming remarks at the 2013 Balloon Fiesta Symposium. Speaking during the Awards Banquet and Installation Lunch, Kim reminded members how pharmacists change lives improve patient

care and urged members to find their own niche in healthcare, their communities and NMSHP. She set goals for the year to include maintain and enhance **relations with student pharmacists, increase NMSHP membership**, enhance our policy and **advocacy efforts**, improve and expand our **educational programs** and continue to foster relationships with our colleagues at UNM and in community practice. [Read her comments](#) on the NMSHP website.

Legislative Call For Ideas. Feeling passionate about something that you would like to see changed in your pharmacy department, your day to day practice, or the profession in general? Now is the time to speak up! Although we may not be able to change the world, the **NMSHP Legislative Committee** is committed to continue advancing our profession and our ability to improve patient care. We cannot be successful without your help. Whether it is wanting to see pharmacists involved in the medication reconciliation process, requesting tools/assistance in developing certain programs in your facility, or any other issues you would like help with or feel need to be addressed, we want to hear from you! Please e-mail our Legislative Committee Chair **Davena Norris** at davena.norris@gmail.com with your ideas. We look forward to hearing from you soon!

STATE, NATIONAL & INTERNATIONAL

Best Places to Work in Healthcare. *Modern Healthcare* has released its list of “Best Places to Work in Healthcare,” identifying the “top 100” suppliers and providers. **Lovelace Women’s Hospital** in Albuquerque has been named the third-best place to work in the U.S. The rankings were published on the magazine’s website last month. It was the fifth consecutive year that the 120-bed hospital, which employs 750, made *Modern Healthcare*’s “top 100” list. It was the only New Mexico Healthcare firm to make this year’s list

Presbyterian Health Plan Praised by Consumer Reports. Presbyterian Health Plan and **Presbyterian Insurance Company, Inc.** are the **highest-ranked commercial health plans in New Mexico**, in the November 2013 issue of *Consumer Reports* magazine. Both also received the “Best Value” designation, according to a news release issued by Presbyterian. The rankings are based on data collected by the National Committee for Quality Assurance for the overall ranking of health plans.

FDA Recommends Schedule II for Hydrocodone. FDA will publish a rule by **early December** to **reclassify hydrocodone-containing drug** products as **Schedule II** controlled substances. About 131 million hydrocodone products were dispensed in outpatient settings in 2011. The Drug Enforcement Administration has been seeking FDA's approval to **reclassify the products since 2004**, noting the growing potential for abuse and misuse. Congressional pressure has been growing on FDA to order the reclassification. The National Community Pharmacists Association said that the FDA decision would "likely pose significant hardships for many patients and delay relief for vulnerable patients with legitimate chronic pain." NACDS echoed the comments, saying "This proposal is not the best avenue to address abuse and would negatively impact access to needed medications for those who suffer from chronic pain. In the interest of patient care, we have worked with patient advocacy groups in opposition to this recommendation as we support and advance workable solutions."

FDA Proposal Aimed at Shortages. FDA has announced a **new proposal to bring further controls on the drug shortage situation.** Under the proposed regulation, companies that make any "life supporting, life sustaining" prescription medications or any used to treat a "debilitating disease or condition" would have to **notify** the agency **6 months ahead of any changes** that could disrupt the U.S. supply. This would include plans to discontinue a product or manufacturing changes that could slow production. The regulations would also expand the requirement to non-drug biologic products, such as vaccines. The rules would expand and strengthen existing requirements passed by Congress last year and President Obama's Executive Order issued in 2011. FDA credits previous actions with **reducing the number of shortages from 251** in 2011 **to 117** last year.

SGR Fix Again Under Discussion. Democratic and Republican leaders of two key congressional committees have agreed on a framework to **scrap the Sustainable Growth Rate (SGR), the Medicare payment formula for physicians.** The plan would be to replace the structure with one that links reimbursement to the quality of care provided, in an attempt to put an **end to the annual "doc fix" debate.** The current SGR would reduce Medicare physician payments by nearly 25% on January 1 unless Congress intervenes. The plan under discussion would repeal the SGR, hold doctors' pay at current levels as the new reimbursement models are tested and could combine some existing Medicare physician quality performance programs into a new initiative starting in 2017. The new model could include Accountable Care Organizations, as well. The Committees will take up hearings on

the bill on November 12, with the goal of having a new system adopted by the end of the year.

Biosimilar Naming Debate Grows. APhA, NACDS and NCPA have petitioned the World Health Organization to **uphold common generic names for biosimilars** and their branded reference products. The 3 national organizations said that they were “concerned” about efforts to give biosimilars different generic names from their branded counterparts. While FDA is preparing to implement its abbreviated regulatory approval pathway for biosimilars, as mandated by the Patient Protection and Affordable Care Act, biotech companies have begun opposing the effort that would allow the generic naming nomenclature to be the same as traditional drug products, where both ‘brand’ and ‘generic’ carry similar names. The trade organization BIO says that **biosimilars and biologics are not identical**, and “giving them the same generic name would result in confusion.”

European regulators have approved biosimilars with the same generic names as their reference biologics for more than 6 years.

Moving Beyond Obamacare? While the country struggles with technical and political glitches of implementing Obamacare, **Vermont** is working on its 2017 launch of the nation’s **first universal health care system**, a type of modified “**Medicare-for-all**” approach. The program will combine universal coverage with new cost controls in an effort to move away from a system in which the more procedures and services that are performed, the higher healthcare providers pay goes. The concept is for providers to have a set budget to care for a set number of patients. The state has a population of about 626,000 and **15 hospitals, all of which are nonprofits**. It also holds a long, liberal approach to government with a community-based sense of values. The state is already close to achieving its goal, with **96% of Vermont children** having **health coverage** and 91% of the overall population insured, second only to Massachusetts.

FDA Begins Education on Misleading Ads. FDA has launched an **e-learning** course aimed at teaching healthcare providers how to **spot drug ads** and promotional materials that **may be untruthful or misleading**, and how to report them to FDA. The program, launched with Medscape, uses case studies to help students “become discerning readers of drug promotional information.” The agency encourages all providers to review the course and use the materials in their practices to help them make informed decisions. See additional information on the [FDA Blog](#). (Ed. Note: is this another opportunity that pharmacists have missed?)

CFC Inhaler Phaseout Nearly Done. All inhalers that use **chlorofluorocarbon (CFC)** propellants will be **off the market** by the **end of the year** according to FDA. Only **Combivent Inhalation Aerosol** and **Maxair Autohaler** remain on the market, and neither will be available after December 31. Most other inhalers have moved to using hydrofloroalkane (HFA) propellants, which don't have the same impact on the ozone layer as CFCs, or they use no propellants at all. The phaseout is the culmination of a decades-long effort to remove CFCs from the environment.

Oregon Puts Therapists on Primary Care Teams. St. Charles Health System in Bend, Oregon is experimenting with including **psychologists** as part of a **team approach to healthcare**. Many primary care physicians deal with **symptoms that stem from mental**, rather than physical **problems**. Patients often resist going to a psychologist even at the recommendation of a physician because of the stigma they feel in seeing a mental health professional. The pilot project puts psychologists in the doctors' offices to engage with the patient during their medical visit. Providing counseling and coping strategies appears to help with many cases of upset stomachs and headache pain. The pilot has so far demonstrated a **slight decrease in average medical costs** (from \$7,650 per patient per year to about \$6,800), even with a minor increase in pharmacy costs for Medicaid patients enrolled in the project.

PRACTICE & PROFESSION

VA System Reduces MRSA. Five years ago the Veterans Affairs medical centers implemented a national initiative to reduce methicillin-resistant *Staphylococcus aureus* (MRSA). In a report to be published in the *American Journal of Infection Control*, the program initially **successfully reduced MRSA infections by 17% in ICUs and 21% in non-ICU care**. Healthcare-associated infection (HAI) rates also dropped by 62% in ICUs and 45% in non-ICUs. The new study updates the earlier findings and reports an additional 13.7% decrease in HAI's and a 44.8% reduction in MRSA transmission in non-ICUs. The initiative focused on screening every patient for MRSA; using gowns and gloves when caring for patients colonized or infected with MRSA; following hand hygiene guidelines; creating an institution culture focusing on individual responsibility for infection control; and establishing an MRSA prevention coordinator position at each medical center.

Workers Fired After Viewing Patients' Records. Patients in **Minnesota and Missouri** are getting notices that healthcare **workers inappropriately viewed their patient records**. In both

cases, the offending employees were fired. A certified medical assistant at **Allina Health in Minneapolis** unnecessarily accessed the electronic health records of 3,807 patients across their system between February 2010 and September 2013. Boone Hospital Center in Columbia, MO says that a staff member from a private physician clinic viewed their records.

National Cyber Security Awareness Month. The security firm Rapid7 has released an awareness note focused on passwords in recognition of National Cyber Security Awareness Month. It advises there are several things you can do to **reduce your risk** and **increase password protections**. Make your passwords long and complex, more than 12 characters including lower case, upper case, numeric and special characters. Don't reuse passwords but use secure storage sites for your passwords. Regularly change your passwords. The company recommends **changing every 8 to 12 weeks**. Use services that offer two-factor authentication and enable them to provide a double layer of protection. Never use a default password that is already setup in a new application.

11 Ways to Get Better at Giving Bad News. Occasionally, you have to give someone bad news – firings, ending a business relationship, transferring a team member, etc. It's always tricky to do it, but it is possible to handle such endings with dignity and compassion, [says Corey Blake of Round Table Companies](#) on *SmartBrief/SmartBlog on Leadership*. Be direct and clear, explain your reasons and remember that you're dealing with a human being.

Your CPE Credit Reminder. Beginning last January, all ACPE-accredited providers were required to upload continuing education credits to the MyCPE monitor website, and had to discontinue providing 'paper statements' to program attendees. Whether you receive continuing education credit from NMSHP or another ACPE-accredited source, you must have an NABP e-Profile ID. Be sure you get your number and keep it with you for any continuing education programs that you participate in. For information, see the [NABP website](#). You will also need to provide your date of birth in a MMDD format at CPE activities, to serve as a double-check on the ID number.

Hospital Hiring May Have Hit a "Recession." *USA Today* reports that hiring in hospitals may be entering a recession period. **Healthcare providers cut more than 8,100 jobs in September**, mostly from hospitals, according to the report. Among the reasons attributed to the reductions are payment cuts from Medicare and other payers in anticipation of the Affordable Care Act's rollout, as well as cuts related to the federal budget sequester. Some

industry experts believe the jobs will be restored as the ACA rolls out and more Americans gain insurance coverage.

Is Genetic Testing the Future of Healthcare? The startup genetic testing company **23andMe** has raised more than \$126 million in capital since being launched in 2006. Most of the company's revenue comes from its \$99 DNA test, but the company eventually wants to become the "Google of personalized healthcare," and **shift the emphasis of healthcare from diagnosis to prevention**. Americans are expected to spend \$25 billion on genetic testing, but insurers are still trying to determine whether or not to cover the tests. There is disagreement on whether test results could lower healthcare costs by leading to better prevention of disease or raise costs by prompting expensive, unnecessary treatments.

Not Your Typical "Innovative Practice." An **injured kangaroo** recently made its way into Australia's Melbourne Airport and **ended up in the pharmacy**. The airport is ringed partly by bushland that is frequented by kangaroos. The Sydney Morning Herald reported that the animal had been hit by a vehicle outside the terminal. It was safely captured while in the pharmacy and placed under the care of a veterinarian.

NEW DRUGS & DEVICES

FDA Approves New Hydrocodone Drug. One day following its announcement of plans to restrict hydrocodone-containing products to Schedule II (see story above), FDA approved **Zohydro ER (hydrocodone bitartrate extended-release capsules)** for patients with pain severe enough to require daily, 24-hour long-term treatment, and for which other pain treatments are inadequate. The approval is based on safety findings from studies of more than 1,100 people with chronic pain and efficacy findings from a study of more than 500 patients with chronic low back pain. Post marketing studies will be required to assess the risks of misuse, abuse, increased sensitivity to pain, addiction, overdose and death. It will be listed as a **Schedule II controlled substance**.

Gastric Cancer Drug Gets Fast Track Status. FDA has granted priority review status to Eli Lilly and Company's **ramucirumab (IMC-1121B)** as a **single-agent treatment for advanced gastric cancer** following disease progression after initial chemotherapy. The drug is designed to directly inhibit angiogenesis. It is a receptor-targeted antibody that blocks the vascular endothelial growth factor (VEGF) receptor-2 and inhibits signaling involved in the formation and maintenance of aberrant blood vessels that

supply blood to tumors.

FDA Approves SQ Delivery for Actemra. FDA has approved marketing of Genentech's **Actemra (tocilizumab)** for subcutaneous injection for treatment of patients with moderately to severely active **rheumatoid arthritis** with insufficient response to disease-modifying anti-rheumatic drugs. Tocilizumab will become the first humanized interleukin 6 receptor-antagonist monoclonal antibody approved for both subcutaneous and intravenous delivery in the U.S. The SQ formulation can be given alone or with methotrexate or other non-biologic anti-rheumatic drugs.

Expanded Use of Entereg Approved. FDA has granted expanded approval for **Entereg (alvimopan)** to accelerate gastrointestinal recovery in patients who undergo surgeries that included a partial bowel resection with primary anastomosis. Entereg is the only drug approved for this use in the U.S.

RECALLS, WARNINGS & SHORTAGES

Iclusig Pulled from Market. At the request of FDA, **Iclusig (ponatinib)** has been **temporarily pulled from the market** by **Ariad Pharmaceuticals** because of safety concerns. Life-threatening **blood clots** and **severe narrowing of blood vessels** have led to the decision. An FDA investigation into the drug was initiated last month. New data indicate that approximately 24% of patients in the Phase 2 clinical trial and approximately 48% of patients in the Phase 1 trial experienced serious adverse vascular events. Patients on ponatinib who are not responding should stop treatment and seek an alternative, according to the agency.

Labeling Changes Ordered for Potiga. FDA has announced approval of changes to labeling for **ezogabine (Potiga, Valeant Pharmaceuticals)** to underscore previously reported risks for retinal abnormalities, potential vision loss and skin discoloration, all of which may become permanent. The revised label for the anti-seizure medication includes a boxed warning recommending that Potiga use be limited to patients who have not responded adequately to several alternative therapies to decrease the frequency of seizures or epilepsy. -The agency is further recommending that patients undergo eye exams prior to starting ezogabine and every 6 months during treatment.

RESEARCH

Hyperthyroid Drugs Linked to Birth Defects. An analysis of data on Danish infants born to mothers taking **propylthiouracil (PTU)** early in pregnancy show a **50% higher risk of birth defects**. Those taking **methimazole (MMI)** had a **75% greater risk** than children born to women in the general population, according to a study reported at the American Thyroid Association meeting. The birth defects associated with the 2 drugs were different, with **MMI associated** with more **musculoskeletal problems**, while **PTU** was **linked to face and neck defects**. Authors of the study called for restricting the use of anti-thyroid drugs in early pregnancy.

Baldness Research Advances. In a study published in the Proceedings of the National Academy of Sciences, researchers have shown that it may be possible to **generate new human hair on human skin**. A new technique for growing new hair is part of a long-term quest to improve the medical treatment of hair loss. The key to the latest development are **dermal papilla**, cells that are at the base of a follicle and provide genetic direction to other cells on how to make hair. Scientists have found a way to transplant rodent papilla into rodent skin to generate new hair. The procedure has now been tested with human dermal cells that have been nudged into multiplying in a lab environment and applied to rodent skin, with partial success. The researchers say they need to learn a lot more about the process before it can be tried in humans, and need a better understanding of how papilla cells interact with skin cells.

HIV Vaccine Breakthrough Reported. A vaccine designed by a team including researchers from the Los Alamos National Laboratory in New Mexico has shown that it may prevent HIV infection. The mosaic vaccine against the AIDS virus has demonstrated some promise when used with monkeys. An article published in "Cell" is being directed by Beth Israel Deaconess Medical Center, and represents the first use of bioinformatically optimized HIV vaccine antigens providing partial protection in rhesus monkeys. Researchers found an 87 to 90% reduction in monkeys' probability of becoming infected each time they were exposed to the virus.

SARS-Like Virus From Bat Contact. A **close cousin of the SARS virus** has been found in **bats** and it appears to be able to **transfer directly to humans**. The SARS epidemic in 2003 killed more than 750 people. The new findings published in the journal Nature may also help scientists deal with a SARS-like coronavirus that was reported in the Middle East that has killed more than 50 people (Middle East Respiratory Syndrome, MERS). The study involves a horseshoe bat colony in Yunnan Province in Southwest

China where SARS was first reported. From samples of hundreds of bats, a genetic analysis revealed at least 7 different strains of SARS-like coronaviruses, and one culture found a live virus that binds to a receptor on a human cell. In some parts of the world bats are captured for human food, increasing the risk of possible transmission.

ANSWER TO TODAY'S TRIVIA

1. "Dances with Wolves" starred Kevin Costner. The movie was also his directorial debut. It earned 12 Academy Award nominations, ultimately winning 7 including Best Picture and Best Director. 2. Carney played Ed Norton opposite Jackie Gleason's Ralph Kramden in the sitcom, "The Honeymooners." In 1974, he won the Academy Award for Best Actor for his performance as Harry Coombes, an elderly man on the road with his pet cat in "Harry and Tonto."

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