

AU InforMed

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Key Inforbits

- One new drug and Plan B
- Can't trust the pusher
- Page One for pharmacists and DI specialists!
- Exercise and diet, AGAIN
- FDA is regulating WHAT?!?
- Phishing Alert

NEW DRUGS, and other related stuff ...

New Drug ... nepafenac (Nevanac™ 0.1% by Alcon Laboratories) is a new ophthalmic, topical, NSAID suspension, indicated for the treatment of pain and inflammation associated with cataract surgery. It was approved by the FDA on August 19, 2005. Its general directions are to use one day prior to cataract surgery t.i.d., and continued through two weeks, postop. For approval history and labeling, go to:

<http://www.accessdata.fda.gov/scripts/cder/drugsatfda/index.cfm?fuseaction=Search.SearchAction&ApplNo=021862&SearchType=AddlSearch&SEARCHOPTION=B>

Plan B for Plan B, again ... The FDA announced August 26, 2005 that they are taking the action of publishing an advance notice of proposed rulemaking to initiate an open public process to consider the important regulatory and policy questions raised with the Barr Laboratories application. It will speak only to the regulatory and policy issues raised by this application. According to the FDA's Center for Drug Evaluation and Research (CDER), it completed its review of this application, as amended, and has concluded that the available scientific data are sufficient to support the safe use of Plan B as an over the counter product, but only for women who are 17 years of age and older. For full text of the announcement:

<http://www.fda.gov/bbs/topics/news/2005/NEW01223.html>

FROM THE MEDICAL LITERATURE ...

Heroin adulteration ... As if addiction to heroin isn't bad enough, now come reports from the east coast that some sources have been adulterated with clenbuterol (a β_2 agonist for veterinary use). The tip-offs were the symptoms of cardiotoxicity and associated symptoms expected of β_2 agonists rather than the CNS depressant effects of opioids. Adulteration is not a new phenomenon, but this particular adulterant is. It's getting where you can't trust your own pusher anymore. But then again, he/she is a criminal ...

CDC. Atypical reactions associated with heroin use – five states, January-April 2005. *MMWR* 2005 Aug 19;(32):793-6.

<http://www.cdc.gov/mmwr/preview/mmwrhtml/mm5432a1.htm>



Alcohol abuse update ... The National Institute on Alcohol Abuse and Alcoholism (NIAAA) has published updated guidelines for assessing and treating alcoholism. Part of the update includes an expanded drug treatment section, listing the three approved drugs and

prescribing information. In addition, a newspaper article did a pretty nice review of the drug treatments available for alcoholism, including off-label and investigational agents.

Spencer J. Fighting alcoholism with a pill. *Wall Street Journal* 2005 Aug 23; p. D1.

NIAAA. Helping patients who drink too much: A clinician's guide. 2005 ed. US Dept. of Health and Human Services; National Institutes of Health; National Institute on Alcohol Abuse and Alcoholism

<http://www.niaaa.nih.gov/publications/Practitioner/guide.pdf> (NIAAA guideline for clinician's)

<http://www.niaaa.nih.gov/> (web site for The National Institute on Alcohol Abuse and Alcoholism (NIAAA))

Reviews of Note ...

- Hatzimouratidis K, Hatzichristou DG. A comparative review of the options for treatment of erectile dysfunction: Which treatment for which patient? *Drugs* 2005;64(12):1621-50.
- Sauer J-M, Ring BJ, Witcher JW. Clinical pharmacokinetics of atomoxetine. *Clin Pharmacokinet* 2005;44(6):571-90.
- Abramowicz M, ed. Screening tests for cancer. *Treatment Guidelines Med Lett* 2005 Sep;3(37):63-8.

FROM THE LAY LITERATURE about medicine ...

YES, drug information skills are useful ... A front page article in the *Wall Street Journal* on Wednesday, August 24, 2005, touted the “detective skills” of a pharmacist in California who in essence, performs drug literature reviews, evaluates the primary drug literature and provides recommendations for Kaiser's formulary for California. These “gatekeepers” are highlighted as is their importance and impact on the six million members of the Kaiser system. As you may expect, some in the pharmaceutical industry take exception with some of the conclusions. The article is very complimentary for pharmacists and one of their roles in health care.

Mathews AW. Detective work: Reading the fine print, insurers question studies of drugs. *Wall Street Journal* 2005 Aug 24; p. A1.



Fat is Alabama ... A recent report focuses on the state of nutrition and obesity in the U.S. and Alabama is the 2nd heaviest state in the union, second only to Mississippi. Seven of the fattest 10 states are in the Southeast. Notice a pattern? About 27.7% of adults in Alabama are obese and when combining the definitions of obese + overweight, 63.5% of Alabamians qualify. The “skinniest” state, as a frame of reference, is Colorado. Many factors contribute such as government policies on nutrition education, physical education, insurance policies, preventive care and lack of sidewalks. See the complete report below.

Glendening PN, Hearne SA, Segal LM, Juliano C, Earls MJ. F as in Fat: How obesity policies are failing in America 2005. Trust for America's Health, 2005 Aug. pp. 1-148.

<http://healthyamericans.org/reports/obesity2005/Obesity2005Report.pdf> (148 page report)

<http://healthyamericans.org/> (Trust for America's Health)



Counterpoint ... The results of the “fat survey” have been contested (big surprise) claiming invalid statistical testing, etc, etc. You be the judge.

Hellmich N. Obesity ranking of states is disputed. *USA Today* 2005 Aug 23.

http://www.usatoday.com/news/health/2005-08-23-obesity-ranking_x.htm



But I don't have time to exercise (whine)... President Bush's health, after his most recent medical evaluation (according to one unconfirmed source), was rated “superior” compared to

99% of American men aged 55-59 years. He has just 16% body fat and weighs 191 pounds. His resting heart rate is 47 bpm and BP is 110/64. His workouts (6 days/week) include free weight training, treadmill exercises, bicycling (15-20 miles at 15-18 mph), elliptical trainer exercises and stretching. So what is your excuse??

Submitted by Dr. Robert Smith



and Speaking of Diet ... Salt limitation is still recommended for some diseases, particularly hypertension, but do you know how hard it is to achieve the sodium restrictions recommended? The 2005 Dietary Guidelines for Americans recommends young, healthy adults consume <2300 mg sodium/day. Hypertensive patients, elderly, etc are urged to consume <1500 mg sodium/day. Look at the web site for the latest comparisons of various prepared and packaged foods and you will see that using the salt shaker is the least of your problems.

CSPI Newsroom. Food industry accused of “salt assault” on America, Center for Science in the Public Interest, 2005 Aug 17. <http://www.cspinet.org/new/200508171.html>

CSPI. Sodium levels in processed foods. Washington, DC: Center for Science in the Public Interest, 2005 Aug, pp. 1-28. http://www.cspinet.org/new/pdf/salt_report_update.pdf

Hospital quality? ... A recent article in the *New York Times* highlighted two medical journal articles^{1,2} concerning quality of care in hospitals. Unfortunately, one of the messages is that hospitals are improving (some better than others, of course) but primarily due to the fact that someone is watching! Hospitals in the North and Northeast seemed to rank highest while Arkansas had the worse ratings. These ratings were comparing care given in certain situations (eg, heart attack, pneumonia, heart failure) where recognized standards exist.

Fessenden F. It's the Simple Things, but Some Hospitals Don't Do Them. *New York Times.com* 2005 Aug 21.

<http://www.nytimes.com/2005/08/21/weekinreview/21fess.html> (New York Times)

¹ Williams SC, Schmaltz SP, Morton DJ, Koss RG, Loeb JM. Quality of care in U.S. hospitals as reflected by standardized measures, 2002-2004. *N Engl J Med* 2005 Aug Jul 21;353(3):255-64

² Jha AK, Li, Orav EJ, Epstein AM. Care in U.S. hospitals – The hospital quality alliance program. *N Engl J Med* 2005 Aug Jul 21;353(3):265-74.



Leeches and maggots regulated ... How would you like to be on this evaluation panel? After centuries of use, the attention of the FDA has turned to these medical critters (officially classified as medical devices). Discussions began this week. Leeches are used typically following limb transplant/reattachment surgery to reduce bleeding and coagulation; maggots are extremely effective wound cleansers, often used in stubborn wounds of diabetic patients.

Harris G. Age-old cures, like the maggot, get U.S. hearing. *New York Times* 2005 Aug 25.

<http://www.nytimes.com/2005/08/25/health/25fda.html?pagewanted=all>

Update ...

Specialty residencies: Pediatrics

Martin KA. Specialized pediatric residency programs. *Am J Health-Syst Pharm* 2005 Sep 1;62:1766, 1768.

AUBURN HSOP FACULTY in the literature ...

Scolaro KL, Stamm PL, Braxton-Lloyd K. Devices for ambulatory and home monitoring of blood pressure, lipids, coagulation, and weight management, part 1. *Am J Health-Syst Pharm* 2005 Sep 1;62:1802-1812

NEW RESOURCES in the DILRC ...

- USP. *USP Pharmacists' Pharmacopeia 2005*. Rockville, MD: United States Pharmacopeial Convention, 2005.
- Jacobs DS, DeMott WR, Oxley DK. *Laboratory Test Handbook*. 3rd ed. Hudson, OH: Lexi-Comp, Inc. 2004.
- Taketomo CK, Hodding JH, Kraus DM. *Pediatric Dosage Handbook*. 11th ed. Hudson, OH: Lexi-Comp, Inc. 2004.
- Lacy CF, Armstrong LL, Goldman MP, Lance LL. *Drug Information Handbook*. 13th ed. Hudson, OH: Lexi-Comp, Inc. 2005.
- Krinsky DL, LaValle JB, Hawkins EB, Pelton R, Willis NA. *Natural Therapeutics Pocket Guide*. 2nd ed. Hudson, OH: Lexi-Comp, Inc. 2003.
- Isada CM, Kasten BL Jr, Golman MP, Gray LD, Aberg JA. *Infectious Diseases Handbook*. 5th ed. Hudson, OH: Lexi-Comp, Inc. 2003.
- Lexi-Comp. *Pharmacology Companion Guide*. Hudson, OH: Lexi-Comp, Inc. 2005.

TIMELY TOP TECH TIP ...



Phishing Alert ... and it's not the next bass tournament. "Phishing" involves Internet fraudsters who send spam or pop-up messages to gain personal information (credit card numbers, bank account information, Social Security number, passwords, or other sensitive information) from you. Phishers claim to be from a business or organization that you may deal with such as an Internet service provider (ISP), bank, online payment service, or government agency. The message may ask you to "update," "validate," or "confirm" your account information. The messages direct you to a website that looks just like a legitimate organization's site. But, it's a bogus site whose sole purpose is to trick you into divulging your personal information so the operators can steal your identity and run up bills or commit crimes in your name. For a "tip sheet" from the Federal Trade Commission (FTC) to help you avoid these scams, go to this web site (no personal information is required):

<http://www.ftc.gov/bcp/online/pubs/alerts/phishingalrt.htm>



The last "dose" ...

Outside of a dog, a book is man's best friend.
Inside of a dog, it's too dark to read.

** Groucho Marx



[1890 - 1977]

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