

AU InforMed

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Key Inforbits

- New antifungal drug approved
- New cancer report out
- New heart failure guidelines
- Free stuff banned at Stanford
- Publication bias countered
- Epitaph to a Dog

NEW DRUGS, and other related stuff ...

New Drug ... The FDA today approved **posaconazole (Noxafil[®])** by Schering Corporation) to prevent fungal infections caused by certain molds and yeast-like fungus called *Aspergillus* and *Candida*. FDA approved the drug for use in patients who have weakened immune systems following bone marrow transplants and for patients with decreased white blood cell counts. The most common side effects included nausea, vomiting, diarrhea, rash, hypokalemia, thrombocytopenia, and abnormalities in liver function tests. Rare adverse events possibly related include QTc prolongation (abnormal heart rhythm) and liver function impairment. It has been shown to interact with several medications, including drugs that suppress the immune system, and these reactions may be serious.

FDA approves novel medicine to prevent invasive fungal infections. *FDA News*. 2006 Sep 18:P06-136.

<http://www.fda.gov/bbs/topics/NEWS/2006/NEW01455.html>

MedWatch ... FDA announced the **seizure** of Ellagimax capsules, Coral Max capsules, Coral Max without Iron capsules, and Advanced Arthritis Support capsules distributed by Advantage Nutraceuticals, LLC, because the products, labeled as dietary supplements, are being promoted to treat serious disease conditions, including but not limited to cancer, arthritis, fibromyalgia, and seizures. The products have not been shown to be safe and effective to treat these conditions and have not been approved by the FDA and are therefore in violation of the new drug and misbranding provisions of the Federal Food, Drug and Cosmetic Act. FDA advises consumers who may be taking these products to consult their physicians.

Read complete MedWatch 2006 Safety Summary, including links to the FDA press release at:

<http://www.fda.gov/medwatch/safety/2006/safety06.htm#seized>

MedWatch ... **Ibuprofen and aspirin** ... The FDA announced that taking ibuprofen for pain relief and aspirin at the same time may interfere with the benefits of aspirin taken for the heart. Ibuprofen can interfere with the anti-platelet effect of low dose aspirin (81 mg per day), that may render aspirin less effective when used for cardioprotection and stroke prevention. Although it is all right to use ibuprofen and aspirin together, FDA recommends that consumers contact their healthcare professional for more information on the timing of when to take these two medicines, so that both medicines can be effective.

Read the complete MedWatch 2006 Safety Summary, including links to the FDA Healthcare Professional Sheet, Drug Information Page and Science Paper at:

<http://www.fda.gov/medwatch/safety/2006/safety06.htm#aspirin>

FROM THE MEDICAL LITERATURE ...

New Cancer Report ... A new report from the nation's leading cancer organizations finds that Americans' risk of dying from cancer continues to drop, maintaining a trend that began in the early 1990s. However, the rate of new cancers remains stable and amongst various populations (eg, male, female) some cancers are declining while others are increasing. This report will be published in the October 15, 2006, issue of *Cancer*. However, the web site below will go to a press release, and provide a html link to the full article. First issued in 1998, the "Annual Report to the Nation" is a collaboration among the North American Association of Central Cancer Registries (NAACCR), the National Cancer Institute (NCI), which is part of the National Institutes of Health, the American Cancer Society (ACS), and the Centers for Disease Control and Prevention (CDC).

Howe HL, Wu X, Ries LA, Cokkinides V, Ahmed F, Jemal A, Miller B, Williams M, Ward E, Wingo PA, Ramirez A, Edwards BK. Annual Report to the Nation on the Status of Cancer, 1975-2003, Featuring Cancer among U.S. Hispanic/Latino Populations. *Cancer*. 2006 Oct 15;107(7):xxx-xxx.

http://www.cancer.org/docroot/MED/content/MED_2_1x_Annual_Report_to_the_Nation_Finds_Cancer_Death_Rates_Continue_to_Drop.asp

Old habits die hard ... The latest National Survey on Drug Use and Health was just released this month. It is a huge report, full of data, with a subcategory for just about any descriptor. Some of the highlights include: illicit drug use in teens continues a slight decline over the last four years, but **increases in adults aged 50 – 59**; a continued increase in alcohol use and a stable use of tobacco products for the year. From just a few of these data, it offers hope that the use in younger age groups are going down in several categories.

Substance Abuse and Mental Health Services Administration. (2006). *Results from the 2005 National Survey on Drug Use and Health: National Findings* (Office of Applied Studies, NSDUH Series H-30, DHHS Publication No. SMA 06-4194). Rockville, MD.

<http://www.oas.samhsa.gov/NSDUH/2k5NSDUH/2k5results.htm>

New Guidelines ... Comprehensive Heart Failure practice guidelines by the Heart Failure Society of America were published this last February. It is available only in electronic form with a subscription. It is comprised of 16 sections addressing various issues of heart failure and totals over 120 pages. An abstract that also provides the titles of the 16 sections is available at the web site given below.

Adams KF, Lindenfeld J, Arnold JMO, Baker DW, Barnard DH, Baughman KL, et al. HFSA 2006 comprehensive heart failure practice guideline. *J Cardiac Failure*. 2006 Feb;12:e1-e122.

<http://www.onlinejcf.com/article/PIIS1071916405013618/abstract>

β-Blocker adherence poor ... In a multicenter retrospective study of over 17,000 patients post myocardial infarction (MI), investigators followed patient adherence to β-blockers for over one year. All patients had insurance coverage of the medications for the entire period of study. All patients should have maintained β-blocker therapy for the entire year, but only 45% did. The primary conclusion was that adherence to therapy under these circumstances was not due to inability to afford the drug. The "worst" demographic were relatively young, female patients in the Southeast. Opportunities for pharmacist counseling?

Kramer JM, Hammill B, Anstrom KJ, Fetterolf D, Snyder R, Charde JP, et al. National evaluation of adherence to β-blocker therapy for 1 year after acute myocardial infarction in patients with commercial health insurance. *Am Heart J*. 2006;152:454.e1-454.e8.

ACE Inhibitor to prevent diabetes ... not yet ... In an early release study from the *New England Journal of Medicine* from the DREAM investigators, a study of 5269 patients revealed that taking an ACE inhibitor (ramipril) did not affect the development of diabetes or death, in patients with impaired glucose tolerance or fasting glucose levels. However, ramipril did cause a slight regression to normoglycemia. The article and accompanying editorial are open access until published.

DREAM Trial Investigators. Effect of ramipril on the incidence of diabetes. *N Engl J Med.* 2006;355.

Ingelfinger JR, Solomon CG. Angiotensin-converting-enzyme inhibitors for impaired glucose tolerance – Is there still hope? *N Engl J Med.* 2006;355.

www.nejm.org

Reviews of Note ...

- Huysse FJ, Stiefel FC, eds. Integrated care for the complex medically ill. *Med Clin N Am.* 2006 Jul;90(4):533-767. [12 articles]
- Teng GG, Nair R, Saag KG. Pathophysiology, clinical presentation and treatment of gout. *Drugs.* 2006; 66(12):1547-63.
- Henness S, Perry CM. Orlistat: A review of its use in the management of obesity. *Drugs.* 2006;66(12):1625-56.
- Spyropoulos AC, Geno M. Management of venous thromboembolism in the elderly. *Drugs Aging.* 2006;23(8):651-71.
- Zhang J, Ding EL, Song Y. Adverse effects of cyclooxygenase 2 inhibitors on renal and arrhythmia events: Meta-analysis of randomized trials. *JAMA.* 2006 Sep 12;296(doi:10.1001/jama.296.13.jrv60015). Early release www.JAMA.com.
- McGettigam P, Henry D. Cardiovascular risk and inhibition of cyclooxygenase: A systematic review of the observational studies of selective and nonselective inhibitors of cyclooxygenase 2. *JAMA.* 2006 Sep 12;296(doi:10.1001/jama.296.13.jrv60011) Early release www.jama.com

FROM THE LAY LITERATURE about medicine ...

Patient information articles ... There are two fairly large review articles in the latest edition of the *FDA Consumer* that may be of interest to your patients. One is timely for the upcoming flu season and it reviews the **flu vaccines**, their importance and general healthy habits during the flu season. The other article is also near and dear to many people: **pain drugs**

for dogs. The article reviews the “history” of canine analgesics and particularly covers the NSAIDs that are FDA approved for use in dogs; great information for pet owners. However, it doesn’t cover (other than brief mention) a useful piece of information, use of generic, OTC analgesic that should or should not be used in animals.

Bren L. Influenza: Vaccination still the best protection. *FDA Consumer.* 2006 Sep/Oct;40(5):12-19.

Bren L. Pain drugs for dogs: Be an informed pet owner. *FDA Consumer.* 2006 Sep/Oct;40(5):21-26.

<http://www.fda.gov/fdac/default.htm> [FDA Consumer magazine home page]

Free Stuff banned at Stanford ... In another small reaction to the “cozy” relationships between the pharmaceutical industry and medical academia, Stanford University Medical Center has banned its employees and associates (eg, physicians, researchers, residents, medical students) from accepting gifts as small as drug samples, logo pens, tote bags and lunches. It also has restricted pharmaceutical company employees from patient-care areas, medical school and research areas, except under well-regulated conditions.

This has been met with support from other crusaders against the industry practice but also with grumbles from residents, students and staff who have come to expect and depend upon free lunches. One supporter of this ban responds "...that defines the problem..."

Mangan K. Stanford cracks down on drug-company gifts to physicians. *Chronicle Higher Education*. 2006 Sep 13. <http://chronicle.com/daily/2006/09/2006091304n.htm> [subscription only]

Publication bias countered ... Publication bias, in a nutshell, is selectively publishing only studies with positive results; which means many quality studies that show no effect from an intervention are not published. This can happen if a sponsor (typically a pharmaceutical company) chooses not to publish a study, but it can also occur in a journal's selection process. This obviously can lead to false claims and assumptions. There are some new journals who do the opposite, publish only papers with negative results. I suppose this is another form of publication bias, but at least they are up-front about it. One is the *Journal of Spurious Correlations*; another is the *Journal of Negative Observations in Genetic Oncology*. It will be interesting to watch the rate of proliferation.

Begley S. New journals bet 'negative results' save time, money. *Wall Street Journal*. 2006 Sep 15; p. B1.



The last "dose" ...



"Epitaph to a dog" [in part]

Near this Spot
are deposited the Remains of one
who possessed Beauty without Vanity,
Strength without Insolence,
Courage without Ferocity,
and all the Virtues of Man without his Vices.
This praise, which would be unmeaning Flattery
if inscribed over human Ashes,
is but a just tribute to the Memory of
BOATSWAIN, a DOG,

--George Gordon Byron, 6th Baron Byron [1788-1824]

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