# **AU InforMed**

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- Two serious MedWatch reports
- # MD's actually influenced by big Pharma
- Too much rest can be bad for the elderly
- Government leading the EMR charge
- Kids wired on caffeine and super pot
- Survival

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

**New Drug** ... (5/9/2007) The FDA announced the approval of **rotigotine transdermal system** (**Neupro**<sup>®</sup> by Schwarz Bioscience of Research Triangle Park, N.C), a skin patch designed to treat symptoms of early Parkinson's disease and is the first transdermal patch approved for the treatment of symptoms of Parkinson's disease. Rotigotine, is a dopamine agonist. The most common side effects for Neupro<sup>®</sup> included skin reactions at the patch site, dizziness, nausea, vomiting, drowsiness and insomnia, most of which are typical of this class of drugs. Other potential safety concerns include sudden onset of sleep while engaged in routine activities such as driving or operating machinery (sleep attacks), hallucinations, and decreased blood pressure on standing up (postural hypotension).

For more information on Parkinson's Disease, go to the National Institute of Neurological Disorders and Stroke at:

http://www.ninds.nih.gov/disorders/parkinsons\_disease/parkinsons\_disease.htm

FDA approves Neupro patch for treatment of early parkinson's disease. FDA News. 2007 May 9; P07-84.

http://www.fda.gov/bbs/topics/NEWS/2007/NEW01631.html

http://www.neupro.com/USHome.html (Schwartz Pharma web site with prescribing information)

**New Dose Form** ... (4/30/2007) The FDA approved a new dose form for **azithromycin**, **a 1% ophthalmic solution** (**Azasite**<sup>TM</sup> by InSite Vision Inc.) for the treatment of bacterial conjunctivitis. AzaSite<sup>TM</sup> is formulated with DuraSite, InSite Vision's patented drug delivery vehicle which enhances the retention time of the antibiotic on the surface of the eye. InSite Vision Incorporated press release, April 30, 2007.

http://phx.corporate-ir.net/phoenix.zhtml?c=86061&p=irol-medianewsArticle&ID=992614&highlight=

**New Generic** ... a generic version of **zolpidem tartrate** (**Ambien**<sup>®</sup>) immediate release tablets, has been approved by the FDA. This may be good news for the many insomniacs who need occasional help getting sleep. Ambien<sup>®</sup> has been in the Top 200 most prescribed list of drugs for some time, #9 in 2005 and #13 in 2006.

http://www.ptcommunity.com/Daily/DailyDetail.cfm?chosen=65087

**MedWatch** ... (5/4/2007) The FDA warned pharmaceutical manufacturers, suppliers, drug repackers, and healthcare professionals who compound medications using glycerin of the importance of **assuring that the glycerin used is not contaminated with diethylene glycol** 

(**DEG**), a known poison used in antifreeze and as a solvent. Glycerin is a sweetener commonly used worldwide in liquid over-the-counter and prescription drug products. Although, at the present time, FDA has no reason to believe that the U. S. supply of glycerin is contaminated with DEG, it is aware of reports from other countries over the past several years in which DEG contaminated glycerin has caused human deaths. FDA emphasizes the importance of testing glycerin for DEG due to the serious nature of this potentially fatal problem. FDA issued guidance to industry recommending methods of testing glycerin and other controls to identify any contamination with DEG before using glycerin in the manufacture or preparation of pharmaceutical products.

Read the complete 2007 safety summary, including a link to the FDA's News Release regarding this issue at:

http://www.fda.gov/medwatch/safety/2007/safety07.htm#Glycerin

MedWatch ... (5/1/2007) The FDA informed consumers and healthcare professionals regarding the dangers associated with buying prescription drugs over the internet. The FDA received information showing that 24 apparently related websites may be involved in the distribution of counterfeit prescription drugs. The websites appear to be operated from outside the United States. On three occasions during recent months, consumers obtained counterfeit versions of Xenical 120 mg Capsules, a weight loss drug, from two different websites. Instead of receiving Xenical, a product manufactured by Hoffmann-LaRoche Inc, consumers received sibutramine, the active ingredient in Meridia. Although Meridia is also used to lose and maintain weight loss, the drug should not be used in certain patient populations and is not a substitute for other weight loss products. Consumers should be wary if there is no way to contact the website pharmacy by phone, if prices are dramatically lower than the competition, or if no prescription from their doctor is required. Additionally, consumers are urged to review the FDA web page at <a href="https://www.fda.gov/buyonline">www.fda.gov/buyonline</a> for additional information prior to making purchases of prescription drugs over the internet. See FDA press release for the list of the 24 web sites that may be involved in the distribution of counterfeit prescription drugs.

Read the complete 2007 MedWatch 2007 Safety summary, including a link to the FDA Press Release regarding this issue at:

http://www.fda.gov/medwatch/safety/2007/safety07.htm#Counterfeit

# FROM THE MEDICAL LITERATURE ...

You want proof? ... Data was analyzed from a survey of U.S. physicians conducted by the Institute on Medicine as a Profession (IMAP); 47 questions focused on professionalism and about 12 questions specifically on physician/industry relationships. Among the results the survey showed that 94% of physicians had some type of relationship with the pharmaceutical industry; small private practice groups were more likely to have contact than hospital-based physicians. The most common gratuities included receiving food in the workplace (83%) and receiving drug samples (78%). Less common were reimbursement for costs of professional meetings, CME and for a variety of "consultant" activities.

Cardiologists were the most likely specialty to receive payments (considered thought leaders for the prescribing community). Perhaps the best time to get an appointment is around lunchtime?

Campbell EG, Gruen RL, Mountford J, Miller LG, Cleary PD, Blumenthal D. A national survey of physician-industry relationships. *N Engl J Med*. 2007 Apr 26;356(17):1742-1750.

Muscle wasting at bed rest ... In a small study of 12 healthy older adults (6 men, 6 women,



avg. age 67 years) who were put at bed rest for 10 days with a measured diet, it was found that they lost a greater amount of lean tissue in 10 days than did young individuals in 28 days. The patients started and continued in a negative nitrogen balance. Although this cannot be extrapolated to ill or frail elderly, it gives an idea how

quickly an otherwise healthy older person can become incapacitated due to treatment. Kortebein P, Ferrando A, Lombeida J, Wolfe R, Evans WJ. Effect of 10 days of bed rest on skeletal muscle in healthy older adults. JAMA. 2007 Apr 25;297(16):1772-1774.

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

For the EMR, the government is a leader ... The electronic medical record (EMR), linking patients, medical data, physicians, pharmacists, etc is almost a dream, but one that is a "goal" for 2014. However, the Veterans Administration (VA) has taken the lead and is setting a standard. The article is definitely a positive piece on the "paperless" environment, but it gives several scenarios of the value of the EMR. To top it off, the software used by the VA is Veterans Information Systems and Technology Architecture (VistA) and its FREE through the Freedom of Information Act. It is also being used in other countries such as Germany, Egypt and Mexico. It makes you want one of your very own! Brown D. VA takes the lead in paperless care. Washington Post. 2007 Apr 10; p. HE01. http://www.washingtonpost.com/wp-dyn/content/article/2007/04/06/AR2007040601911.html?referrer=email

**AOL** to the rescue ... The founder of AOL, Stephen Case, is set to unveil a new company web site, RevolutionHealth.com. In addition to having a stake in the growing market of health clinics in retail establishments, in this case, RediClinic's, Mr. Case seeks to save us from ourselves, courtesy of the Web. The site is intended to be the "one-stop-shop" for health-related needs and be the dominant brand (eg, the Nike or Starbucks of health care). It intends to compete with the likes of WebMD Health, National Institutes of Health, Mayo Clinic, and Google, in terms of providing health care solutions for busy consumers. The site is initially being targeted at women. Very wealthy investors are contributing and expecting financial returns. As always, the financial returns are via advertising, and where is the big money for health advertisers??? Freudenheim M. AOL founder hopes to build new giant among a bevy of health care web sites. New York Times. 2007 Apr 16.

http://www.nytimes.com/2007/04/16/technology/16case.html? r=1&ref=health&oref=slogin



**WIRED** ... An extensive article on the new "coffee culture" that is growing in the ranks of the teens and young adults. High school students are becoming dependent on coffee and a wide range of caffeinated drugs are becoming more numerous and available. Some drinks contain the equivalent of several cups of coffee, and when consumed rapidly, can be problematic. Combining caffeine drinks with alcohol is also popular, either mixing vodka with Red Bull<sup>®</sup>, or premixed, eg, Bud Extra<sup>®</sup>. There are

numerous brands of caffeinated "energy" drinks that are being mixed with caffeine tablets, and other serious stimulants such as Ritalin<sup>®</sup> and Adderall<sup>®</sup>. This generation seems to be developing a real habit of stimulants and not necessarily for "necessity" (eg, studying for a test). The dangers of caffeine use and abuse have been documented for centuries. Human physiology hasn't changed recently, nor, apparently, has the impetuousness of youth. The down side will not be pleasant.

Shute N. Over the limit? Americans young and old crave high-octane fuel, and doctors are jittery. US News and World Report. 2007 Apr 23;142(14):60-68.

http://www.usnews.com/usnews/health/articles/070415/23caffeine.htm

Marijuana v. 2.0 ... According to the National Institute for Drug Abuse (NIDA) this is not your father's pot! The marijuana on the market today is more than twice as potent as the varieties from the 1960's and 1970's. In 1988 the average level of tetrahydrocannabinol (THC) was 3.5%; today it is up to 8.5%. Apparently there are more medical emergencies showing up in emergency rooms due to marijuana. The arguments of harmful effects may now hold more sway, even for the boomers.

'Pot 2.0': U.S. Marijuana growing stronger. CNN. 2007 Apr 25.

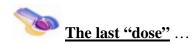
http://www.cnn.com/2007/HEALTH/04/25/marijuana.strength.reut/index.html

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

- Braxton Lloyd K, Berger BA. Communication concerning sensitive issues: Psoriasis. *US Pharm.* 2007 Apr;32(4):49-50, 52, 55.
- Kleppinger EL, Helms K. The role of vildagliptin in the management of type 2 diabetes mellitus. *Ann Pharmacother*. 2007 May;41(5):824-832.
- Stump AL, Kelley KW, Wensel TM. Bazedoxifene: A third-generation selective estrogen receptor modulator for treatment of postmenopausal osteoporosis. *Ann Pharmacother*. 2007 May;41(5):833-839.
- Starr JA. Leuconostoc species-associated endocarditis. *Pharmacotherapy*. 2007 May;27(5):766-770.

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

- Trissel LA. *Handbook on Injectable Drugs*. 14<sup>th</sup> ed. Bethesda, MD: American Society of Health-System Pharmacists, 2007.
- Trissel LA. *Pocket Guide to Injectable Drugs*. Bethesda, MD: American Society of Health-System Pharmacists, 2007.
- Lacy CF, Armstrong LL, Goldman MP, Lance LL. *Drug Information Handbook*. 15<sup>th</sup> ed. Hudson, OH: Lexi-Comp, 2007.
- American Hospital Formulary Service (AHFS) and AHFS Essentials are now on Lexi-Comp Online, available through the <u>HSOP Intranet Online Resources</u>. This should allow a little easier access to these two references.



It is not the strongest of the species that survives, nor the most intelligent, but the one most responsive to change."

-- Charles Darwin, English Naturalist [1809 - 1882]

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

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