

AU InforMed

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Key Inforbits

- New (old) contraceptive option
- New guidelines published for eating disorders
- Bad news on teenage smoking
- “Adaptive” trials are something new
- Cost of cancer drugs rising dramatically
- World village of 100 ...

NEW DRUGS, and other related stuff ...

New Dose Form ... The FDA approved a new contraceptive device on July 18, 2006, **Implanon™** (etonogestrel implant 68 mg, by Organon). It is a single-rod implantable contraceptive that is effective up to three years. The rod is about the size of a matchstick and is intended to be implanted subdermally on the inner side of a woman’s upper arm, by a specially trained healthcare provider, as an in-office procedure. Based on anticipated training programs, wide availability is expected in 2007. A similar product (Norplant® by Wyeth) was removed from the market six years ago due to injuries (it was a “six stick” implant) and adverse effects. <http://www.IMPLANON-USA.com> (Organon web site, also includes package insert)

Implantable contraceptive gets federal approval. *USA Today* 2006 Jul 18.

http://www.usatoday.com/news/health/2006-07-18-implanon_x.htm

MedWatch ... The FDA announced a warning not to purchase or consume **Zimaxx, Libidus, Neophase, Nasutra, Vigor-25, Actra-Rx, or 4EVERON**, illegal drugs with undeclared ingredients that are promoted and sold on web sites as "dietary supplements" for treating erectile dysfunction and enhancing sexual performance. These products have not been approved by the FDA, and there is no guarantee of their safety and effectiveness, or of the purity of their ingredients. They pose a threat to consumers because the undeclared ingredients may interact with nitrates found in some prescription drugs (such as nitroglycerin) and lower blood pressure to dangerous levels. The FDA advises consumers who have used any of these products to discontinue use and to consult their healthcare provider.

Read the complete MedWatch Safety summary, including a link to the FDA News Release, at: <http://www.fda.gov/medwatch/safety/2006/safety06.htm#enhance>

MedWatch ... Roxane Laboratories and the FDA announced a **nationwide recall of a single manufacturing lot of Azathioprine** tablets, 50 mg (Lot 558470A, Exp Mar 2009) used to help prevent rejection in kidney transplant patients, and to manage severe rheumatoid arthritis. The recall was initiated due to concerns that bottles from this single lot # 558470A, labeled as Azathioprine may contain Methotrexate, 2.5 mg tablets. Information has been sent to pharmacists alerting them of the details pertaining to this recall. Pharmacists who may have dispensed Azathioprine tablets to patients from manufacturing lot 558470A are instructed to contact those patients to assure they did not inadvertently receive Methotrexate tablets.

Read the complete MedWatch Safety summary, including a link to the firm press release, at: <http://www.fda.gov/medwatch/safety/2006/safety06.htm#azathioprine>

MedWatch ... Safety-related drug labeling changes for May 2006 are posted on the MedWatch website. The May 2006 posting includes 19 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/may06_quickview.htm

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

The Detailed view --

<http://www.fda.gov/medwatch/SAFETY/2006/may06.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.

FROM THE MEDICAL LITERATURE ...

Vocabulary ... Incidentaloma ... an incidental finding during diagnostic tests for some other problem that often leads to whole batteries of additional tests, not otherwise planned. According to the author of this short op-ed, this leads to great additional expense along with patient discomfort and anxiety; and it will probably get worse with increasing technologic capabilities. Stone JH. Incidentalomas – Clinical correlation and translational science required. *N Engl J Med*. 2006 Jun 29;354(26):2748-9.



New Guidelines ... have been published by the American Psychiatric Association for the **treatment of patients with eating disorders**. The guidelines are the 3rd edition and published as a separate supplement to the *American Journal of Psychiatry*.

Yager J, Chair, Devlin MJ, Halmi KA, Herzog DB, Mitchell JE III, Powers P, Zerbe KJ. Treatment of patients with eating disorders, 3rd ed. *Am J Psychiatry*. 2006 Jul;163(7):1-54.

Teen Smoking ... is flat. That is, the decline of smoking in this age group that was dropping from the late 1990's to 2003, has leveled out. The use of tobacco by teens is the same as it was in 2003. The CDC analyzed data from the Youth Risk Behavior Study and found, among other things, that current cigarette use among teens was 23%. The goals of the National Health Objective are to be $\leq 16\%$ by 2010. The rate of decrease needs to pick up to previous levels.



Cigarette use among high school students – United States, 1991 – 2005. *MMWR*. 2006 Jul 7;55(226):724-6.

Pharmacy compounding under the Congressional microscope ... Sen. Charles Grassley (R-Iowa), Chairman of the Senate Finance Committee has caught wind that some home care companies and pharmacies are substituting compounded respiratory medications for commercial products, without informing the physician or patient, and charging for the higher priced product. Pharmaceutical companies have performed tests on these products and found bacterial contamination and unspecified doses. More to come, I'm sure.



Appleby J. Grassley questions switching of drugs. *USA Today*. 2006 Jul 13.

http://www.usatoday.com/news/health/2006-07-13-drug-switch-usat_x.htm

Reviews of Note ...

- Stacy ZA, Dobesh PP, Trujillo TC. Cardiovascular risks of cyclooxygenase inhibition. *Pharmacotherapy*. 2006 Jul;26(7):919-938.
- Ito MK, Cheung RJ, Gupta EK, Birtcher KK, Chong PH, Bianco TM, Bleske BE. Key articles, guidelines, and consensus papers relative to the treatment of dyslipidemias – 2005. *Pharmacotherapy*. 2006 Jul;26(7):939-1010.
- OTC Products: 2006 Survey of pharmacist recommendations. *Pharmacy Times*. 2006 Jun;72(Suppl):1-60.
- Miller AJ, Mihm MC Jr. Melanoma. *N Engl J Med*. 2006 Jul 5;355(1):51-65.
- Aguilar D, Solomon SD. ACE inhibitors and angiotensin receptor antagonists and the incidence of new-onset diabetes mellitus: An emerging theme. *Drugs*. 2006;66(9):1169-1177.
- Rados C. A focus on vision. *FDA Consumer*. 2006 Jul/Aug;40(4):10-17. http://www.fda.gov/fdac/features/2006/406_vision.html
- Meadows M. Medication use and older adults. *FDA Consumer*. 2006 Jul/Aug;40(4):20-26. http://www.fda.gov/fdac/features/2006/406_olderadults.html

FROM THE LAY LITERATURE about medicine ...

“Adaptive trials” ... May become more commonplace, according to one article. Adaptive trials are those designed to change during the regular course, in response to a predetermined plan, usually done by computer simulations. They are fundamentally different from current practice when once a study is started, nothing can change its course (except premature ending based on unexpected positive or negative findings). The advantages of adaptive trials include: fewer patients needed, time savings, potential patient benefit, and of course, money savings. Disadvantages include: More potential bias if those blinded become aware of treatments, premature design changes and significant statistical challenges. Stay tuned.

Mathews AW. FDA signals it's open to drug trials that shift midcourse. *Wall Street J*. 2006 Jul 10; p. B1.

Conscience ... We've heard much about the pharmacist's duty/obligation to dispense medication (usually in regards to emergency contraceptives) regardless of their personal beliefs. Here is a more general article that gives some wider perspective of the issue and the situations many other health professionals may encounter, which calls for a reckoning of professional obligations and personal beliefs. It doesn't solve anything, but tells us that pharmacists are not the only ones with conflicting values.



Stein R. A medical crisis of conscience. *Washington Post*. 2006 Jul 16; p. A01.

<http://www.washingtonpost.com/wp-dyn/content/article/2006/07/15/AR2006071500846.html?referrer=email>

Costs of Cancer Drugs

... are going up, way up. Two recent articles have highlighted the costs of recently approved cancer drugs and the plight of some patients. Even when insurance covers the “usual” costs, patients may still be out several hundred dollars a month. There are also patients who decide to forego the treatments, which unfortunately may give the patient only a few more months to live, rather than bankrupt their family. The pharmaceutical companies counter with the usual arguments of the money needed for research, and that they have

compassionate programs for those who can't afford the therapies. Methinks they protest too much.

Szabo L. Prices soar for cancer drugs. *USA Today*. 2006 Jul 11.

http://www.usatoday.com/news/health/2006-07-10-cancer-costs_x.htm

Szabo L. Cost of cancer drugs crushes all but hope. *USA Today*. 2006 Jul 11.

http://www.usatoday.com/news/health/2006-07-10-cancer-drugs_x.htm

AUBURN HSOP FACULTY and STUDENTS in the literature ...

- Wargo KA, Eiland EH III, Hamm W, English TM, Phillippe HM. Comparison of the modification of diet in renal disease and Cockcroft-Gault equations for antimicrobial dosage adjustments. *Ann Pharmacother*. 2006;40:xxxx. Online 2006 Jul 11, www.theannals.com, DOI 10.1345/aph.1G635.

NEW RESOURCES in the DILRC ...

- Committee on Infectious Diseases, American Academy of Pediatrics. *Red Book: 2006 Report of the Committee on Infectious Diseases*. 27th ed. Elk Grove Village, IL: American Academy of Pediatrics, 2006.

TIMELY TOP TECH TIP ...



Open this web site for a look at our world today: A village with 100 people from around the world..... No guarantee of its accuracy, but it is interesting. Click here: <http://users.gazinter.net/melan/Warn/Warnenu.htm>



The last "dose" ...



"That's one small step for (a) man; one giant leap for mankind."



-- Neil Alden Armstrong [1930 -]. Spoken on July 21, 1969 as the first man to step onto the moon's surface.

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

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