

# AU InforMed

Volume 6 Number 19 (Issue 196)

Tuesday, July 29, 2008



## Key Inforbits

- Stroke guidelines for infants and children
- Diets – some better than others
- Influenza vaccines recommendations updated
- Street drug is really deadly
- Disease prevention is really worth the cost
- Not to mention, drugs are expensive!

## NEW DRUGS, and other related stuff ...

**MedWatch** ... (7/24/2008) The FDA informed healthcare professionals that serious and sometimes fatal **hypersensitivity reactions (HSR) caused by abacavir** (Ziagen by GlaxoSmithKline) therapy are significantly more common in patients with a particular human leukocyte antigen (HLA) allele, HLA-B\*5701. FDA reviewed data from two studies that support a recommendation for pre-therapy screening for the presence of the HLA-B\*5701 allele and the selection of alternative therapy in positive subjects. Genetic tests for HLA-B\*5701 are available and all patients should be screened for the HLA-B\*5701 allele before starting or restarting treatment with abacavir or abacavir-containing medications. Development of clinically suspected abacavir HSR requires immediate and permanent discontinuation of abacavir therapy in all patients, including patients negative for HLA-B\*5701.

Read the complete MedWatch 2008 Safety Summary, including a link to the Information for Healthcare Professionals document, at:

<http://www.fda.gov/medwatch/safety/2008/safety08.htm#Abacavir>

**Update ... Seizure...** (7/24/2008) At the request of the FDA, U.S. Marshals **seized nearly \$74,000 worth of Xiadafil VIP tablets**, Lots 6K029 and 6K209-SEI, distributed by SEI Pharmaceuticals, Inc. of Miami, Fla. Although marketed as a dietary supplement to treat erectile dysfunction (ED) and for sexual enhancement, these lots represent an illegally marketed drug containing an undeclared ingredient hydroxyhomosildenafil, which is chemically similar to sildenafil (Viagra). The company had refused a previous request to recall their product. Consumers should discontinue the use of Xiadafil VIP tablets immediately and consult their health care professional if they have experienced adverse events that they believe may be related to the use of this product.

For more information, visit:

[www.fda.gov/consumer/updates/erectiledysfunction010408.html](http://www.fda.gov/consumer/updates/erectiledysfunction010408.html).

<http://www.fda.gov/bbs/topics/NEWS/2008/NEW01864.html>

**MedWatch** ... (7/29/2008) Mitoxantrone HCl (Novantrone and generics). The FDA reminded health care professionals who treat patients with **mitoxantrone** about recommendations that **left ventricular ejection fraction (LVEF)** be evaluated before initiating treatment and prior to administering each dose of mitoxantrone. The FDA offered additional recommendations for cardiac monitoring to detect late-occurring cardiac

toxicity, and provided information for patients with multiple sclerosis who receive the drug. These recommendations were established in 2005 in response to post-marketing reports and case reports that described decreases in LVEF or frank congestive heart failure in patients with MS who had received cumulative doses of mitoxantrone that were lower than 100 mg/m<sup>2</sup>. Read the complete MedWatch 2008 Safety summary, including links to the Information for Healthcare Professionals sheet and the previous 2005 safety alert, at: <http://www.fda.gov/medwatch/safety/2008/safety08.htm#Mitoxantrone>

## **FROM THE MEDICAL LITERATURE ...**

**Guidelines ... Management of Stroke in Infants and Children ...** From the American Heart Association Stroke Council and the Council on Cardiovascular Disease in the Young come evidence-based recommendations for the prevention of ischemic stroke caused by sickle cell disease, moyamoya disease, cervicocephalic arterial dissection and cardiogenic embolism; hemorrhagic stroke is also included. In addition to the evidence-based review, the American Heart Association Stroke council's levels of evidence grading algorithm was used as well as rigorous peer review.

Roach ES, Chair, Golomb MR, Adams R, Biller J, Daniels S, deVeber G, Ferriero D, Jones BV, Kirkham FJ, Scott RM, Smith ER. Management of stroke in infants and children: A scientific statement from a special writing group of the American Heart Association Stroke Council and the Council on Cardiovascular Disease in the Young. *Stroke*. 2008;39: DOI: 10.1161/STROKEAHA.108.189696.

<http://stroke.ahajournals.org/cgi/reprint/STROKEAHA.108.189696v1>

**Diets ... its Greek for me ...** A study published in the *New England Journal of Medicine*



compared three types of diets over two years: low-fat, restricted-calorie; Mediterranean, restricted calorie; and low-carbohydrate, non-restricted calorie. Adherence to the diets was remarkable in that it was 95.4% at one year and 84.6% at two years. The daily calorie restrictions were 1500 kcal for women and 1800

kcal for men. The low carbohydrate diet was based on the Atkins diet plan. Overall the Mediterranean and low carbohydrate diet were most effective with a weight loss for those completing the study of 4.6 kg and 5.5 kg, respectively (low-fat diet was 3.3 kg).

Shai I, Schwarzfuchs D, Henkin Y, Shahar DR, Witkow S, Greenberg I, et al, for the Dietary Intervention Randomized controlled Trial (DIRECT) Group. Weight loss with a low-carbohydrate, Mediterranean, or low-fat diet. *N Engl J Med*. 2008 Jul 17;359(3):229-241.

**Vocabulary ... Synesthesia ...** “joined sensation” is an inherited condition in which individuals can “hear” colors, “taste” sounds, “smell” shapes, and “see” music. This short article does a great job in describing some of the historical references to its description as far back as the Old Testament.



Bub B. Synesthesia: Are you listening? *Acad Med*. 2008 Jul;83(7):660-661.

**Influenza Vaccine Recommendations, 2008-2009 ...** The Centers for Disease Control and Prevention (CDC) has released the 2008 recommendations for influenza vaccination. The principal updates and changes include 1) a new recommendation that annual vaccination be



administered to all children aged 5 to 18 years, beginning in the 2008-09 influenza season, if feasible, but no later than next season; 2) a recommendation that annual vaccination of all children aged 6 months through 4 years (59 months) continue to be a primary focus of vaccination efforts; 3) a new recommendation that either trivalent inactivated influenza vaccine or live, attenuated influenza vaccine (LAIV) be used when vaccinating healthy

persons aged 2 through 49 years (the previous recommendation was ages 5 to 49 years); 4) a recommendation that vaccines containing the 2008-09 trivalent vaccine virus strains A/Brisbane/59/2007 (H1N1)-like, A/Brisbane/10/2007 (H3N2)-like, and B/Florida/4/2006-like antigens be used; and, 5) new information on antiviral resistance among influenza viruses in the United States. This report and other information are available at CDC's influenza website (<http://www.cdc.gov/flu>), including any updates or supplements to these recommendations that might be required during the 2008-09 influenza season.

Fiore AE, Shay DK, Broder K, Iskander JK, Uyeki TM, Mootrey G, Bresee JS, Cox NJ. Prevention and control of influenza: Recommendations of the Advisory Committee on Immunization Practices (ACIP), 2008. MMWR. 2008 Jul 17;57(Early Release):1-60.

<http://www.cdc.gov/mmwr/preview/mmwrhtml/rr57e717a1.htm>

**Old drug, new problem ...** An “epidemic” of **fentanyl-related deaths** was reported by the Centers for Disease Control and Prevention (CDC), for a 2-year period of April 2005 to March 2007. It was based on data collected from six jurisdictions of Delaware; Cook County, IL; Wayne County, MI; St. Louis City and County, MO; New Jersey; and Philadelphia. Over 1000 deaths were recorded in that time. Street fentanyl is easily manufactured using N-phenethyl-4-piperidone (NPF). Fentanyl is 30 to 50 times more potent than heroin and 1 g can be cut into 7000 doses for street sale. Street fentanyl and pharmaceutical-grade fentanyl are not distinguishable in body fluids, so drug samples must be used. The CDC also feels this death rate is likely underreported. Although use of these drugs dates back to the 1970’s, increased supply may be attributable to illicit manufacturing in Mexico. Nonpharmaceutical fentanyl-related deaths – multiple states, April 2005 – March 2007. MMWR. 2008 Jul 25;57(29):793-796. <http://www.cdc.gov/mmwr/preview/mmwrhtml/mm5729a1.htm>



### Reviews of Note ...

- Liu H, Bravata DM, Olkin I, Friedlander A, Liu V, Roberts B, et al. Systematic review: The effects of growth hormone on athletic performance. *Ann Intern Med.* 2008 May 20;148(10):747-758.
- King AE, Umland EM. Osteonecrosis of the jaw in patients receiving intravenous or oral bisphosphonates. *Pharmacotherapy.* 2008 May;28(5):667-677.
- Mohr J, Johnson M, Cooper T, Lewis JS II, Ostrosky-Zeichner L. Current options in antifungal pharmacotherapy. *Pharmacotherapy.* 2008 May;28(5):614-645.
- Sarma DN, Barrett ML, Chavez ML, Gardiner P, Ko R, Mahady GB, et al. Safety of green tea extracts: A systematic review by the US Pharmacopeia. *Drug Safety.* 2008;31(6):469-484.
- Kissack JC, Bishop J, Roper AL. Ethylglucuronide as a biomarker for ethanol detection. *Pharmacotherapy.* 2008 Jun;28(6):769-781.

### **FROM THE LAY LITERATURE about medicine ...**


**Vytorin® ... new data doesn't help ...** The “Seas” trial results were reported July 21, that apparently showed that Vytorin® (simvastatin + ezetimibe) did not help patients with heart-valve disease avoid further cardiovascular complications. In fact, there was a small trend of cancer development in patients taking Vytorin®. However, although the results have been thoroughly evaluated and analyzed, the study has yet to be peer-reviewed and published so judgments should be restrained. In addition, the cancer possibility is likely due to chance and should not be the sole factor in decision-making. Several other larger trials are also underway. Conclusion:

the trial report appears to be confirmatory of the previous trial (ENHANCE), that the combination product Vytorin<sup>®</sup> is no more effective than simvastatin alone.

Berenson A. Trial intensifies concerns about safety of Vytorin. New York Times. 2008 July 22.

<http://www.nytimes.com/2008/07/22/business/22drug.html?ref=health>

**Disease prevention worth the cost?** ... Yes, according to the Trust for America's Health.

Based on an economic model developed at the Urban Institute and review of evidence-based studies done by the New York Academy of Medicine, the study concluded that the return on investment (ROI) of \$1 yielded over \$5 in health cost savings. The results are presented by state so each state has a calculated ROI.  Alabama's figures were for

\$250 million, the ROI within 5 years would be 5.6. The report focused on disease prevention programs that did not require medical intervention such as increased access to affordable nutritious foods, sidewalks and parks in neighborhoods and raising tobacco taxes.

<http://healthyamericans.org/newsroom/releases/release071708.pdf> [Press Release]

<http://healthyamericans.org/reports/prevention08/> [Full report, 72 pages]

**Drugs really are expensive** ... It is conventional wisdom to most clinical practitioners that patients will sometimes forego having prescriptions filled due to financial pressures in other areas (eg, food, housing). Now it is apparently bad enough that it is showing up in national



prescription numbers. The numbers of prescriptions dispensed by pharmacies in the U.S. still grew, but at a much slower rate and is being hailed as an indicator of the growing burden of increasing health care costs, particularly those out-of-pocket. One figure quoted is that out-of-pocket costs to cover family insurance premiums have increased 84% since 2001. This has many people ringing their hands, including the pharmaceutical and pharmacy industries.

Johnson A. Patients curb prescription spending. Wall Street Journal. 2008 Jul 16.

### **AUBURN HSOP FACULTY and STUDENTS in the literature ...**

- Fox BI, Poikonen J, Gumper K. Informatics exchange: Sharing experiences with information technology. Am J Health-Syst Pharm. 2008 Jun 1;65:1012, 1014.
- Felkey BG, Fox BI. Pharmacist PDA document management considerations. Hosp Pharm. 2008 Jun;43:518-519.
- Duke LJ, Unterwagner WL, Byrd DC [Acknowledgements to Brackett PD, Staton A, Stevenson L]. Establishment of a multi-state experiential pharmacy program consortium. Am J Pharm Ed. 2008;72(3):Article 62.



### **The last "dose" ...**



I know that if odour were visible, as colour is,  
I'd see the summer garden in rainbow clouds.

Robert Bridges [1844 - 1930, English poet]



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