

AU InforMed

Volume 4 Number 24 (Issue 121)

Thursday, August 24, 2006



Key Inforbits

- Plan B approved
- MedWatch summary for June
- Boomer's on borrowed time?
- Coffee is now a health food!
- Tanning salons however, are not
- Genericide?

NEW DRUGS, and other related stuff ...

Plan B Approved ... The FDA today, August 24, 2006, announced approval of Plan B, a emergency contraceptive drug (or the “morning after pill”), as an over-the-counter (OTC) option for women aged 18 and older. It contains oral contraceptive hormones but in higher doses and different dosage regimen. Plan B has been available only as a prescription drug and will remain so for women age 17 and under. When used as directed, Plan B effectively and safely prevents pregnancy. Duramed, a subsidiary of Barr Pharmaceuticals, will make Plan B available with a rigorous labeling, packaging, education, distribution and monitoring program. In the CARE (Convenient Access, Responsible Education) program Duramed commits to:

Provide consumers and healthcare professionals with labeling and education about the appropriate use of prescription and OTC Plan B, including an informational toll-free number for questions about Plan B;

Ensure that distribution of Plan B will only be through licensed drug wholesalers, retail operations with pharmacy services, and clinics with licensed healthcare practitioners, and not through convenience stores or other retail outlets where it could be made available to younger women without a prescription;

Packaging designed to hold both OTC and prescription Plan B.

Plan B will be stocked by pharmacies behind the counter because it cannot be dispensed without a prescription or proof of age; and Monitor the effectiveness of the age restriction and the safe distribution of OTC Plan B to consumers ≥ 18 and prescription Plan B to women < 18 .

FDA approves over-the-counter access for Plan B for women 18 and older: Prescription remains required for those 17 and under. FDA News. 2006 Aug 24; P06-118.

<http://www.fda.gov/bbs/topics/NEWS/2006/NEW01436.html>

MedWatch ... Safety-related drug labeling changes for June 2006 have been posted on the MedWatch website. This posting includes 37 drug products with safety labeling changes to the Boxed Warning, Contraindications, Warnings, Precautions, or Adverse Reactions sections.

The Summary page --

http://www.fda.gov/medwatch/SAFETY/2006/jun06_quickview.htm

-- provides drug names and a listing of the sections changed.

The Detailed view --

<http://www.fda.gov/medwatch/SAFETY/2006/jun06.htm>

-- includes sections/subsections changed and a description of new or modified safety information in the Boxed Warning, Contraindications, or Warnings sections. The full labeling may be accessed by clicking on the drug name in the detailed view.

MedWatch ... FDA and GlaxoSmithKline notified healthcare professionals of changes to the Boxed Warning, Warnings and Precautions sections of the prescribing information for **Dexedrine® (dextroamphetamine sulfate)**, approved for the treatment of Attention-Deficit Hyperactivity Disorder and narcolepsy. The warnings describe reports of sudden death in association with CNS stimulant treatment at usual doses in children and adolescents with structural cardiac abnormalities or other serious heart problems.

Read the complete MedWatch 2006 Safety summary, including links to the manufacturer's Dear Healthcare Professional Letter and the product's approved labeling at:

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

FROM THE MEDICAL LITERATURE ...



Boomers on borrowed time? ... In a huge cohort study of 527,265 men and women, ages 50-71 years, investigators examined deaths over a 10 year period (1996-2005) and made correlations after separating out various risks (eg, smoking, preexisting disease) with weight and mortality. Obesity (BMI ≥ 30) and overweight (BMI 25.0 to 29.9).

Overweight people's risk of death increased 20% to 40%, while those in the obese category saw their risk of death increase 2 to 3-fold. The short conclusion statement says a lot: "Excess body weight during midlife, including overweight, is associated with an increased risk of death."

Adams KF, Schatzkin A, Harris TB, Kipnis V, Mouw T, Ballard-Barbash R, et al. Overweight, obesity, and mortality in a large prospective cohort of persons 50 to 71 years old. *N Engl J Med.* 2006 Aug 24;355(8):763-778.

Reviews of Note ...

- Appell RA. Pharmacotherapy for overactive bladder. *Drugs.* 2006;66(10):1361-1370.
- Schurch B. Botulinum toxin for the management of bladder dysfunction. *Drugs.* 2006;66(10):1301-1318.
- Moen MD, Wagstaff AJ. Nebivolol: A review of its use in the management of hypertension and chronic heart failure. *Drugs.* 2006;66(10):1389-1409.
- Abramowicz M, ed. Pharmaceutical drug overdose. *Treat Guidelines Med Lett.* 2006 Sep;4(49):61-66.
- Arepally GM, Ortel TL. Heparin-induced thrombocytopenia. *N Engl J Med.* 2006 Aug 24;355(8):809-17.
- Tarsy D, Simon DK. Dystonia. *N Engl J Med.* 2006 Aug 24;355(8):818-29.

FROM THE LAY LITERATURE about medicine ...

New health food ... Coffee ... For those who have been around long enough, you know that this is a remarkable transition. Coffee was nearly reviled a decade or two ago, but now, with the support of a few studies, it appears to have definite health benefits. This health benefit appears to be independent of caffeine, as decaffeinated coffee confers similar benefits. To be sure, there still may be situations where drinking coffee (at least caffeinated) isn't such a good idea (eg, where blood flow to the heart may be impaired). So belly up to the coffee bar, and order an extra large!



Bakalar N. Coffee as a health drink? Studies find some benefits. *New York Times.* 2006 Aug 15.

http://www.nytimes.com/2006/08/15/health/nutrition/15coff.html?_r=1&ref=health&oref=slogin

NDC Directory ... out of date ... According to a report from the Inspector General of the Department of Health and Human Services (HHS), the federal prescription drug directory (National Drug Code Directory or NDC Directory) is woefully out of date. The FDA, who is responsible for the Directory, apparently agrees and is working to fix the problems. The NDC Directory contained 123,856 prescription drug products as of February 2005. According to the report there are at least 9200 products missing and 34,200 other errors.

Associated Press. FDA drug guide has thousands of omissions. *Wall Street Journal*. 2006 Aug 15; p. A4.

Associated Press. FDA's drug directory is far out of date. *Washington Post*. 2006 Aug 15; p. A05.

<http://www.washingtonpost.com/wp-dyn/content/article/2006/08/14/AR2006081401026.html?referrer=email>

NDC Directory update: The FDA has proposed new regulations that, among other things, will require pharmaceutical manufacturers to file information electronically with the FDA, for inclusion in the NDC Directory. Currently the FDA receives the information on paper and must manually enter the data; 15 staff are assigned to this task. In addition, the manufacturers must update the file every six months rather than "prn" as in the past. The proposed rule goes out for a 90-day comment period, the FDA analyzes the feedback then proposes a final rule. Bottom line – change will likely happen, but it won't be soon.

Dooren JC. FDA proposes regulations to update drug database. *Wall Street Journal*. 2006 Aug 23.

News Services. Findings. *Washington Post*. 2006 Aug 24; p. A10.

<http://www.washingtonpost.com/wp-dyn/content/article/2006/08/23/AR2006082301720.html>

How much is your life worth? ... Another article about the cost of new therapies and the hard choices some patients must make. Some patients simply make the choice that the exorbitant costs of some drugs (some of the newer cancer drugs are among the most common) for the few months it may extend life is not worth it, and they refuse therapy. According to the article, many health economists view \$50,000 to \$100,000 per year as the "reasonable" upper limit. That may depend on from which end of the checkbook you view the world.

Associated Press. To high a price for life? *CNN.com* 2006 Aug 15.

<http://www.cnn.com/2006/HEALTH/08/15/spending.to.death.ap/index.html>

Target ... Tanning Salons ... In the last two years, the World Health Organization (WHO), the American Medical Association (AMA) and the American Academy of Dermatology have equated tanning beds with cigarette smoking, in terms of health peril. There has been a significant rise in skin cancer and the current effort is attempting to restrict the access to tanning beds to those ≥ 18 years old. The arguments sound strangely familiar; physicians are calling for regulation and restriction while the tanning bed industry counters there is absolutely no proof of any harm to anyone and legislation is infringing on individual rights!



Vitello P. Skin cancer is up; Tanning industry a target. *New York Times*. 2006 Aug 14.

http://www.nytimes.com/2006/08/14/nyregion/14tanning.html?pagewanted=1&_r=1

EtG ... ethyl glucuronide ... There is a new urine test available that is revolutionizing the monitoring of recovering alcoholics. It is known as of ethanol, ethyl glucuronide, which remains in the body for about 80 hours. Until now, it was very difficult to monitor such people because of the short time ethanol remains in the body. All good, right? According to this article, the test appears reliable; the problem is in the interpretation of the results. The test sensitivity is such that it can



detect the metabolite after such things as washing with an alcohol-based hand sanitizer, not to mention the use of medications containing alcohol. Some laws/regulations have been written interpreting the results so that ANY trace constitutes violation which could have devastating effects such as loss of job, license, profession, or children. As stated in the article, "Use of this screen has gotten ahead of the science."

Helliker K. A test for alcohol – and its flaws. *Wall Street Journal*. 2006 Aug 12; p. A1.

Vocabulary ... genericide ... A term may have been coined by Google™ trademark attorneys. Taking offense to the use of "Google™" as a verb and not as the specific product identity that it is. Hence, to "google" someone or something is inappropriate and a violation of Google's™ trademark. Use of the term in this respect is tantamount to "genericide" and you will be dealt with appropriately!

Ahrens F. So Google is no brand X, but what is 'genericide'? *Washington Post*. 2006 Aug 5; p. D01.

<http://www.washingtonpost.com/wp-dyn/content/article/2006/08/04/AR2006080401536.html?referrer=email>

AUBURN HSOP FACULTY and STUDENTS in the literature ...

- Hester EK, Chandler HV, Sims KM. Fosamprenavir: Drug development for adherence. *Ann Pharmacother*. 2006 Jul/Aug;40(7/8):1301-10.



The last "dose" ...

"We have met the enemy and he is us."

As spoken by Pogo Possum.

--Kelly W. We have met the enemy and he is us [poster]. Earth Day. 1970



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