

AU InforMed

Volume 5 Number 20 (Issue 155)

Monday, June 18, 2007



Key Inforbits

- Lyme Disease: New guidelines and stats
- New syndrome: Acute Witiitis
- Topical analgesics deadly?
- Ovarian cancer – early warning symptoms?
- Fallibility of computer systems?!?
- Who are our enemies?

NEW DRUGS, and other related stuff ...

New Drug ... (6/15/2007) The FDA has approved **ambrisentan (Letairis™ by Gilead Sciences, Inc.)** for the treatment of pulmonary arterial hypertension and it has been granted orphan drug status. The safety and effectiveness of ambrisentan were demonstrated in two international clinical trials involving 393 patients. The drug significantly improved physical activity capacity compared with a placebo, as shown by a six-minute walk, a standard test. Ambrisentan also delayed the worsening of the pulmonary hypertension. The most common side effects included swelling of legs/ankles, nasal congestion, sinusitis, and flushing. Ambrisentan should not be used by women who are pregnant or may become pregnant because the drug may cause birth defects. Patients must have monthly blood tests to check for potential liver injury. Letairis™ will be available in 5 mg and 10 mg once-daily tablets.

FDA approves new orphan drug for treatment of pulmonary arterial hypertension. *FDA News*. 2007 Jun 15; P07-104.

<http://www.fda.gov/bbs/topics/NEWS/2007/NEW01653.html>

<http://www.letairis.com/> [manufacturer web site]

MedWatch ... (6/15/2007) Confidence, Inc. informed consumers and healthcare professionals of a nationwide recall of **Long Weekend**, a product sold as a dietary supplement through mail orders and retailers located nationwide. The product was recalled because it contained undeclared tadalafil, an FDA approved drug used to treat male Erectile Dysfunction (ED). This poses a threat to consumers because tadalafil may interact with nitrates found in some prescription drugs (such as nitroglycerin) and may lower blood pressure to dangerous levels. Long Weekend is not approved by FDA; therefore, the safety and effectiveness of this product is unknown. Consumers should discontinue use of Long Weekend and consult their healthcare professional about approved treatments for ED.

<http://www.fda.gov/medwatch/safety/2007/safety07.htm#confidence>

MedWatch ... (6/15/2007) The FDA informed healthcare professionals of changes to the ADVERSE REACTIONS and POST-MARKETING sections of **RotaTeq (Rotavirus, Live, Oral, Pentavalent) Vaccine** prescribing information. The ADVERSE REACTIONS section was updated to include six cases of Kawasaki disease that were observed during the Phase 3 clinical trial. There were five cases among the 36,150 infants who received RotaTeq and one case among the 35,536 infants who received placebo. The POST-MARKETING section of the prescribing information was revised to reflect three reports of Kawasaki disease to the Vaccine Adverse Event Reporting System (VAERS) since licensure on February 3, 2006. There is not a known

cause and effect relationship between receiving RotaTeq, or any vaccine and the occurrence of Kawasaki disease. The cases reported to date are not more frequent than what could be expected to occur by coincidence. FDA and the Centers for Disease Control and Prevention will continue to monitor the safety of RotaTeq and encourage that all severe adverse events, including any additional cases of Kawasaki disease after administration of RotaTeq, be reported to VAERS. Read the complete MedWatch 2007 Safety Summary, including a link to the FDA Information Page and Company's revised prescribing information for RotaTeq regarding this issue at: <http://www.fda.gov/medwatch/safety/2007/safety07.htm#RotaTeq2>

MedWatch ... (6/15/2007) The FDA informed healthcare professionals about several clusters of patients who experienced **chills, fever, and body aches shortly after receiving propofol** for sedation or general anesthesia. Multiple vials and several lots of propofol used in patients who experienced these symptoms were tested and there was no evidence that the propofol vials or prefilled syringes used were contaminated with bacteria or endotoxins. Propofol is an intravenous sedative-hypnotic agent for use in the induction and maintenance of anesthesia or sedation. To minimize the potential for bacterial contamination, propofol vials and prefilled syringes should be used within six hours of opening and one vial should be used for one patient only. Patients who develop fever, chills, body aches or other symptoms of acute febrile reactions shortly after receiving propofol should be evaluated for bacterial sepsis. Read the complete MedWatch 2007 Safety Summary, including a link to the FDA Drug Information Page regarding this issue at: <http://www.fda.gov/medwatch/safety/2007/safety07.htm#Diprivan>

FROM THE MEDICAL LITERATURE ...

New Guidelines ... Lyme Disease ... The American Academy of Neurology recently released evidence-based recommendations for the treatment of neurologic symptoms of Lyme disease and post-Lyme syndrome. The guidelines sought to answer three questions: 1) Which antimicrobial agents are effective? 2) Are different regimens preferred for different manifestations of nervous system Lyme disease? 3) What duration of therapy is needed? Several effective antibiotics were identified; oral therapy is effective for most infections; children appear to respond similarly to adults (less data); and there is little evidence for use of prolonged antibiotic therapy. The full guidelines are available at: <http://www.aan.com/globals/axon/assets/2878.pdf>



Halperin JJ, Shapiro ED, Logigian E, Belman AL, Dotevall L, Wormser GP, et al. Practice parameter: Treatment of nervous system Lyme disease (an evidence-based review): Report of the Quality Standards Subcommittee of the American Academy of Neurology. *Neurology*. 2007;69:1-1.

Lyme Disease statistics ... A new report from the CDC shows that Lyme Disease infection is remaining steady. Over the 3 years of 2003 to 2005 in 10 reference states, the incidence of the disease is 29.2 cases per 100,000 population. The goal, based on the *Healthy People 2010* target is 17.4 cases per 100,000 population. The most active areas are in the northeast, mid-Atlantic and north-central states. Simple steps to prevent Lyme Disease in endemic areas include daily self-examination, selective use of acaricides and tick repellents, landscaping barriers and (my favorite) stay out of tick-infested areas. Alabama has very little problem, but coastal Florida has some pockets of infestation.

CDC. Lyme disease – United States, 2003-2005. *MMWR*. 2007 Jun 15;56(23):573-576.
<http://www.cdc.gov/mmwr/preview/mmwrhtml/mm5623a1.htm>

Sunburn incidence increasing ... In a telephone survey of adults for the years 1999, 2003 and 2004, it was found that the incidence of sunburn in the most common group, white males increased from 31.8% to 33.7% (experienced at least one sunburn in the previous year), despite what seems like a constant barrage of information/warning about sun protection. To make it worse, 2/3 of this group had more than one sunburn in the same period. Also noted was that



sunburn incidence is increasing in some “nonsusceptible” populations such as Hispanic, Asian/Pacific Islander and American Indian/Alaska Natives. Some advice is given concerning sun protection and one study is cited that looked at 20 Internet sites for such advice and found very little agreement among them.

Sunburn prevalence among adults – United States, 1999, 2003, and 2004. *MMWR*. 2007 Jun 1;56(21):524-528.

<http://www.cdc.gov/mmwr/preview/mmwrhtml/mm5621a2.htm>

Vocabulary ... **Acute Wiiiitis** ... Considered a variant of “Nintendinitis” which is a general term for the intensive use of recreational technologies, first described in 1990. It usually involves strain of the extensor tendon of the thumb, mainly in children. Acute Wiiiitis is specific to the Nintendo Wii machine which allows use of a handheld controller to mimic the action of action games, such as tennis, and overuse causing shoulder pain. Yet another coup of diagnosis!



Bonis J. Acute wiiiitis. *N Engl J Med*. 2007 Jun 7;356(23):2431-2432.

Reviews of Note ...

- Lee TA, Pickard AS. Meta-Analysis of azelastine nasal spray for the treatment of allergic rhinitis. *Pharmacotherapy*. 2007 Jun;27(6):852-859.
- Ferrone M, Raimondo M, Scolapio JS. Pancreatic enzyme pharmacotherapy. *Pharmacotherapy*. 2007 Jun;27(6):910-920.
- Gellad ZF, Lyles KW. Direct-to-consumer advertising of pharmaceuticals. *Am J Med*. 2007 Jun;120:475-480.
- Marik PE, Varon J. Hypertensive crises: Challenges and management. *Chest*. 2007 Jun;131(6):1949-1962.

FROM THE LAY LITERATURE about medicine ...

Topical analgesic deadly ... The death of a female high school cross-country runner from Staten Island has been attributed to significant overuse or exceptional absorption of **methy salicylate**, commonly found in topical analgesic preparations such as BenGay® and Icy Hot®, according to the New York City medical examiner. If enough is absorbed, it can result in salicylate poisoning. One explanation was that heat and exercise may have accentuated the absorption. A quote from the victim’s mother once again emphasizes our role as medication health professionals, “I did not think an over-the-counter product could be unsafe.”



Associated Press. Muscle-pain reliever is blamed for Staten Island runner’s death. *New York Times*. 2007 June 10.

http://www.nytimes.com/2007/06/10/nyregion/10cream.html?_r=1&ref=health&oref=slogin

Ovarian cancer symptoms ... early warning ... Ovarian cancer is one of the more deadly, partly because there are few early symptoms recognized and the diagnosis is often made after it has begun to spread. This year it will be the cause of 22,430 new cases and 15,280 deaths in the U.S. Now, clinicians may have pieced together some early associated symptoms, and if noticed may warrant a physician visit for an exam. The admittedly general symptoms include: bloating, pelvic or abdominal pain, difficulty eating or feeling full quickly and feeling a frequent or urgent

need to urinate. If any of these symptoms occur nearly every day for two to three weeks, a visit to the gynecologist is advised. It's not much, but it's better than what we've had up until now. Official recommendations are to be forthcoming at the end of the month from several cancer societies, including the American Cancer Society.

Grady D. Symptoms found for early check on ovary cancer. *New York Times*. 2007 Jun 13.

http://www.nytimes.com/2007/06/13/health/13cancer.html?_r=1&oref=slogin&ref=health&pagewanted=print

AUBURN HSOP FACULTY in the literature ...

Breland BD. Believing what we know: Pharmacy provides value. *Am J Health-Syst Pharm*. 2007 Jun 15;64:1284-1291.

NEW RESOURCES in the DILRC ...

- Olsen KR, ed. *Poisoning & Drug Overdose*. 5th ed. New York: Lange Medical Books/McGraw-Hill, 2007.
- Katzung BG, ed. *Basic and Clinical Pharmacology*. 10th ed. New York: Lange Medical Books/McGraw-Hill, 2007.
- Rovers RP, Currie JD. *A Practical Guide to Pharmaceutical Care: A Clinical Skills Primer*. 3rd ed. Bethesda, MD: American Society of Health-System Pharmacists, 2007.
- Stuart MC, ed. *The Complete Guide to Medical Writing*. London: The Pharmaceutical Press, 2007.
- Hess M. *Integrating Critical Care Skills into Your Practice: A Case Workbook*. Bethesda, MD: American Society of Health-System Pharmacists, 2007.

TIMELY TOP TECH TIP ...

Pharmacy computer systems are not infallible ... A small study was done in 30 Pennsylvania hospitals to test the pharmacy computers system's abilities to detect drug errors. The results were not reassuring. Test files were entered then analyzed by the computer system as any drug order would be. The systems' average for detection was 44%, with the best being 94%. In addition, the systems allowed easy overrides for even the most serious errors. All systems were current with vendor updates (minimum of quarterly, but many updated monthly or weekly). Pennsylvania Patient Safety Reporting System. Results of the PA-PSRS workgroup on pharmacy computer system safety. *Patient Safety Advisory*. 2007 May 31;4(Suppl 2):1-8.

[http://www.psa.state.pa.us/psa/lib/psa/advisories/vol. 4, sup. 2 may 31, 2007/v4 s2 suppl advisory_may_31_2007.pdf](http://www.psa.state.pa.us/psa/lib/psa/advisories/vol.4_sup.2_may_31_2007/v4_s2_suppl_advisory_may_31_2007.pdf)



The last "dose" ...

Our worst enemies here are not the ignorant and the simple, however cruel; our worst enemies are the intelligent and corrupt.

-- Graham Greene [1904-1991], *The Human Factor* [1978], pt III, ch. 3.

An electronic bulletin of drug and health-related news highlights, a service of ...

Auburn University, Harrison School of Pharmacy, Drug Information Center

• Phone 334-844-4400 • Fax 334-844-8366 • <http://www.pharmacy.auburn.edu/dilrc/dilrc.htm>

Bernie R. Olin, Pharm.D., Director