AU InforMed

Volume 5 Number 33 (Issue 168) *Wednesday, October 3, 2007*

Key Inforbits

- MedWatch – unapproved drugs
- MedWatch – atrial fib with bisphosphonates
- Top 6 prevention services
- Vitamin D resurges
- Patches are poison?
- FDA is on the defensive

NEW DRUGS, and other related stuff …

New Indication … (9/19/2007) The FDA has approved expanding the population for use of the **nasal influenza vaccine FluMist®** (by MedImmune Vaccines, Inc) to **include children between the ages of 2 and 5**. Approval for the vaccine, which contains a weakened form of the live virus and is sprayed in the nose, was previously limited to healthy children 5 years of age and older and to adults up to age 49. Commonly observed adverse events from the vaccine were generally mild and included runny nose and/or nasal congestion, as well as a slight fever in children 2 to 6 years of age. FluMist® should not be administered to anyone with asthma or to children under the age of 5 years with recurrent wheezing because of the potential for increased wheezing after receiving the vaccine. People who are allergic to any of FluMist's® components, including eggs or egg products, should also not receive the vaccine.
http://www.fda.gov/bbs/topics/NEWS/2007/NEW01705.html

MedWatch … (9/21/2007) MOM Enterprises Inc., and the FDA informed consumers and healthcare providers that **Baby's Bliss Gripe Water**, apple flavor, with a code of 26952V and expiration date of October 2008 (10/08) is being **recalled due to the presence of Cryptosporidium infection**. The product is labeled Baby's Bliss. Pediatrician Recommended Gripe Water. Apple Flavor. An herbal supplement used to ease the gas and stomach discomfort often associated with colic, hiccups, and teething in infants and children. The most common symptom of Cryptosporidium infection is watery diarrhea. Other symptoms include dehydration, weight loss, stomach cramps or pain, fever, nausea, and vomiting. Symptoms generally begin two to ten days after becoming infected with the parasite and generally last 1-2 weeks. The infection could be life-threatening for certain individuals, including infants, children, and individuals with weakened immune systems. FDA advises parents/caregivers of children who have recently consumed Baby's Bliss Gripe Water, apple flavor, and have these symptoms to seek immediate medical attention and stop using this product and throw away bottles of the product immediately.
Read the complete MedWatch 2007 Safety Summary including a link to the FDA News Release at: http://www.fda.gov/medwatch/safety/2007/safety07.htm#Bliss

MedWatch … (9/21/20007) TWC Global LLC, Inc., issued a **nationwide recall of Axcil and Desirin, both marketed as dietary supplements, because they contain potentially harmful, undeclared ingredients**. FDA laboratory analysis of Axcil and Desirin found that the lot of 02B07 contained 3mg/g of sildenafil. The products also contained sulfosildenafil and

sulfohomosildenafil, which are analogs of sildenafil. All of these undeclared chemicals pose a threat to consumers because they may interact with nitrates found in some prescription drugs (such as nitroglycerin) and may lower blood pressure to dangerous levels. Consumers who have these products should stop using them immediately and consult their healthcare professional if they experience any problems that may be due to these products.
Read the complete MedWatch 2007 Safety Summary including a link to the manufacturer's Recall Notice at: http://www.fda.gov/medwatch/safety/2007/safety07.htm#Axcil

MedWatch … (9/28/2007) FDA informed healthcare professionals and consumers of its intent to take action against companies that market **unapproved prescription products containing hydrocodone**, a narcotic widely used as a cough suppressant and to treat pain. The FDA has received reports of medication errors associated with formulation changes in unapproved hydrocodone products and reports of confusion over the similarity of the names of unapproved products to approved drug products. Most of the hydrocodone formulations now marketed to suppress coughs have not been approved. The agency is particularly concerned about improper pediatric labeling and the risk of medication error involving the unapproved products. No hydrocodone cough suppressant has been established as safe and effective for children under 6 years of age. Anyone marketing unapproved hydrocodone products that are currently labeled for use in children younger than 6 years of age must end further manufacturing and distribution of the products on or before 10/31/2007. Those marketing any other unapproved hydrocodone drug products must stop manufacturing such products on or before 12/31/2007, and must cease further shipment in interstate commerce on or before 3/31/2008.
Read the complete MedWatch 2007 Safety Summary including a link to the FDA News Release at: http://www.fda.gov/medwatch/safety/2007/safety07.htm#Hydrocodone

MedWatch … (10/1/2007) FDA issued an early communication about the ongoing review of new safety data regarding the association of **atrial fibrillation with the use of bisphosphonates**. FDA reviewed spontaneous postmarketing reports of atrial fibrillation reported in association with oral and intravenous bisphosphonates and did not identify a population of bisphosphonate users at increased risk of atrial fibrillation. In addition, as part of the data review for the recent approval of once-yearly Reclast for the treatment of postmenopausal osteoporosis, FDA evaluated the possible association between atrial fibrillation and the use of Reclast. Most cases of atrial fibrillation occurred more than a month after drug infusion. Also, in a subset of patients monitored by electrocardiogram up to the 11th day following infusion, there was no significant difference in the prevalence of atrial fibrillation between patients who received Reclast and patients who received placebo. Upon initial review, it is unclear how these data on serious atrial fibrillation should be interpreted. Therefore, FDA does not believe that healthcare providers or patients should change either their prescribing practices or their use of bisphosphonates at this time.
Read the complete MedWatch 2007 Safety Summary including a link to the FDA Early Communication at: http://www.fda.gov/medwatch/safety/2007/safety07.htm#Bisphosphonates

FROM THE MEDICAL LITERATURE …

Prevention saves lives … A new report from the National Commission on Prevention Priorities has identified the **TOP 6** preventive services that would save the most lives in the U.S. if practiced by 90% of the eligible adults:

- Daily aspirin to prevent heart disease
- Stopping smoking when encouraged by a health professional

- Being screened for colorectal cancer
- Influenza vaccination
- Breast cancer screening
- Screening for chlamydial infection

See the full 46-page report outlining data and recommendations for 12 preventive services examined by the Commission.

National Commission on Prevention Priorities. *Preventive Care: A National Profile on Use, Disparities, and Health Benefits*. Partnership for Prevention, August 2007.

National Commission on Prevention Priorities. *Data Needed to Assess Use of High-Value Preventive Care: A Brief Report from the National Commission on Prevention Priorities.* Partnership for Prevention, August 2007.

http://www.prevent.org/content/view/129/72/

Another vitamin deficiency may affect pregnancy outcomes … in a case-controlled study, 274 pregnant women were followed from <16 weeks gestation to delivery. There were 219 women who did not develop preeclampsia and 55 women that did. Serum 25(OH)D concentrations were measured and it was found that the women who developed preeclampsia had lower serum levels. This small sample suggests further study is needed, including whether vitamin D supplementation would be of benefit.

Bodnar LM, Catov JM, Simhan HN, Holick MF, Powers RW, Roberts JM. Maternal vitamin D deficiency increases the risk of preeclampsia. *J Clin Endocrinol Metabol*. 2007 Sep;92(9):3517-3522.

More on Vitamin D … Two diverse, meta-analyses looking at the effects of vitamin D on total mortality and in combination with calcium for fracture risk in the elderly. One meta-analysis identified 18 randomized controlled trials that included 57,311 participants. The mean vitamin D supplement dose was 528 IU (range 300-2000 IU). The intake of ordinary doses was associated with decreases in mortality rates. The other meta-analysis was a well-done study that included 29 studies and a total of 63,897 patients. The treatment effect was better with calcium doses of ≥1200 mg and with vitamin D ≥800 IU. Vitamin D combined with calcium did not significantly change the treatment effect compared to no vitamin D, but there was a greater risk reduction in patients with a low vitamin D serum.

Autier P, Gandini S. Vitamin D supplementation and total mortality. *Arch Intern Med*. 2007 Sep 10;167(16):1730.

Tang BMP, Eslick GD, Nowson C, Smith C, Bensoussan A. Use of calcium or calcium in combination with vitamin D supplementation to prevent fractures and bone loss in people aged 50 years and older: A meta-analysis. *Lancet*. 2007 Aug 25;370:657-666.

Reviews of Note …

- Rank MA, Li JTC. Concise Review for Clinicians: Allergen immunotherapy. *Mayo Clin Proc*. 2007 Sep;82:1119-1123.
- Vassallo P, Trohman RG. Prescribing amiodarone: An evidence-based review of clinical indications. *JAMA*. 2007 Sep 19;298(11):1312-1322.
- Braunstein GD. Gynecomastia. *N Engl J Med*. 2007 Sep 20;357(12):1229-1237.
- Abramowicz M, ed. Drugs for parkinson's disease. *Med Lett Treat Guidelines*. 2007 Oct;5(62):89-94.
- Fardet L, Kassar A, Cabane J, Flahault A. Corticosteroid-induced adverse events in adults. *Drug Safety*. 2007;30(10):861-881.
- Sicherer SH, Sampson HA. Peanut allergy: Emerging concepts and approaches for an apparent epidemic. *J Allergy Clin Immunol*. 2007 Sep;120:4910503.
- Meyer TW, Hostetter TH. Uremia. *N Engl J Med*. 2007 Sep 27;357(13):1316-1325.

FROM THE LAY LITERATURE about medicine …

Patches are poison … an article in the *Los Angeles Times* brings to the public eye the problem of using transdermal patch technology with various drugs. Two products were highlighted: Duragesic® (fentanyl) patches and Ortho Evra® (hormonal contraceptive) patch. Using case reports and interviews of patients/family, the overdoses of fentanyl patches, resulting in death, was highlighted as was reports of blood clots in women using the contraceptive patch. Some discussion of the patch technology, its unreliability and simple improper prescribing all work their way into the story. There are certainly problems that need to be addressed.

Alonso-Zaldivar R. Dangers of drug patches overlooked. *Los Angeles Times*. 2007 Aug 27.
http://www.latimes.com/news/science/la-na-patches27aug27,1,1522391.story

FDA on the defensive … Two stories have pointed out deficiencies at the FDA and leaves one wondering, what else? The first item reviews the number of drugs on the U.S. market that have never had benefit of FDA review. These **"unapproved" drugs** are produced and marketed as any new drug. Physicians and pharmacists generally have no idea of the legal status of the products they prescribe/dispense; and most have a National Drug Code (NDC). This is not a secret as the FDA has known about the situation for decades; they are possibly now taking more notice. HOWEVER, another report indicates that it may not get better as the **FDA is seriously understaffed** at least in the area of clinical trials. The FDA has 200 inspectors to monitor clinical trials in approximately 350,000 testing sites. This means that the vast majority of clinical drug trials are unmonitored. Further data showed that in a 5-year period, the FDA disqualified investigators in 26 clinical trials and disqualified data only twice, although 348 serious problems were found at various trial sites. Members of Congress are also jumping on calling for more oversight and money. Implications were also present concerning the Agency's tendency to defer to the pharmaceutical industry.

Gruber A. FDA fails to vet many prescription drugs. *CNN.com*. 2007 Sep 26.
http://www.cnn.com/2007/HEALTH/conditions/09/26/unapproved.drugs/index.html
Harris G. Report assails FDA oversight of clinical trials. *New York Times*. 2007 Sep 28.
http://www.nytimes.com/2007/09/28/health/policy/28fda.html?_r=1&ref=health&oref=slogin

AUBURN HSOP FACULTY and STUDENTS in the literature …

- Marlowe KF, Howard D, Chung A. New onset diabetes with ketoacidosis attributed to quetiapine. *So Med J*. 2007 Aug;100(8):829-831.

The last "dose" …

There's only one corner of the universe you can be certain of improving, and that's your own self.

Aldous Huxley [1894-1963]

An electronic bulletin of drug and health-related news highlights, a service of …
Auburn University, Harrison School of Pharmacy, Drug Information Center
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