NMSHP Pager

January 20, 2014

ON THIS DATE

*On **January 20, 1841**, China ceded the island of Hong Kong to the British during the First Opium War. In **1898**, Britain was granted an additional 99 years of rule over Hong Kong. Ultimately, in **1997** the British relinquished control of Hong Kong to China in exchange for a pledge to preserve the city's capitalist system. In **1980**, President Jimmy Carter proposed that the 1980 Summer Olympics be moved from the planned host city, Moscow, if the Soviet Union failed to withdraw its troops from Afghanistan within a month. Calling the Soviets' invasion of Afghanistan a danger to world peace, Carter ultimately called on U.S. athletes to boycott the Olympics. The U.S. was one of 60 nations that did not participate. In **1981**, minutes after the inauguration of Ronald Reagan as President, the 52 U.S. captives held hostage at the U.S. Embassy in Teheran, Iran were released, ending the 444-day Iran Hostage Crisis. Today's Birthdays: George Burns (1896-1996, comedian/actor); Aristotle Onassis (1906-1975, Turkish-Greek businessman); DeForest Kelley (1920-1999, actor); Frederico Fellini (1920-1993, Italian director). Today's Trivia (just fun stuff from all over): 1. What room in the average American home is the scene of the greatest number of arguments? 2. In 1960, the citizens of Hot Springs, New Mexico, voted to rename their town in honor of a popular radio show. What is it now called? 3. How much time, in months, does the average American motorist spend during his lifetime waiting for red lights to turn green? 4. Ninety six percent of American children can recognize who? 5. On the reverse side of the $100 bill, what time is shown on the Independence Hall clock?*

PRESIDENT'S CORNER

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

Happy New Year!! Wishing you joy and goodness in 2014!

The Pursuit of Provider Status: I have a feeling 2014 is going to be a great year for pharmacists!! As pharmacy organizations on a national level continue working together to find the most appropriate way to make provider status for pharmacists a reality, there is no better time than the present to get involved. How can you help in this endeavor? I know how valuable your efforts and skillset on the healthcare teams and in the lives of your patients, but we need to spread the word. Here are some ways you can make a difference:

1. **UNM Legislative Day:** Join the Legislative Committee and the UNM College of Pharmacy on February 5th at the State Capitol. We will be conducting healthcare screenings and educating legislators about pharmacists and our contributions to the healthcare team. Contact Davena Norris at Davena.norris@gmail.com for more information.
2. **Provide us a testimonial:** The NMSHP Legislative Committee is collecting testimonials (a few sentences or short paragraph) from providers, patients, and other key community members about their experiences with pharmacists. Legislators value the input of their constituents! This is a wonderful opportunity to demonstrate our worth from the perspective of key players in health care. Testimonials can be sent to the Legislative Committee Chair, Davena Norris (davena.norris@gmail.com), by **January 31, 2014.**
3. **Be the rockstars you are!** Often times when we think of advocating for the profession we think of law, legislators, and lobbying. Good news--- these aren't the only ways!! By making a commitment to help your patients and striving to give your very best each day, you will showcase your talents and value to providers, patients, and other important parties. The more lives you touch, the more people will hear about it, and the easier it will be for those lobbying for things such as provider status to be successful in these endeavors.

Communications Task Force: Are you a Facebook addict? Are you an Instagram expert or possibly Facebook challenged? Do you have no idea what I am talking about and/or prefer snail mail above all other forms of communication? No matter what your preference, we want your insight! Determining the most effective and all-encompassing means of communication is important to ensure all members are aware of news, upcoming events/opportunities, and other important information in a timely fashion. If you are interested in being a part of the brainstorming to determine the best way to relay information to our members, I invite you to be a part of our Communications Task Force. Please contact me at kimbo1202@gmail.com if you are interested!

Dates to remember:

- January 31: Deadline for submitting testimonials
- February 5: UNM Legislative Day at the State Capitol
- March 8: NMSHP Spring Meeting, 8:00am-12:30pm, up to 4 hours of CPE.

NMSHP/ASHP

NMSHP MIDYEAR Meeting Announced.
Introducing a brand new event! The 2014 NMSHP Midyear Meeting will be held March 8 in Albuquerque. Four hours of continuing pharmacy credit will be available.

Location: University of New Mexico North Campus (Health Sciences Center)
Domenici Auditorium, Domenici 1 Building
1101 Yale Blvd NE Albuquerque, NM 87106
click here for a map

Preliminary Schedule of Events:
7:00 a.m. 8:00 a.m.
Registration

7:50 a.m. 8:00 a.m.
Welcome Remarks

8:00 a.m. 9:00 a.m.
New Lipid Guidelines

9:05 a.m. 10:05 a.m.
Controlled Substances, Pain & Safety

10:05 a.m. 10:25 a.m.
Snack Break

10:25 a.m. 11:25 a.m.
Tuberculosis Treatment

11:30 a.m. 12:30 p.m.
To Be Determined

This activity is eligible for ACPE credit; see the final CPE activity announcement for specific details.

ASHP Ambulatory Care Conference and Summit. ASHP will hold its inaugural conference provides 10hrs of continuing education on hot topics and emerging issues in the practice of ambulatory care pharmacy in Dallas, TX, March 3-4, 2014 . This event also offers ambulatory care practitioners a unique and valuable opportunity to influence the future of practice through consensus building activities held during the Summit portion of the conference. Our goal is to create a vision for forward thinking pharmacy practice models that will ensure pharmacists are members of the ambulatory healthcare team who are responsible and accountable for patient and healthcare system outcomes.

Meeting Highlights include:

- 10 hours of CPE on emerging issues led by expert faculty
- Consensus activities with briefing documents
- Post meeting/follow up webinars
- Receptions, breakfasts and lunches
- Networking opportunities with leaders in ambulatory care

To register and learn more about the education, Summit, speakers, and networking opportunities available at the conference; visitwww.ashp.org/ambulatorycareconference14

STATE, NATIONAL & INTERNATIONAL

New Mexico Doctor Shortage to Worsen. The *Albuquerque Journal* reports that the federal government says that the state is facing its **worst shortage of primary care providers** at the same time **more people are becoming eligible for healthcare insurance coverage**. The latest figures show that the state has 1,429 active primary care physicians, but another 219 are needed, based on the population. It is anticipated that 160,000 new Medicaid patients will be added to the rolls this year, along with residents purchasing coverage under the Affordable Care Act. According to a 2012 survey by the New Mexico Primary Care Association, 76 federally funded health clinics reported wait times

for non-urgent calls between 1 and 4 weeks. Governor Susana Martinez has announced a package of initiatives to increase and support primary care physicians and nurse practitioners. The shortage is also exacerbated by an anticipated wave of retiring physicians.

NM Healthcare.gov Enrollment Soars. More than **7,500 New Mexicans** have**selected a health insurance plan** on the federal insurance exchange for individuals by December 28 according to the U.S. Department of Health and Human Services. A total of 21,422 New Mexicans had applied for coverage through the exchange, but of those 12,327 were found to be eligible for Medicaid. However, it is estimated that nearly 300,000 residents, or 71% of the state's 422,000 uninsured residents, are eligible for health insurance subsidies or Medicaid under the Affordable Care Act.

CMS Proposes MTM Program Improvements. The Centers for Medicare and Medicaid Services (CMS) has released a proposed rule for the 2015 Medicare Part D program that would target **2 chronic diseases** for **medication therapy management**(MTM) services. If implemented, that change could expand the number of MTM-eligible patients in **Part D** programs. The rule begins on page 131, under Medication Therapy Management Program (MTM) under Part D (§ 423.153(d)), of the full set of proposalsonline.

CMS Seeks to Remove Protected Status from Some Drug Types. CMS has proposed removing regulations that ensure the access of seniors to several classes of drugs. The "protected status" is no longer needed, according to CMS, due to increased access to generic alternatives, and its removal could result in significant savings for Medicare beneficiaries and taxpayers. Currently the Medicare **Part D prescription drugs plan** must include on their formularies "all or substantially all" drugs within six categories: **antidepressants, antipsychotics, anticonvulsants, antineoplastics**and **immunosuppressants**. The policy has been in effect since the inception of Part D. The Affordable Care Act codified the protected classes into federal statute, but granted CMS the authority to specify what criteria it would use to identify protected classes. The new proposed regulation says that its criteria to continued protected status would be 1) failure to receive the drug would result in the patient's hospitalization within 7 days; and 2) drugs in that class are not interchangeable. The new criteria**exclude antidepressants** and **immunosuppressants** from protected status beginning in 2015. CMS has also determined that **antipsychotics** fail to meet the new criteria, however, they will not immediately be excluded from protected status.

FDA Urges Compounding Pharmacies to Register. FDA has sent 'thousands of letters" to hospitals asking them to **encourage compounding pharmacies** to**register** with the agency under the new federal law that sets up a voluntary registration program. FDA Commissioner Margaret Hamburg's letter notes that by registering the pharmacies would agree to submit to FDA inspections and Good Manufacturing Practices. Hamburg also wrote state governments urging them to persuade compounders that are based outside their states but sell products into their states to consider registering with FDA.

Healthcare Insurance Globalization Underway. A group of **U.S. Blue Cross Blue Shield** insurers, including WellPoint, Inc., is collaborating with the **United Kingdom's Bupa** to create the **worlds' biggest provider network** for international health-insurance customers. Bupa, the largest private medical insurer in Great Britain will form a combined provider network with BCBS that will include more than 11,500 hospitals in more than 190 countries. Bupa will also purchase a 49% stake in Highway to Health, Inc, a company owned by the Blue Cross plans that sells global insurance products.

PRACTICE & PROFESSION

California Provider Status Law Effective January 1. The **California provider status law** (SB 493) went into effect January 1, including the language that declares pharmacists as healthcare providers. However, much of the law requires regulations to actually implement the details. The California State Board of Pharmacy intends to begin the rulemaking process on many of those in March, with the average time of 9 months required to finalize rules. Some portions of the law, such as the new Advanced Practice Pharmacist recognition, may take longer, according to a board representative. The law authorizes all licensed pharmacists to administer drugs and biologics when ordered by a prescriber; provide consultation, training and education about drug therapy, disease management and disease prevention; participate in multidisciplinary review of patient progress, including appropriate access to medical records; furnish travel medications recommended by CDC not requiring a diagnosis; initiate and administer immunizations to patients 3 years of age and older if appropriately trained and certified; and order and interpret tests for the purpose of monitoring and managing efficacy and toxicity of drug therapies in coordination with the patient's primary care provider or diagnosing prescriber. By the end of 2014 the state anticipates that regulations will be in place to allow all pharmacists to furnish self-administered hormonal contraceptives pursuant to a statewide protocol and furnish prescription nicotine replace products for smoking cessation pursuant to a statewide protocol if appropriately trained and certifies. Probably after 2014 the Advanced Practice Pharmacist recognition, which will require additional training, will be implemented to work in coordination and under protocols with the patent's primary care provider.

"Nightmare Bacteria" Outbreak in Chicago. The latest drug-resistant outbreak of infections has occurred in a hospital in a Chicago suburb. The "**nightmare bacteria**," as it is called by the media, has infected 44 people over the past year, according to CDC. The bacteria is a **carbapenem-resistant enterobacteriaceae**, and it contains a rare enzyme that breaks down antibiotics. A similar outbreak occurred in 2012 among 8 patients at a Denver hospital. While no problems were found with the Park Ridge, IL hospital's cleaning methods for endoscopic devices, the bacteria were found on 3 of the instruments. The hospital is now using gas sterilization to clean devices, rather than simply washing and disinfecting them.

FDA Undertakes Another Pradaxa Review. Since the anticoagulant **Pradaxa**(**dabigatran etexilate mesylate**) was approved in 2010, the FDA has been concerned over the potential for greater bleeding issues among patients than those taking warfarin. Clinical research has not proven the risk to be any greater for Pradaxa, but it continues to top the list of adverse reaction reports received by the agency. Consequently, FDA is seeking comments on the protocol for an "assessment of selected safety outcomes in adults with atrial fibrillation who are new users of dabigatran or warfarin" through today. The review will be done by a search of electronic healthcare data through the FDA Mini-Sentinel program. The protocol announcement isonline. There are over 2,000 lawsuits pending in Illinois accusing Boehringer Ingelheim of failing to provide adequate warnings regarding the risk of Pracdaxa bleeding.

Healthcare Spending Growth Remains Low. Nationwide spending on healthcare remains low for the fourth consecutive year, according to CMS. Spending grew at an annual rate of 3.7% in 2012, to $2.8 trillion, in part due to slower growth in prescription drug, nursing home, private health insurance and Medicare expenditures. Additionally, the percentage of the overall economy devoted in health spending fell from 17.3% to 17.2%. Some of the slowdown was due to aspects of the Affordable Care Act, but other factors played a role. While Medicare enrollment grew, Medicare spending increased

only by 4.8% compared to 5% in 2011.

RFID Cuts Infection Rates. A 17-hospital system in Ohio is planning on **reducing hospital acquired infections** by implementing a real time monitoring system using**radio frequency identification (RFID) technology**. The monitoring system has been placed in the hospitals' facilities, and the pilot program demonstrated that its use could achieve more than 90% compliance with hand washing standards in the test facility. The system automatically detects hand hygiene opportunities and records hygiene actions. Badges worn by nurses in the pilot were connected with sensors in patient areas. The devices buzzed whenever the nurses failed to wash their hands. A poster presented at the American Public Health Association's Annual Meeting this past fall shows that hospitals could reduce nosocomial infections through the use of the technology, even with additional uses such as alarms for scheduled filter changes or pressurized mats in front of hand-washing areas that ensure employees spend enough time at the sink.

Sometimes, Leaders Must Speak First. While leaders shouldn't be too quick to speak out, there are times when issues must be addressed without hesitation, according to John Baldoni, writing on SmartBrief/SmartBlog on Leadership. While it's important to give others a chance to be heard, when immediate moral or strategic questions must be addressed, it's essential that leaders speak up.

NEW DRUGS & DEVICES

FDA Approves New Diabetes Drug. FDA has approved **dapagliflozin** (**Farxiga**) for the treatment of **type 2 diabetes in adults**, along with diet and exercise. The drug, a sodium glucose co-transporter 2 inhibitor, will be supplied in tablet form by Bristol-Myers Squibb and AstraZeneca. The product blocks the reabsorption of glucose by the kidney, increases glucose excretion and lowers blood glucose levels, according to the companies. It was initially denied approval in 2012 when FDA asked for additional risk and benefit data. Safety and efficacy were established in 16 clinical trials of over 9,400 patients with demonstrated improvements in HbA1c levels. Dapagliflozin should not be used by patients who have type 1 diabetes, increased ketones in their blood or urine, moderate or serve renal impairment, end-stage renal disease, those who have active bladder cancer, or those on dialysis. Adverse events include genital mycotic infection and urinary tract infection, and it has been associated with hypotension, particularly among older patients, those with impaired renal function and those receiving diuretics.

FDA Approves Pain Management Device. FDA has approved **Smiths Medical**application to market the **CADD-Solis system**, which features the firm's Programmed Intermittent Bolus and Piaitne Controlled Analgesics application. The infusion pump is intended for use in **managing post-operative pain** as well as in administration of epidural analgesia.

FDA Approves New MRSA Test. FDA has approved BD Diagnostics to market the **BD Max MRSA XT test**, the company's second assay that can be used to diagnose strains of methicillin-resistant *Staphylococcus aureus* with the mecC gene. The assay, which will run on the company's' BD Max platform, is designed to aid hospitals in their active surveillance efforts.

Low Blood Pressure Drug Receives Preliminary Approval. An FDA advisory panel has endorsed a drug to treat a rare form of low blood pressure. The 16-1 vote recommends that **Northera** (**droxidopa**) by **Chelsea Therapeutics International Ltd.** Be approved for neurogenic orthostatic hypotension (NOH), a rare chronic type of low pressure that occurs on standing and is associated with certain

neurological disorders such as Parkinson's disease. The drug is converted into norepinephrine in the body. The agency still must approve the panel's recommendation before the drug can be marketed.

Cancer Drug Gets Breakthrough Designation. GSK's **Tafinlar** (**dabrafenib**) has received **breakthrough therapy designation** from FDA as a treatment for metastatic BRAF V600E-positive nonsmall cell lung cancer. The decision was based on interim efficacy and safety data from an ongoing midstage trial. Tafinlar was approved last May for use as single-agent therapy in treating unresectable or metastatic melanoma in patients with the BRAF V600 or V600K mutation. The designation will allow the product to be approved in a shorter period of time for the NSCLC indication.

RECALLS, WARNINGS & SHORTAGES

Clinimix/Clinimix E Injection Recall. Baxter International and FDA have issued a voluntary recall of **two lots** of **CLINIMIX** and one lot of **CLINIMIX E Injection**parenteral nutrition products due to complaints of particulate matter found in the products. The affected product codes are 2B7729 (lot P287045, exp 06/14), 2B7717 (lot P275883, exp 10/13) and 2B7709 (lot P28512, exp 05/14). The affected lots were distributed to customers between May 2012 and October 2013. Baxter has notified customers, who have been directed not to use product from the recalled lots and to locate and remove all affected product from their facility.

Nipro Diagnostic Glucose Meter Recall. Nipro Diagnostics initiated a voluntary recall and replacement of a limited number of **TRUEbalance** and **TRUEtrack Blood Glucose Meters** distributed both in the United States and outside the United States. The company has determined that certain isolated TRUEbalance and TRUEtrack Blood Glucose Meters have an incorrect factory-set unit of measure that displays the glucose result in mmoi/L rather than mg/dL. If a consumer were not to notice the incorrect unit of measure, it is possible that the meter result could be read as a lower than expected blood glucose result. There are 501 affected TRUEbalance meters and 105 affected TRUEtrack meters that were distributed in the United States from September 2008 to May 2013. The company is sending notifications to pharmacies, durable medical equipment providers, mail order companies and distributors where the TRUEbalance and TRUEtrack meters are recommended or sold in the United States.

Sodium Phosphate OTC Products – Drug Safety Communication. FDA has issued a warning that using more than one dose in 24 hours of over-the-counter (OTC)**sodium phosphate drugs** to treat constipation can cause rare but serious harm to the kidneys and heart, and even death. The agency has become aware of reports of severe dehydration and changes in the levels of serum electrolytes from taking more than the recommended dose of OTC sodium phosphate products, resulting in serious adverse effects on organs, such as the kidneys and heart, and in some cases resulting in death. According to the reports, most cases of serious harm occurred with a single dose of sodium phosphate that was larger than recommended or with more than one dose in a day.

t:slim Insulin Cartridge Recall. Tandem Diabetes Care is initiating a voluntary recall of specific lots of insulin cartridges that are used with the **t:slim Insulin Pump**. The affected cartridges may be **at risk for leaking**. A cartridge leak could potentially result in the device delivering too much or too little insulin, which can lead to a serious adverse event. Affected lots were shipped on or after December 17, 2013. The affected lots represent approximately 4,746 boxes of cartridges (10 cartridges per box). Customers should discontinue using cartridges labeled with the affected lots.

FDA Acetaminophen Recommendations. FDA is recommending health care professionals discontinue prescribing and dispensing prescription combination drug products that contain more than 325 mg of **acetaminophen** per tablet, capsule or other dosage unit. There are no available data to show that taking more than 325 mg of acetaminophen per dosage unit provides additional benefit that outweighs the added risks for liver injury. Limiting the amount of acetaminophen per dosage unit will reduce the risk of severe liver injury from inadvertent acetaminophen overdose, which can lead to liver failure, liver transplant, and death. Cases of severe liver injury with acetaminophen have occurred in patients who:

- took more than the prescribed dose of an acetaminophen-containing product in a 24-hour period;
- took more than one acetaminophen-containing product at the same time; or
- drank alcohol while taking acetaminophen products.

FDA also recommends that when a pharmacist receives a prescription for a combination product with more than 325 mg of acetaminophen per dosage unit that they contact the prescriber to discuss a product with a lower dose of acetaminophen. A two tablet or two capsule dose may still be prescribed, if appropriate. In that case, the total dose of acetaminophen would be 650 mg (the amount in two 325 mg dosage units). When making individual dosing determinations, health care providers should always consider the amounts of both the acetaminophen and the opioid components in the prescription combination drug product.

Merck Recalls Liptruzet. Packaging defects have prompted a recall of **Liptruzet**(**ezetimibe and atorvastatin**) by Merck & Co., temporarily affecting the entire U.S. stock. The company announced that foil pouches holding the tablets could allow air and moisture inside, allowing degradation of the drug. The recall covers all 4 dose strengths and every batch that has been distributed since Liptruzet entered the market in May.

INDUSTRY MATTERS

Healthcare Expense Reductions Tied to Patent Expirations. The **rise in the use of generic products**, and **expiration of patents** for many brand name products, helped account for the slowdown in healthcare costs reported last week by CMS. Generic drugs made up 77% of all 2012 retail prescriptions, up from about 70% of the prior year. Total prescription drug spending increased 0.4% to $263 billion, down from the 2.5% increase in 2011. IMS Health has said generic utilization was at its highest level ever in 2012, and they estimate the rate can still increase by a few more percentage points before maxing out.

RESEARCH

HIV Cure Experiment "Disappointing." Two men with HIV had received successful bone marrow transplants in Boston as treatment for blood cancers. Following the procedures, tests could find no sign of the HIV virus. In July it was announced that the 2 had stopped antiretroviral therapy, and there was no sign of HIV replication at the time. However, in December it was reported that both men, after 12 and 32 weeks respectively of being off HIV therapy, had experienced a viral rebound and were back on treatment. Researchers called the results "disappointing, but scientifically significant."

ANSWER TO TODAY'S TRIVIA

1. The kitchen. 2. Truth or Consequences-known as T or C for short. The change was made after radio (and later TV) show host Ralph Edwards promised to hold a program there annually. 3. Six months. 4. Ronald MacDonald. 5. 4:10.

CORRECTIONS

Well, we actually got more than a few calls and notes from NMSHP members to remind us that New Mexico didn't enter the Union in 1969. . . but just about everyone noticed the typo in the January 6 Pager, saying that New Mexico became a state on January 6, 1969. We could easily explain if we had said 1812 or 1921, since the state joined on January 6, 1912 . . .but where 1969 came from we have no idea! Our apologies to our members who remember the world before the 1960s!