# **AU InforMed**

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- Gabapentin now generic
- Wages of sloth include obesity
- Bitter orange is a bitter pill

- Healing powers of art
- Soap and water is all you need!
- National Pharmacy week is coming!

# NEW DRUGS, and other related stuff ...

**New Generic** ... The generic version of Neurontin<sup>®</sup> was recently approved by the FDA. Gabapentin capsules will be available in 100 mg, 300 mg, and 400 mg doses. The Office of Generic Drugs of the FDA has determined that the formulation is bioequivalent and has the same therapeutic effect as that of the reference drug Neurontin<sup>®</sup> capsules. http://www.ptcommunity.com/Daily/DailyDetail.cfm?chosen=64335

Coming soon ... Cephalon, Inc. announced October 21, 2005 that it has received an approvable letter from the FDA to market another brand of modafinil (currently ProVigil® for excessive sleepiness associated with narcolepsy, obstructive sleep apnea/hypopnea syndrome and shift work sleep disorder, in adults), **Sparlon<sup>TM</sup> Tablets** [C-IV], for a new indication, attention-deficit/hyperactivity disorder (ADHD) in children and adolescents 6 to 17 years of age. The company expects to launch the product in early 2006 subject to final FDA approval. Cephalon will co-promote the product with McNeil Consumer & Specialty Pharmaceuticals Division of McNeil-PPC.

http://phx.corporate-ir.net/phoenix.zhtml?c=81709&p=irolnewsArticle&ID=771069&highlight= (Cephalon web site)

MedWatch ... Eli Lilly and the FDA notified healthcare professionals of revision to the PRECAUTIONS/Hepatotoxicity section of the prescribing information for Cymbalta® (duloxetine HCl), indicated for treatment of major depressive disorder and diabetic peripheral neuropathic pain. Postmarketing reports of hepatic injury (including hepatitis and cholestatic jaundice) suggest that patients with preexisting liver disease who take duloxetine may have an increased risk for further liver damage. The new labeling extends the Precaution against using Cymbalta® in patients with substantial alcohol use to include those patients with chronic liver disease. Cymbalta® not be administered to patients with any hepatic insufficiency. Read the complete MedWatch 2005 Safety Summary, including links to the Dear Healthcare Professional letter and revised label, at:

http://www.fda.gov/medwatch/safety/2005/safety05.htm#Cymbalta

# FROM THE MEDICAL LITERATURE ...

**No good reason to use it** ... A recent review of the new indications for azithromycin extended-release (Zmax<sup>®</sup>) to treat mild to moderate community-acquired pneumonia (CAP) and acute bacterial sinusitis (ABS) in adults gave a nice summary of the literature. The last sentence of the review really sums it up ... "There is no good reason to use it." *Submitted by Robert Smith, Pharm.D.* Abramowicz M, ed. Azithromycin extended-release (*Zmax*) for sinusitis and pneumonia. *Med Lett Drugs Ther* 2005 Sep 26;47(1218):78-80.

Wages of sloth ... Cost of obesity ... There is general agreement that obesity and inactivity contribute to the health care costs of the U.S. for both morbidity and mortality; but how much? A recent study has attempted to quantify this. In a cohort study of 8000 members of a health plan, total health care charges were estimated to the national population. The results indicated that 27% of national health care charges were associated with physical inactivity, overweight and obesity. Submitted by Robert Smith, Pharm.D.

Anderson LH, Martinson BC, Crain L, Pronk NP, Whitebird RR, Fine LJ, O'Connor PJ. Health care charges associated with physical inactivity, overweight, and obesity. *Prev Chronic Dis* 2005 Oct;2(4):1-12. http://www.cdc.gov/pcd/issues/2005/oct/pdf/04\_0118.pdf

**Death before Dementia?** ... A new meta-analysis of 15 trials involving 3353 patients with Alzheimer's or other dementias, showed that the use of antipsychotic agents (4 "atypicals") increase the risk of death from 2.3% to 3.5% (calculated odds ratios). While pause should be taken, newspapers may make the results sound a bit more dramatic. An accompanying editorial also lends some perspective to the issue.

Schneider LS, Dagerman KS, Insel P. Risk of death with atypical antipsychotic drug treatment for dementia: Metaanalysis of randomized placebo-controlled trials. *JAMA* 2005 Oct 19;294(15):1934-43. Rabins PV, Lyketsos CG. Antipsychotic drugs in dementia: What should be made of the risks? *JAMA* 2005 Oct 19:294(15):1963-65.

### **Reviews of Note ...**

- Choi HK, Mouint DB, Reginato AM. Pathogenesis of gout. *Ann Intern Med* 2005 Oct 4;143:499-516.
- Rhen T, Cidlowski JA. Antiinflammaotry action of glucocorticoids New mechanisms for old drugs. *N Engl J Med* 2005 Oct 20;353(16):1711-23.

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

Bitter Orange could be a bitter pill ... When the FDA banned ephedra from the supplement market in 2004, bitter orange (also known by its scientific name, Citrus aurantium or in traditional Chinese medicine, Zhi shi) was predicted to be one of the compounds that would take its place, and it has. The active ingredient is synephrine and is a related stimulant. It is often combined with caffeine in weight loss supplements, and other products. It can raise the heart rate and blood pressure. The lesson is again reiterated, "natural" does not equal "safe." Duenwald M. Bitter orange under scrutiny as new ephedra. *New York Times.com* 2005 Oct 11. http://www.nytimes.com/2005/10/11/health/policy/11cons.html

ATM drug dispensers ... again ... This time, insurance companies are placing ATM-like vending machines in physicians' offices, but stocked with generic drugs. This is one company's, Aetna, attempt to control drug costs. The insurance company pays for the machines (supplied by MedVantx) and the drugs, to encourage physicians to use generic drugs. They are studying selected sites to see if this method will ultimately change prescribing habits from trade name to generic prescribing, and therefore save the insurance company money. Unfortunately, it completely cuts the pharmacist out of the picture.

Hensley S. Generic drugs sampled freely in Aetna test. Wall Street Journal.com 2005 Oct 12; p. B1.

Art for what ails you ... From a study done in Sweden, a group of 20 elderly women were compared to a control group. Both groups met for weekly for four months. The "active treatment" group discussed works of art (presumably at a museum) while the "control group" discussed hobbies, etc. The art group showed a lower blood pressure and less need for laxatives. There you have it!

Agence France-Presse. Constipated? Go to a museum. *USA Today* 2005 Oct 14. http://www.usatoday.com/news/offbeat/2005-10-14-art-constipation\_x.htm

**Health Science Fiction** ... or is it? ... Interesting, and short, article about some of the medical marvels that are here and now, and the coming debates, ethical and otherwise. Some of the topics include miniature cameras that could replace colonoscopies (I'm all for that!), potential of the human genome project and what will we really do with all of this information particularly as it relates to employment and insurance!

Sloane M. Medical advances not science fiction: Some new technologies raise new ethical questions. *CNN.com* 2005 Oct 19.

http://www.cnn.com/2005/HEALTH/10/19/25.years.advances/index.html

Soap and water is all you need ... An FDA Advisory Panel on Nonprescription Drugs gave their recommendations on Thursday, October 20, 2005 concerning antibacterial soaps. Some of the outcomes included that antibacterial soaps are no more effective than plain soap and water to decrease infections. The panel was concerned though without hard data, that such general use of antibacterials could give rise to more resistant strains of bacteria; the FDA was called upon to study to various products risks vs. benefits. No direct action was recommended, but the manufacturers of the antibacterial products disagreed with the Panel's conclusions. Associated Press. Anti-bacterial soaps no better than soap and water. *USA Today* 2005 Oct 21. <a href="http://www.usatoday.com/news/health/2005-10-21-soap-and-water\_x.htm">http://www.usatoday.com/news/health/2005-10-21-soap-and-water\_x.htm</a>

# **NEW RESOURCES in the DILRC** ...

- LaGow B, ed. *PDR for Herbal Medicines*. 3<sup>rd</sup> ed. NJ: Thomson PDR, 2004.
- Pray WS. *Nonprescription Product Therapeutics*. 2<sup>nd</sup> ed. Philadelphia: Lippincott, Williams and Wilkins, 2006.
- Finkel R, Pray WS. Pocket Guide for Nonprescription Product Therapeutics. Philadelphia: Lippincott, Williams and Wilkins, 2005.

# 🗪 The last "dose" ...

Díd you know ... that "pill" is from the French pilule which is taken from the Latin pilula, the diminutive of pila, "a ball." Pills were originally spherical, where a dose of active ingredient was mixed with an excipient plastic substance, usually lactose, then rolled by hand into a little ball. A coating was applied for the finished product.

Haubrick WS. *Medical Meanings: A Glossary of Word Origins*. 2<sup>nd</sup> ed. Philadelphia: American College of Physicians, 2003: p. 182.

