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To: Paul Davis
Subject: NMSHP Pager - December 16, 2013



NMSHP Pager

December 16, 2013

ON THIS DATE

*On **December 16, 1773**, a group of Massachusetts colonists disguised as Mohawk Indians boarded 3 British tea ships and dumped 342 chests of tea into the Boston Harbor. In **1944**, the Battle of the Bulge began. In **1973**, O.J. Simpson became the first player in the NFL to rush for more than 2,000 yards in a single season. In **2009**, "Avatar" was released internationally. Today's Birthdays: Ludwig van Beethoven (1770-1827, composer); Arthur C. Clarke, (1917-2008, author). Today's Trivia: A different twist today: Researchers at MIT have created a new tongue twister that they claim may be the toughest one yet. Stefanie Shattuck-Hufnagel, an MIT psychologist who specializes in speech errors as a way of understanding normal brain function and one of the creators of the phrase, dares anyone to repeat it ten times quickly: "pad kid poured curd pulled cod." Now you have your Monday assignment (!)*

NMSHP/ASHP

ASHP Ambulatory Care Conference. ASHP will host an Ambulatory Care Conference and Summit designed for practitioners who want to advance ambulatory care through education and consensus building. The program will provide **10 hours of CPE** on contemporary topics and emerging issues in ambulatory care pharmacy. A goal of the Summit is to create a

vision for pharmacy practice models that will ensure pharmacists are members of the healthcare team. The conference is scheduled for **March 3-4** in **Dallas, TX**. For more information, see the [ASHP website](#).

ASHP Seeks Inputs on Policies. The ASHP Board of Directors has approved a plan to encourage members to provide feedback on proposed policies before the Board considers them. To share your opinions with House delegates and other ASHP members, visit **ASHP Connect** and join the House of Delegates Community [discussion](#) of draft [policy recommendation](#) the Board will consider in January. You can also read the policy recommendations and submit comments directly to ASHP.

ASHP Foundation Releases New Pharmacy Forecast. The ASHP Foundation has released [Pharmacy Forecast 2014-2018](#) with an updated look at **8 domains that will likely challenge health-system pharmacy practice leaders**. The issue includes information on fiscal issues, quality of care, health care analytics, the pharmaceutical marketplace, the pharmacy practice model, ambulatory care, pharmacy department operations and leadership. The Forecast was the subject of a **special session** at the **ASHP Midyear** meeting in Orlando.

PhORCAS 2.0 Launched. The pharmacy residency application process known as **PhORCAS** has released its **version 2.0**. The update increases the speed and allows carryover of data to subsequent years and applications. The software includes direct links and updates occur automatically. The program is now live on the [ASHP website](#).

STATE, NATIONAL & INTERNATIONAL

ASHP Seeks Comments on Compounding Rules. FDA has published 5 documents that spell out how compounders will be defined and regulated and cover both sterile and non-sterile compounding, citing USP Chapters <795> and <797>. While state Boards of Pharmacy will have primary responsibility for oversight of pharmacy compounding, **FDA will be watching compounders that are not registered as outsourcing facilities** and the agency will work with state board to address any pharmacy compounding that violates the Food Drug and Cosmetic Act. FDA has published draft [guidances](#) on implementation of the new federal compounding law. ASHP plans to comment on the proposals and encourages members to review the documents and provide input via a survey. For information on the guidances and a link to the

survey, see the ASHP News Capsule [online](#).

FDA Seeks Authority of Superbug Fight. FDA is urging Congress to adopt legislation that would allow the agency to create a program to help develop **drugs used to treat antibiotic-resistant “superbugs.”** FDA may have the authority to undertake the project on its own, but it believes that legislation would be the best way to start the initiative swiftly and forcefully. According to Janet Woodcock, FDA’s director of drug evaluation, the “need is very great,” with at least **2 million people** being **infected with drug-resistant bacteria** in the U.S. annually. FDA recently released plans to **phase out the use of antibiotics in meat**, which can lead to the growth of drug-resistant strains of bacteria.

Grassley Working on ACO Changes for Pharmacists. Sen. Chuck Grassley (R-IA) is working on an amendment which would include **pharmacists as providers in Medicare Accountable Care Organizations (ACOs)** as part of the Sustainable Growth Rate (SGR) bills that are working their way through House and Senate Committees. APhA has announced it is working with the Senator on an amendment that would strengthen the role of pharmacists within Medicare ACOs by amending the Social Security Act to include licensed pharmacists as providers of services in team-based or integrated care activities. The House has passed a **3-month SGR extension to delay the 20% cut in physician Medicare reimbursement** that was scheduled to go into effect in January. Both the House and Senate Committees have passed a version of an SGR-fix bill which are scheduled to be voted on in early 2014.

PRACTICE & PROFESSION

Soaring Healthcare & Hospital Costs Coming Under Scrutiny. A [new study](#) in the *Journal of the American Medical Association* looks at the **spiraling cost of healthcare** in the U.S. between 1980 and 2011. By 2011, the cost of healthcare amounted to **\$2.7 trillion**, nearly doubling as a percentage of Gross Domestic Product to 17.9%. Since 2000, 91% of the cost increases including hospital prices, professional service, drugs and devices and administrative costs have driven the sector, not demand for services or aging of the population. Chronic illnesses account for 84% of overall costs among the entire population, not just the elderly. The factors the article suggest that have produced the most change include consolidation (with fewer general hospitals and more single-specialty hospitals and physician groups), along with concentration in insurers, pharmacies and benefits managers; information technology; and the changing role of the **patient as a**

consumer who goes outside of traditional channels to obtain information, guidance and self-management. A recent *New York Times* [article](#) drills down on the high prices of hospitals, citing examples of charges averaging **\$500 per stitch** made in treating cuts, and cases of hospitals charging up to \$12,500 per day.

Med Error Reduction Through Improved Patient Handoffs. A new study in the *Journal of the American Medical Association* shows that hospital can significantly **reduce** medical **errors** by **adopting standardized communication** during patient handoffs without adding burdens to existing workflows. A study at Boston Children’s Hospital focused on 1,255 patient admissions and used a resident handoff bundle, consisting of standardized communication and handoff training, a verbal mnemonic, and a new team handoff structure. Medical errors decreased from 33.8 per 100 admissions to 18.3/100 admissions, and preventable adverse events decreased from 3.3/100 admissions to 1.5/100.

Preventable Readmissions Declining. According to a [blog](#) post from CMS, after a steady rate of 19% from 2007 to 2011, the **all-cause 30-day readmissions rate fell to 18.5% in 2012**. Preliminary claims data shows the Medicare readmission rate averaged less than 18% over the first 8 months of 2013, or an estimated 130,000 fewer hospital readmissions between January 2012 and August 2013.

Specialty Pharmacy Group Establishes Residency. The [National Association of Specialty Pharmacy](#), a new group representing specialty practices has announced that it will begin accrediting a **new student residency program** to help undergraduates transition into the field. The program is scheduled to begin late next spring. The association currently offers certificate programs in rheumatoid arthritis and multiple sclerosis.

National Drug Monitoring Program Called for by Docs. The American College of Physicians (ACP) has called for a **national prescription drug-monitoring program** as one of 10 recommendations to help reduce prescription drug abuse. A [policy paper](#) published in the *Annals of Internal Medicine* laid out the recommendations. The policy applies to medications to treat **sleep disorders, nerve conditions, and weight loss as well as painkillers**. ACP also supports electronic prescribing and urges use of non-opioid treatments before prescribing narcotics.

NEW DRUGS & DEVICES

FDA OK’s Oral Hepatitis C Drug. FDA has approved **Sovaldi**

(**sofosbuvir**) by Gilead Science for the **treatment of chronic hepatitis C**. The drug is designed for once daily dosing and is the first approved treatment for hepatitis C infection **without the use of interferon**. It can be used in combination with ribavirin for those with genotypes 2 and 3 infections. For patients with genotype 1, which accounts for about 70% of U.S. infections, sofosbuvir must still be used with both interferon and ribavirin, although it can be considered for use in patients with genotype 1 infections who cannot use interferon. It is in a class of medications known as nucleotide analogue inhibitors, designed to block a protein that the hepatitis C virus needs to replicate. Anticipated cost of the therapy is \$7,000 per week, with therapy anticipated to last 12 weeks.

Peyronie's Disease Drug Approved. FDA has approved **Xiaflex (Collagenase Clostridium Histolyticum)** for an additional indication of treatment of **Peyronie's disease**. Peyronie's is caused by untreated inflammation of the penis that occurs through injuries obtained during sex that don't heal correctly. Xiaflex works by breaking down buildups of scar tissue underneath the skin that cause the penis to curve as much as 90 degrees when erect. Between 65,000 and 120,000 men are diagnosed each year with the condition according to Auxilium Pharmaceuticals, Inc. manufacturer of the drug.

FDA Panel Approves Crohn's Disease Drug. An FDA advisory panel voted to recommend that the agency approve **vedolizumab** for use in **ulcerative colitis and Crohn's disease**. The product, developed by Takeda Pharmaceutical Co., received overwhelming support for use in both diseases, but concerns of the potential for progressive multifocal leukoencephalopathy (PML) were widely discussed. No patient in clinical trials experienced PML. The drug will be sold under the brand name **Entyvio**. It is a monoclonal antibody that controls inflammation by blocking alpha4beta7 integrin.

FDA Approves 26 New Entities. FDA has issued a preliminary report noting that it has approved 26 new molecular entities during 2013. The agency approved 35 entities in 2012, but there were fewer applications this year than in the past. Rare diseases account for about 36% of the novel drug approvals, and **3 of this year's drugs** were approved with the "**Breakthrough Therapy**" designation.

FDA Puts Gaucher Disease Drug on Priority Review. FDA has given **Sanofi** a 6-month priority review status for its **experimental oral Gaucher disease drug eliglustat**. The drug is a novel ceramide analog given orally and was designed to partially inhibit

the enzyme glucosylceramide synthase, resulting in reduced production of glucosylceramide. Glucosylceramide is the substance that builds up in the cells and tissues of people with Gaucher disease, an inherited condition affecting fewer than 10,000 people worldwide. People with Gaucher disease do not have enough of the enzyme, β -glucosidase (glucocerebrosidase) leading to the accumulation of its substrate, glucosylceramide. As a result, lipid engorged cells (Gaucher cells) amass in different parts of the body, primarily the spleen, liver and bone marrow. Accumulation of Gaucher cells may cause spleen and liver enlargement, anemia, excessive bleeding and bruising, bone disease and a number of other signs and symptoms. The most common form of Gaucher disease, type 1, generally does not affect the brain.

Chronic Liver Disease Drug Granted Orphan Status. FDA has granted orphan status to **Conatus Pharmaceuticals Inc.** for its experimental drug for use in chronic liver disease. **Emricasan**, which has been studied in over 500 subjects through 10 clinical trials, is targeted at patients with acute-or-chronic liver failure, chronic liver failure and patients who have developed liver fibrosis postorthotopic liver transplant due to Hepatitis C infection. The company plans additional trials in 2014. It is estimated that **5.5 million Americans have chronic liver disease or cirrhosis.**

FDA OK's Unapproved Vaccine For Meningitis Outbreak. Novartis is providing **Bexsero (meningococcal group B vaccine [rDNA, component, adsorbed])** to Princeton University to deal with an outbreak of **potentially fatal meningitis** that has affected at least 8 students. Bexsero is currently approved in Canada, Europe and Australia, and FDA allowed a conditional approval in response to a request from CDC for its use on the Princeton campus. It is currently in Phase I and Phase II clinical trials in the U.S. Meningococcal serogroup B, or **MenB**, is a rare but devastating infection that progresses rapidly and can lead to **death or permanent disability within 24 hours of symptom onset.**

RECALLS, WARNINGS & SHORTAGES

[Onfi \(clobazam\) Warning – Risk of Serious Skin Reactions.](#)

FDA is warning the public that **Onfi (clobazam)** can cause **rare but serious skin reactions** that can result in permanent harm and death. FDA approved changes to the Onfi drug label and the Patient Medication Guide to describe the risk of **Stevens-Johnson syndrome (SJS)** and **toxic epidermal necrolysis (TEN)** that can

occur at any time during Onfi treatment. However, the likelihood of skin reactions is greater during the first 8 weeks of treatment or when Onfi is stopped and then re-started. All cases of SJS and TEN in the FDA case series have resulted in hospitalization, one case resulted in blindness, and one case resulted in death. Patients should be closely monitored for signs or symptoms of SJS/TEN, especially during the **first 8 weeks of treatment** or when re-introducing therapy. Health care professionals should discontinue use of Onfi and consider an alternate therapy at the first sign of rash, unless it is clearly not drug-related.

Baxter Nitroglycerin in 5% Dextrose Injection Recall. Baxter International Inc. has initiated a **voluntary recall** of one lot of **Nitroglycerin in 5% Dextrose Injection** due to **particulate matter** found in one vial. If infused, particulate matter could lead to potential venous and/or arterial thromboembolism. The product is packaged in 250 mL glass containers, with 12 glass containers per carton. The affected product code is 1A0694, and the affected lot number is G105197. Product affected by this recall was **distributed** to healthcare centers and distributors in Colombia, Saudi Arabia and the United States **between January 17, 2013, and October 10, 2013**. Unaffected lot numbers can continue to be used according to the instructions for use. Affected product should be **returned to Baxter** for credit by contacting Baxter Healthcare Center for Service at 1-888-229-0001 between the hours of 7:00 a.m. and 6:00 p.m., Central Time.

FDA Issues Warning On Breast Screening Alternative. FDA is alerting the public that a nipple aspirate test is not a replacement for mammography, other breast imaging tests, or breast biopsy, and should not be used by itself to screen for or diagnose breast cancer. The FDA is not aware of any valid scientific data to show that a nipple aspirate test by itself is an effective screening tool for any medical condition including the early detection of breast cancer or other breast disease. Certain manufacturers are promoting the use of nipple aspirate tests as a stand-alone evaluation tool for screening and diagnosing breast cancer, claiming they are an alternative to biopsy or mammography. Possible health consequences include false negative test results, indicating the absence of breast cancer when cancer exists, and false positive test results, indicating the presence of breast cancer when none exists. The **National Comprehensive Cancer Network (NCCN) 2013 guidelines** state that the **clinical utility of nipple aspiration is still being evaluated** and it should **not be used as a breast cancer screening technique**.

RESEARCH

Men and Women are Different. Researchers have found that the brains of women and men display **distinctive differences** in how **nerve fibers connect various regions of their brains**. No one has yet explained how the brain wiring might relate to thought and behavior, or how it may influence the different genders' perception, formation of judgments, social behavior or processing of information, but the discovery is leading to a renewal of interest and controversy in the subject.

Prostate Cancer Study Shows Success with Drug Combo. Men with advanced prostate cancer survived significantly longer on a combination of 2 types of drugs than if they were started on the standard single treatment, according to a federally sponsored study. The 790-patient trial which began in 2006 found that **69% of men who started with a combination of hormone therapy to suppress testosterone levels and docetaxel were alive after 3 years**, compared with 52.5% who were started on hormone therapy alone. Results of the National Cancer Institute-funded study were reported by Christopher Sweeney, a medical oncologist at the Dana-Farber Cancer Institute in Boston, lead investigator for the study.

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