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From: New Mexico Society of Health-System Pharmacists <nmshp@nmshp.org>

Sent: Monday, November 18, 2013 9:30 AM

To: Paul Davis

Subject: NMSHP Pager e-Newsletter - November 18, 2013



NMSHP Pager

November 18, 2013

ON THIS DATE

On November 18, 1883, at exactly Noon the use of time zones took effect in the U.S. and Canada. In 1928, "Steamboat Willie," the first fully synchronized sound cartoon was released, featuring the third appearance of cartoon characters Mickey Mouse and Minnie Mouse. In 1963, the first push-button telephone went into service. In 1978, Peoples Temple founder Jim Jones led hundreds of his followers in a mass murder-suicide at their commune in a remote part of Guyana. The final death toll was 909. In 1991, Shiite Muslim kidnappers in Lebanon freed Anglican Church envoy Terry Waite after more than 4 years of captivity. In 1999, 12 people were killed and 27 injured in College Station, TX when the 59-foot tall Aggie Bonfire collapsed while under construction. Today's birthdays: George Gallup (1901-1984, statistician and pollster); Alan B. Shepard, Jr. (1923-1998, naval aviator, test pilot), David Ortiz (1975, baseball player). Today's trivia: 1. What brought about the establishment of continental time zones in 1883? 2. What special event does the Disney Corporation associate with November 18, 1928? 3. What unique place in history does Alan B. Shepard, Jr. hold?

PRESIDENT'S CORNER

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

As Thanksgiving approaches, I would like to express my sincere

gratitude to all of you for the hard work you put in each and every day. Thank you for taking the extra time to educate patients and families on their multiple new medications before patients are discharged. Thank you for working on a holiday when everyone else is at home with their families. Thank you for saving lives by intervening on dangerous



and/or incorrect medication orders. Thank you for bringing your unique skillset to the medical teams to better the health and well-being of your patients. No matter what capacity it is that you work in, you make a difference! I think I speak for patients, families, doctors, nurses, and many others in saying THANK YOU for all you do! Wishing you a safe and Happy Thanksgiving!

Advocacy in Action

The pursuit of provider status continues, with many pharmacy organizations across the nation making this one of their top priorities in the coming year. Grassroots advocacy efforts are as important as ever to showcase pharmacists' contributions to optimizing patient outcomes through medication management. On November 19, ASHP, APhA, and other pharmacy organizations will be conducting a health fair on Capitol Hill. What a great way to illustrate pharmacists' clinical capabilities by having these legislators see pharmacists in action. The more legislators know about what it is pharmacists really do, the more likely we will be successful in attaining provider status.

What can you do to ensure this event is a success? Call or e-mail our New Mexico legislators to encourage them to attend. If you want more information, please email President Kim Neff at kimbo1202@gmail.com or Legislative Committee Chair Davena Norris at davena.norris@gmail.com. To find contact information on the New Mexico Congressional delegation, click here. The event is just around the corner so we need to take action right away. Thanks in advance for advocating for your profession!

NMSHP/ASHP

UNM/NMSHP ASHP Reception Announced. The UNM/NMSHP Reception at the ASHP Mid-Year Clinical Meeting will be held on 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 New Mexico and beyond!

STATE, NATIONAL & INTERNATIONAL

Healthcare Biggest Part of ABQ Economy. New data from the U.S. Census Bureau indicates that the healthcare industry is the main driver of the 4-county Albuquerque metropolitan area's private sector economy. In 2011, healthcare employed 48,591 people and had an annual payroll of \$2.1 billion, or about 20.5% of the area's annual private sector payroll.

Low Medicaid Enrollment Seen for State. According to *The New Mexican*, thousands of people who qualify for insurance under New Mexico's expanded Medicaid program still haven't applied for the program. A total of 25,309 New Mexicans have applied for Medicaid since October 1, and of those, about 3,600 qualified under the expanded program. According to the State Human Services Department, that's a fraction of the 219,000 people who the state figures are eligible for coverage through the Centennial Care program.

NM HealthCare.Gov Enrollment Weak. Following the nationwide figures that resulted from the botched roll-out of the Obamacare HealthCare.Gov website, only 172 New Mexicans bought health insurance policies on the individual health insurance exchange during the first month of operation according to the U.S. Department of Health and Human Services. A total of 7,529 state residents applied for individual coverage, and 4,249 of those had been determined to be eligible to purchase insurance. While the state's enrollment was low, it wasn't the lowest. Alaska had 53 individuals enroll in plans, Delaware, 97; Ohio, 42; South Dakota, 58; and West Virginia, 174.

Lovelace Sells Plan to the Blues. The failure of Lovelace Health Plan to win a contract to be part of New Mexico's Medicaid program earlier this year led to the plan's agreement to sell to Blue Cross and Blue Shield of New Mexico. Not becoming a part of the Medicaid program led to the loss of 84,000 members of the Lovelace plan and more than 30% of its revenue. LHP sold its Medicaid business to Molina Healthcare of New Mexico earlier this year, leaving Lovelace with just 108,000 members. LHS will now focus on running its 6 hospitals in New Mexico and continuing to grow its physician practice. BCBSNM will use Lovelace Health System hospitals and clinics under terms of the agreement. Terms of the deal were not disclosed, and the sale is subject to regulatory approval.

Christus St. Vincent Cuts Job. Christus St. Vincent Regional

Medical Centers announced it is **laying off 36 employees and eliminating 58 positions.** According to the Santa Fe New Mexican, the reductions will **cut \$4 million** from the payroll. Those losing their jobs will be paid until the end of the year and efforts will be made to find them other positions, according to the hospital.

IHS and ACA. A recent Q&A column from Kaiser Health answered a pertinent question: "If our son is able to get healthcare from the local Indian Health Clinic, is he still required to get Obamacare insurance?" According to the response, "He may not be." Kaiser noted that most people have to have health insurance that qualifies as "minimum essential coverage" or face a penalty. About 2 million American Indians and Alaskan native tribe members receive healthcare at 600 Indian Health Service (IHS) facilities, but IHS services aren't health insurance, nor do they meet the standards for minimum essential coverage. However, members of federally recognized tribes are one of several groups exempt from the penalty for not having insurance. Members of Indian tribes who qualify can complete a form to apply for an exemption from the requirement to have insurance, which is currently under development, according to IHS.

Pharmacy Groups Split on Hydrocodone Rescheduling. Several national pharmacy organizations have publically opposed rescheduling of hydrocodone combination products via a letter to Department of Health & Human Services Secretary Kathleen Sebelius. Among the groups opposing the increased controls on the drugs are the Academy of Managed Care Pharmacy, American Society of Consultant Pharmacists, American Pharmacists Association, National Alliance of State Pharmacy Associations, National Association of Chain Drug Stores and the National Community Pharmacists Association. The groups said that "rescheduling will have a profoundly negative impact on patients who legitimately need these medications and negligible impact on drug abuse." The group says that the rescheduling would create serious barriers to patient access such as the inability to refill products, new burdens on the overextended healthcare system and new pharmacy requirements, including the need for additional secure storage, recordkeeping and inventory management. Meanwhile, ASHP commended the FDA decision to recommend the rescheduling via a letter to the Secretary, noting a policy approved in June by the ASHP House of Delegates. ASHP's position "called concerns regarding recordkeeping and security processes resulting from rescheduling 'valid,' but believes that they are outweighed by the public health benefit arising from increased control of drugs with high abuse potential."

Hospital Groups Urge Halt to Medicare/Medicaid Cuts. Nine hospital groups have urged Congressional budget negotiators to not make further cuts to Medicare and Medicaid reimbursement. In a letter, the American Hospital Association, the Association of American Medical Colleges, Catholic Health Association of the U.S., the Children's Hospital Association, the Federation of American Hospitals, the National Association of Psychiatric Health Systems, Premier Healthcare Alliance, America's Essential Hospitals and VHA, Inc. told the committee that hospitals can't continue to meet the needs of their communities if the federal government makes further cuts. "With total cuts approaching nearly a half a trillion over the next 10 years, including nearly \$45 billion in Medicare sequestration cuts, many local hospitals are nearing a breaking point in their ability to ensure patients have the care they need, when they need it," the group said.

FDA Consumer Video on Rogue Pharmacies. FDA has released a new video that warns consumers against buying drugs from rogue-Internet pharmacies, part of the ongoing effort by the agency to keep fake and contaminated drugs out of the U.S. supply chain. The video highlights the agency's efforts to combat fraudulent online pharmacies and offers tips for recognizing them. While the crackdown has shut down thousands of illegal pharmacy websites in the last few years, it remains a growing problem. So far FDA has arrested and convicted more than 400 people involved with rogue pharmacies and collected more than \$178 million in restitution for consumers. It has collaborated with other law enforcement agencies in 99 countries to take action against more than 9,600 rogue Internet pharmacies.

Student Loan Repayment Legislation Proposed. APhA has joined a coalition of other professional organizations to support proposed legislation that would amend the tax code to provide healthcare professionals, including pharmacy students, who receive student loan repayments from the Indian Health Service the same tax-free status as those who receive National Health Service Corps loan repayments. The legislation will be offered by Rep. David Valadao (R-CA). Other entities supporting the proposal include the American Academy of Physician Assistants, American Association of Colleges of Nursing, American Association of Colleges of Pharmacy and the American Dental Association.

PRACTICE & PROFESSION

Martinez Seeks to Lure Nurses to New Mexico. Gov. Susana Martinez has proposed streamlining the requirements for nurses

from other states to become licensed in New Mexico. Her proposal includes asking the Legislature to approve nearly \$220,000 in recurring marketing and advertising funds to **recruit nurse practitioners to move to and practice in New Mexico.** The state is one of 24 participating in the Nurse Licensure Compact (NLC), a partnership that allows licensed nurses to cross state lines and practice without additional applications and fees in the member states. The proposal would also minimize the time it takes for licensed nurses relocating to New Mexico from Non-NLC states to obtain the necessary licensure to practice.

Nursing Schools Agree to Common Curriculum. Schools offering nursing programs in New Mexico have agreed to establish a common curriculum so that students moving within the State will find it easier to transfer academic credits. The announcement was made by Gov. Susana Martinez and members of the New Mexico Nursing Education Consortium. The Governor said the change also means students throughout New Mexico would be able to pursue a bachelor of science in nursing degree without having to physically attend large universities like UNM or New Mexico State. Local community colleges will be able to partner with one of the larger universities to offer BS degrees.

New Guidelines Change Cardio Therapy. New guidelines from the American Heart Association and American College of Cardiology decrease the focus on the low-density lipoprotein cholesterol and encourage consideration of age, weight, blood pressure and other factors such as smoking or diabetes when treating patients. The target of keeping LDL under 100 or 70 for people at high risk has been abandoned in favor of a more total patient risk assessment. Those with a moderate risk of heart attack or stroke should be prescribed statins according to the update, regardless of LDL levels. One source indicated that about 50-60% of African American men and a third of white men in their 50s will probably qualify for therapy under the new guidelines, dramatically expanding the potential patient pool for statin treatment. Four risk groups now include:

Those with a history of atherosclerotic cardiovascular disease.

Those with an LDL level of 190 mg/dL or more, which includes many patients with familial hypercholesterolemia.

Patients with diabetes ages 40 to 75 who do not have a history of clinical atherosclerotic cardiovascular disease and have an LDL level of 70 to 189 mg/dL

Those with a 10-year cardiovascular risk - assessed using the new

equation - of 7.5% or higher and an LDL level of 70 to 189 mg/dL but no history of cardiovascular disease

High-intensity statin therapy -- that which reduces LDL cholesterol by at least 50% -- is indicated in the first two groups. For patients with diabetes, the new risk equation can be used to determine whether high-intensity or moderate-intensity statin therapy (that associated with LDL cholesterol reductions of 30% to 49%) should be used. Moderate-intensity statin therapy should be sufficient in the last group.

There is a strong recommendation to consume a diet rich in fruits, vegetables, whole grains, low-fat dairy, legumes, fish, poultry, and nuts and low in sweets, sugar-sweetened beverages, and red meats -- along the lines of the DASH or Mediterranean diets. The writing group also found evidence backing restrictions on saturated fat and trans fat to reduce cholesterol levels, and restrictions on sodium to reduce blood pressure.

Physical activity is included as well, with the authors concluding that the evidence supports guidance released by the Department of Health and Human Services in 2008, which recommends 40 minutes of moderate-to-vigorous activity 3 or 4 days a week.

Billing for Waste – Lost Revenue Opportunity? An article in *Pharmacy Practice News* highlights a potential new revenue source for hospital pharmacy that is seldom used and little understood. According to Bonnie Kirschenbaum, MS, FASHP, Medicare created the ability to bill for expensive wastes in the outpatient area after moving to the use of "billing units representing actual dose given," abandoning the "whole vial" method of billing under the Outpatient Prospective Payment System (OPPS). Medicare does not mandate billing for waste but makes it possible to recoup some lost dollars by paying strict attention to the OPPS rules. Failure to bill for waste creates an understated picture of the cost of medications being included in bundled payment systems. She urges a dialogue on moving more systems to take advantage of the opportunity.

No ICD-10 Consistency for ADEs. An article published in the *Journal of the American Medical Informatics Association* finds **wide variability in medical research** when the authors set out to create a comprehensive set of ICD-10 codes used to identify adverse drug events (ADEs) from administrative data. The study focused on 41 published studies that used administrative data to ascertain the prevalence of ADEs in certain populations. Researchers found 827 ICD-10 codes that have been used for the purpose, including 175 citing external injury and 652 based on

NEW DRUGS & DEVICES

FDA Approves Mantle Cell Lymphoma Drug. FDA has approved Imbruvica (ibrutinib) to treat mantle cell lymphoma. A second approval of the drug for chronic lymphocytic leukemia is expected by February, 2014. Ibrutinib is the first among a new class of B-cell lymphoma drugs that can be taken orally, as opposed to via injection. Mantle cell lymphoma represents about 6% of non-Hodgkin cases in the U.S. with about 5,000 patients currently diagnosed with the disease. The anticipated cost of therapy will be \$10,900 per month, or \$130,800 annually. The drug will be co-marketed by Pharmacyclics Inc. and Johnson & Johnson. Media reports indicate that Pharmacyclics will offer two months' worth of the drug for free to patients who have trouble with insurance reimbursement and the company is setting up copay assistance plans for patients who can't afford their share of the cost.

FDA OKs Fish Skin Treatment for Chronic Wounds. FDA has granted 510(k) clearance for the marketing of a proprietary fish-skin, omega-3 tissue-regeneration product for treating chronic wounds. MariGen Omega3 is indicated for the management of wounds including diabetic, vascular and other hard-to-heal ulcers. It consists of intact, decellularized fish skin sheets devoid of all cells and antigenic materials. It is produced in Iceland from North Atlantic-harvested fish. According to a news release from Kerecis Limited, "when the product is inserted into or onto damaged human tissue protease activity is modulated, the fish skin is vascularized and populated by the patient's own cells, and ultimately converted into living tissue."

RECALLS, WARNINGS & SHORTAGES

Low Molecular Weight Heparins – Drug Safety
Communication. FDA is recommending that health care professionals carefully consider the timing of spinal catheter placement and removal in patients taking anticoagulant drugs, such as enoxaparin, and delay dosing of anticoagulant medications for some time interval after catheter removal to decrease the risk of spinal column bleeding and subsequent paralysis after spinal injections, including epidural procedures and lumbar punctures. These new timing recommendations, which can

decrease the risk of epidural or spinal hematoma, will be added to the labels of low molecular weight heparins, including Lovenox and generic enoxaparin products and similar products. Epidural or spinal hematomas are a known risk of enoxaparin in the setting of spinal procedures and are already described in the Boxed Warning and the Warnings and Precautions sections of the labels for Lovenox and generic enoxaparin products. However, these serious adverse events continue to occur. To address this safety concern, FDA worked with Sanofi-Aventis to further evaluate this risk and to update the Warnings and Precautions section of the Lovenox label with these additional timing recommendations. The labels for generic enoxaparin products will also be revised accordingly, as will those of other low molecular weight heparin-type products. It is important to note that all anticoagulants carry the risk of causing spinal bleeding when used in conjunction with epidural/spinal anesthesia or spinal puncture.

Health care professionals and institutions involved in performing spinal/epidural anesthesia or spinal punctures should determine, as part of a **pre-procedure checklist**, whether a patient is receiving anticoagulants and identify the appropriate timing of enoxaparin dosing in relation to catheter placement or removal. To reduce the potential risk of bleeding, consider both the dose and the elimination half-life of the anticoagulant:

- For enoxaparin, placement or removal of a spinal catheter should be delayed for at least 12 hours after administration of prophylactic doses such as those used for prevention of deep vein thrombosis. Longer delays (24 hours) are appropriate to consider for patients receiving higher therapeutic doses of enoxaparin (1 mg/kg twice daily or 1.5 mg/kg once daily).
- A post procedure dose of enoxaparin should usually be given no sooner than 4 hours after catheter removal.
- In all cases, a benefit-risk assessment should consider both the risk for thrombosis and the risk for bleeding in the context of the procedure and patient risk factors.

Fentanyl Patch Fatality Reminder. The Institute for Safe Medication Practices has issued a reminder about the danger of access to Fentanyl patches by children. A 15 month-old boy, who had been sleeping on his mother's chest while they both took a nap died after ingesting the patch which had been on her chest to treat pain. The autopsy showed signs of acute Fentanyl intoxication. ISMP says the accidental overdosing is a recurring story with patches which are often taken inadvertently. Transdermal patches are designed to release the drug over 72

hours via topical application but uncontrolled quantities may be rapidly absorbed via the buccal route if the patch is ingested. Chewing is particularly dangerous because it releases a full dose in a much shorter period of time. A 50 mcg/hour patch tested by ISMP showed nearly 8,400 mcg of Fentanyl, which will vary by the patch design. Children have also been victims of fatal Fentanyl patches after they applied a patch intended for an adult on their own skin. Patients should be reminded of their personal responsibility with the patches when used in an ambulatory environment, and all should be reminded of the danger to small children.

FDA Acting to Withdraw Approval for 14 Drugs. FDA has begun the process of withdrawing its approval for 14 drugs by providing the affected manufacturers the opportunity for a hearing to discuss the proposed action. The agency is taking the action because the manufacturers "have repeatedly failed to file required annual reports for their applications." The products include Multi-Vitamin Tablets by Smith Miller and Patch, Inc.; Methostan (methandriol) tablets, USV; Corticotropin Injection, Vitarine Pharmaceuticals, Inc; ACTH Injection, Parke-Davis; Hyrye Injection, S.F. Durst and Co., Inc; Flamotide Injection, Philadelphia Ampoule Laboratories; Duracton Injection, Nordic Biochemicals, Inc.; Rubivite Injection, Bel Mar Laboratories; Corticotropin Injection, Organics/LaGrange, Inc; RU-B-12-1000 **Injection**, Dow Pharmaceutical Corp.; **Efacin Tablets**, Person and Covey, Inc; Acthar Gel Synthetic Injection, Armour Pharmaceutical Co; and Thyrel TRH Injection, Ferring Pharmaceuticals, Inc.

OTC Topical Antiseptic Drug Safety Communication. FDA is requesting label and packaging changes for certain over-the-counter (OTC) topical antiseptic products as a result of the agency's evaluation of infrequent but continuing reports of infections resulting from antiseptic products labeled for preoperative or pre-injection skin preparation. Contamination of topical antiseptics occurs when organisms are introduced into the product by users. Therefore, health care professionals and patients should follow all label directions to decrease the chances of infection.

Outbreaks associated with the use of contaminated topical antiseptics have been reported in the medical literature and to CDC. Clinical infections have also been reported to FDA, leading to some product recalls. The reported outcomes ranged from **localized infections at injection sites** to **systemic infections** that resulted in death. FDA has reviewed reports of four deaths, five cases of wound infection, seven cases of peritonitis, 10 cases of

septic arthritis, 14 cases of indwelling catheters requiring replacement, 16 cases of injection site infection, and 32 cases of bacteremia. These infections have been confirmed to be caused by contaminated antiseptic products. Affected products included **all commonly used antiseptic ingredients**, including alcohol, iodophors, chlorhexidine gluconate, and quaternary ammonium products. Organisms implicated in the outbreaks included Bacillus cereus, Burkholderia cepacia, Pseudomonas aeruginosa, Achromobacter xylosoxidans, Ralstonia pickettii, Serratia marcescens, and Mycobacterium abscessus. To further reduce the risk of infection with improper topical antiseptic use and the possibility of these products becoming contaminated with bacteria during use, the agency is requesting that manufacturers package antiseptics indicated for preoperative or pre-injection skin preparation in single-use containers.

- To reduce the risk of infection, ensure the products are used according to the directions on the label.
- The antiseptics in these single-use containers should be applied only one time to one patient.
- Health care professionals and patients should not dilute antiseptic products after opening them.
- Applicators and any unused solution should be discarded after the single application.

INDUSTRY MATTERS

Feds Launch Probe of Brilinta Study. The U.S. Justice Department's civil division is probing the PLATO clinical trial of AstraZeneca's Brilinta (ticagrelor), and the company announced that it is cooperating with investigators. There were no details provided about what Justice is seeking in the "documents and information" that they have demanded on the study, but the study was the subject of harsh criticism from two researchers in a report published in the International Journal of Cardiology. They highlighted concerns that study results reviewed by an outside organization demonstrated a worse outcome than the clopidogrel arm of the trials and that half of the favorable results for PLATO were drawn from just Hungary and Poland. PLATO researchers have fought back against the accusations.

Merck has issued a notice that **500 jobs** at the company's West Point, PA facility will be cut between December 23 and January 5. A month ago the manufacturer announced it would remove 8,500 employees worldwide, or about 20% of its workforce. Most of the 500 jobs will be eliminated at the manufacturing and research site.

Johnson & Johnson has agreed to pay more than \$2.2 billion in criminal and civil fines to settle accusations that it improperly promoted Risperdal (risperidone) for use in older adults, children and people with developmental disabilities. The agreement is the 3rd largest pharmaceutical settlement in U.S. history. The settlement will also resolve accusations that the company inappropriately promoted Natrecor (nesiritide) and Invega (paliperidone). The U.S. Justice Department claimed that J&J paid kickbacks to doctors and pharmacists for use of the drugs for dementia, a non-approved use, and in people with mental disabilities and children prior to FDA's 2006 approval for use in children.

RESEARCH

New Drug reduces LDL Cholesterol. An investigational monoclonal antibody, administered subcutaneously every 2 to 4 weeks appears to significantly reduce low density lipoprotein (LDL) cholesterol, according to a recent report. In four Phase II trials, mean changes in LDL at week 12 ranged from -40% to -59% when compared with placebo for all dose groups. AMG-145, under development by Amgen which sponsored the study, is a fully human monoclonal antibody to PPCSK9, a new and compelling target for lowering LDL.

Positive Results for New Leukemia Drug. Roche Holding AG announced that patients in a clinical trial taking the company's new leukemia drug Gazyva (obinutuzumab) lived about a year longer without their disease worsening than patients taking Rituxan (rituximab). At the present time, Rituxan is the top selling Roche drug and one of the biggest in the industry. It loses patent protection in Europe later this year and in the U.S. in 2018. All patients in the trial received chlorambucil. Those taking obinutuzumab lived a median 26.7 months without worsening of their disease, compared with 15.2 months for those taking rituximab plus the chemotherapy. About a third of patients on Gazyva experienced low white blood cell counts versus 27% in the Rituxan group, and 20% of Gazyva experienced "infusion-related reactions," versus 4% in the Rituxan group.

ANSWER TO TODAY'S TRIVIA

1. The need for time zones stemmed directly from the problems encountered by the railroads moving passengers and freight over

thousands of miles of rail lines that covered North America by the 1880s. Even as late as the 1880s most U.S. towns had their own local time, generally based on "high noon." American and Canadian railroads began using the time zones on this day. 2. The Disney corporation considers November 18, 1928 to be Mickey Mouse's birthday. 3. Alan Bartlett Shepard, Jr. was the first American (and second person) to travel into space. His Mercury spacecraft flight was the U.S.'s first sub-orbital flight. Ten year later, at age 47, he became the oldest astronaut in the program, and commanded the Apollo 14 mission to the moon, becoming the 5th person to walk on the Moon and the only astronaut of the Mercury Seven to walk on the Moon. He famously hit two golf balls on the lunar surface.

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