

AU InforMed

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Key Inforbits

- Many MedWatches
- Natural products, naturally dangerous
- Vioxx – drug literature evaluation-this is why
- Pandemic flu – basic, mass measures
- Pharmacy Careers – new resource
- Continuing education – why and who pays?

NEW DRUGS, and other related stuff ...

MedWatch ... Genentech informed healthcare professionals of preliminary safety information from a planned interim analysis in an ongoing study (SAILOR) which confirmed the higher incidence of stroke in the 0.5 mg dose group compared to the 0.3 mg dose group (1.2% versus 0.3%, respectively; P=0.02) of patients with neovascular (wet) age-related macular degeneration who received intravitreal Lucentis. The rates of stroke for both dose groups are lower than the rates seen in the controlled clinical trials and included in the approved labeling. The planned frequency of dosing was not the same as that described in the approved labeling. This comparison was one of many made during this interim analysis.

Read the complete MedWatch 2007 Safety summary, including links to the Sponsor's Dear Healthcare Provider Letter regarding this issue and prescribing information for Lucentis at:
<http://www.fda.gov/medwatch/safety/2007/safety07.htm#Lucentis>

MedWatch ... Amgen notified the oncology medical community of the results of a large, multicenter, randomized, placebo-controlled study showing that **Aranesp was ineffective** in reducing red blood cell transfusions or fatigue in patients with cancer who have anemia that is not due to concurrent chemotherapy. The study also showed **higher mortality in patients receiving Aranesp**. Aranesp is approved for the treatment of patients with anemia caused by the chemotherapy treatment of the malignant disease and should only be used in accordance with its approved product labeling.

Read the complete MedWatch 2007 Safety summary, including a link to the Dear Healthcare Professional letter, at:

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

MedWatch ... The FDA and Ebek, Inc. notified healthcare professionals and consumers of a voluntary **nationwide recall** of the company's dietary supplement because the product contains tadalafil, a drug used to treat erectile dysfunction. **Liviro3** is not approved by FDA to treat this condition. Tadalafil may interact with nitrates found in some prescription drugs and may lower blood pressure to dangerous levels. Consumers who have Liviro3 should stop using it immediately and contact their physician if they experience any problems that may be related to taking this product.

Read the complete MedWatch 2007 Safety summary, including links to the Manufacturer's press release regarding this issue at:

<http://www.fda.gov/medwatch/safety/2007/safety07.htm#Liviro3>

FROM THE MEDICAL LITERATURE ...

Pharmacy Education standards (and numbers) changing ... A recent update from the American Council on Pharmaceutical Education (ACPE) revealed some upcoming changes in Continuing Education requirements (eg, conflict of interest resolution for authors; differentiation of programs for pharmacists and technicians; and development of programs for Continuing Professional Development). Also, there is an update on the number of colleges of pharmacy; there are 99 accredited schools and of these, 87 have full accreditation status, the remainder have not enrolled students or graduated a class. There are another 6 to 12 schools with applications pending within the next three years.

Chi J. Get set for changes in your CE requirements. *Drug Topics*. 2007 Jan 8.

<http://www.drugtopics.com/drugtopics/article/articleDetail.jsp?id=394815>

Antihypertensives associated with incident diabetes ... A network meta-analysis was conducted to determine the effects of several classes of antihypertensives on incident diabetes. There were 22 clinical trials identified that comprised 143,153 patients. Odds ratios showed that the effects of the following classes of drugs on incident diabetes (ranked least to most): angiotensin receptor blockers (ARBs), angiotensin converting enzyme inhibitors (ACEIs), calcium channel blockers, beta-blockers and diuretics.

Elliott WJ, Meyer PM. Incident diabetes in clinical trials of antihypertensive drugs: a network meta-analysis. *Lancet*. 2007 Jan 20;369:201-207.

What have we learnt? ... In an opinion piece in the *British Medical Journal*, a brief history of the “Vioxx case” is presented by a physician from Yale who has had access to internal documents from Merck due to being an expert witness in some of the trials against the company. It is a very enlightening recount of how things got so far and particularly the complicity of the company, researchers and of course, the root of all evil, money. Many of the things we try to take into account when evaluating studies for possible bias all seemed to come together for this story. So for those who instruct students in the finer points of journal evaluation and you see those disbelieving looks, you need only refer them to this article...

Krumholz HM, Ross JS, Presler AH, Egilman DS. What have we learnt from Vioxx? *BMJ*. 2007 Jan 20;334:120-3.



Pandemic Influenza ... containment other than drugs ... The CDC has issued a large report that outlines planning guidance for communities, focusing on the measures that can be taken in addition to vaccines and medications. These include isolation, quarantine, closings of schools and social distancing measures to limit contact between individuals and the general public. There is a great deal of data in this 108-page report, which can be found at:

<http://www.pandemicflu.gov/plan/community/mitigation.html>

Centers for Disease Control and Prevention. Interim Pre-pandemic planning guidance: Community strategy for pandemic influenza mitigation in the United States. Feb. 2007.

http://www.pandemicflu.gov/plan/community/community_mitigation.pdf [.pdf document]

Reviews of Note ...

- Winkelman JW. Recognizing and treating restless legs syndrome: Current standards. *Am J Med*. 2007 Jan;120(1A):S1-S29.

- Kasliwal R, Wilton LV, Cornelius V, Aurich-Barrera B, Shakier SAW. Safety profile of rosuvastatin: Results of a prescription-event monitoring study of 11,680 patients. *Drug Safety*. 2007;30(2):157-170.
- Takkouche B, Montes-Martinez A, Gill SS, Etminan M. Psychotropic medications and the risk of fracture: A meta-analysis. *Drug Safety*. 2007;30(2):171-184.

FROM THE LAY LITERATURE about medicine ...

Natural and safe are becoming harder to equate ... In an essay based on the author's newly published book, a case is made that natural products can produce adverse events similar to drug products. Data collected from poison control centers indicate thousands of people report adverse reactions, and even deaths, from vitamin, mineral and herbal products. New legislation was signed in December 2006 that will require manufacturers of these products to pass along to the FDA any reports received about adverse events with these products. If someone continues to argue that all natural products are safe, you may also point out the recent case of death due to water intoxication.

Hurley D. Diet supplements and safety: Some disquieting data. *NY Times*. 2007 Jan 16.

<http://www.nytimes.com/2007/01/16/health/16diet.html?ref=health>

Associated Press. Woman drinks so much water she dies. *CNN.com* 2007 Jan 13.

<http://www.cnn.com/2007/US/01/13/water.intox.ap/index.html>

Hormonal contraceptives, newer is less effective? ... A lot of press preceded and followed a two-day meeting of the Reproductive Health Drugs Advisory Committee of the FDA. The prepress was so bad the FDA issued a statement reiterating the agenda of the scheduled meeting and to stress that it did not include an evaluation of the effectiveness criteria of newer hormonal contraceptive products. The meeting itself was anticlimactic with the Committee agreeing that approval reviews need to be more flexible and allow individual judgment of risks and benefits.

FDA: Newer birth control pills less effective. *USA Today*. 2007 Jan 23.

<http://www.cnn.com/2007/HEALTH/01/23/birth.control.ap/index.html>

FDA statement on effectiveness of newer birth control pills. *FDA Statement*. 2007 Jan 23.

<http://www.fda.gov/bbs/topics/NEWS/2007/NEW01550.html>

Stein R. FDA panel supports flexibility in the approval of hormonal contraceptives. *Washington Post*. 2007 Jan 25; p. A18. <http://www.washingtonpost.com/wp-dyn/content/article/2007/01/24/AR2007012401693.html?referrer=email>

Who should pay for CE? ... You! ... While directed at physicians, this article attacks the ingrained practice of pharmaceutical company-sponsored continuing education, usually accompanied by a meal or other perks - \$1.7 billion worth. Pharmacy is only slightly less guilty. A new program has been developed by a Georgetown physician and sponsored by initial federal funding "PharmedOut" that offers free CE online. The programs are often sponsored by the FDA or National Institutes of Health. This is a good start, but the ultimate belief of a few physicians is that CE programs should be free of real or potential bias, and the recipients should pay for their own eventually.

Boodman SG. Hold the hors d'oeuvres. *Washington Post*. 2007 Jan 23; p. HE01.

<http://www.washingtonpost.com/wp-dyn/content/article/2007/01/19/AR2007011901433.html?referrer=email>

Update ...

Pharmacy Careers ... a new supplement issue from *Pharmacy Times* is aimed at students/residents and explores issues of various careers in pharmacy. There are several articles on aspects of community practice (independents, several chains) but also military, research and managed care. Also, there are the seven deadly sins of putting together a resume and for interviews; and the top 10 tips for passing the pharmacy boards.

There are a stack of free copies in the Drug Information Center. Help yourself!

Eckel F, ed. Pharmacy Careers. *Pharmacy Times* 2007 Jan;Suppl:1-40.

AUBURN HSOP FACULTY in the literature ...

- **Whitley HP**, Fermo JD, Ragucci K, Chumney EC. Assessment of patient knowledge of diabetic goals, self-reported medication adherence, and goal attainment. *Pharmacy Practice*. 2006;4(4):183-190. <http://www.pharmacypractice.org/vol04/04/toc.htm>
- **Boothby LA**, Doering PL. Buprenorphine for the treatment of opioid dependence. *Am J Health-Syst Pharm*. 2007 Feb 1;64:266-72.
- **Andrus MR, Clark DB**. Provision of pharmacotherapy services in a rural nurse practitioner clinic. *Am J Health-Syst Pharm*. 2007 Feb 1;64:294-97.
- **Braxton-Lloyd K, Berger B**. Communication concerning sensitive issues: Counseling on menopause. *U.S. Pharm*. 2007 Jan;32(1):73-76.

NEW RESOURCES in the DILRC ...

- Jellin JM, ed. *Natural Medicines Comprehensive Database* 2007. 9th ed. Stockton, CA: Therapeutic Research Faculty, 2006.
- *Physicians' Desk Reference* 2007. 61st ed. Montvale, NJ: Thomson PDR, 2007.
- Aronson JK, ed. *Meyler's Side Effects of Drugs: The International Encyclopedia of Adverse Drug Reactions and Interactions*. 15th ed. 6 volumes. Amsterdam: Elsevier, 2006.



The last “dose” ...

Continuing Education



The physician's [pharmacist's] continuing education...is largely a process within himself, one he pursues on his own. Most of his true learning - the part that sticks with him- is what he does for himself, by himself.

-- George T. Harrell, 1958, *Journal of Medical Education*

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