

AU InforMed

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Key Inforbits

- New generics
- MedWatches for Mifeprex[®] and Ontak[®]
- Women's health issues
- Top 200's are published
- Boomer's not in such bad shape
- Personal information in emergencies

NEW DRUGS, and other related stuff ...

First Time Generics ... March 28. The FDA has approved two first-time generic drugs. One is **zidovudine capsules, 100 mg**, to be used in combination with other anti-retroviral medications to treat HIV infection. This product was reviewed under the President's Emergency Plan for AIDS Relief. The other first-time generic is **glipizide extended-release tablets, 2.5 mg** for the control of hyperglycemia in patients with type 2 diabetes.

<http://www.fda.gov/cder/>

MedWatch ... The FDA issued a public health advisory about two additional deaths following medical abortion with **mifepristone (Mifeprex[®])** by Danco Labs). The Agency received verbal notification of the deaths in the U.S. from the manufacturer. The FDA is investigating all circumstances associated with these cases and is not able to confirm the causes of death. However, all providers of medical abortion and their patients need to be aware of the specific circumstances and directions for use of this drug and all risks including sepsis when considering treatment. In particular, physicians and their patients should fully discuss early potential signs and symptoms that may warrant immediate medical evaluation.

Read the complete MedWatch 2006 Safety summary, including links to the Public Health Advisory, previous safety alerts and other supporting information, at:

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

MedWatch ... Ligand Pharmaceuticals and FDA notified healthcare professionals of changes to the WARNINGS section of the prescribing information for **Ontak[®] (denileukin diftitox)**, indicated for the treatment of patients with persistent or recurrent cutaneous T-cell lymphoma. Loss of visual acuity, usually with loss of color vision, has been reported following administration of Ontak[®]. While recovery was reported in some of the affected patients, most patients reported persistent visual impairment.

Read the complete MedWatch 2005 Safety summary, including links to the Dear Healthcare professional letter and revised label, at:

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

FROM THE MEDICAL LITERATURE ...



Women's Health Issue ... This week's issue of the *Journal of the American Medical Association* (JAMA) is devoted to women's health. Articles include original contributions on gene mutations of women at high risk of breast cancer; the benefits to the child upon treatment of maternal depression; exercise and cardiac death, and body mass index, etc. Most of the other articles and columns in the issue are also devoted to women's health.

JAMA. 2006 Mar 22;295(12).

ADHD drugs and CV risk ... Early release ... an editorial/perspective was published as an early release article in the *New England Journal of Medicine* last week concerning the recommendation by the Drug Safety and Risk Management Advisory Committee to add a "black box" warning about cardiovascular risk to ADHD drugs. Some of the rationale was presented by a consultant to the Committee. The article will be published in the April 6th issue.

Nissen SE. ADHD drugs and cardiovascular risk. *N Engl J Med* 2006 Apr 6;354(14).

www.nejm.org (free until article is published)



Tuberculosis is not gone ... In conjunction with a report on developing resistance of *Mycobacterium tuberculosis* (TB) to second-line drugs¹, the CDC has also published a report on tuberculosis trends in the U.S.² After the unprecedented 1985-1992 resurgence in TB in the U.S., the annual TB rate steadily decreased during 1993-2005; but that trend is decelerating, raising concerns that the progress toward eliminating TB is slowing. A large portion of the increase is due to immigration patterns. Also, recently the number of multi-drug resistant (MDR) TB cases increased by 13.3%. The good news is that for the first time in 50 years, six new TB drugs will soon be tested in humans. These drugs might reduce the duration of therapy by 30% to 70%, making treatment completion more likely, and may increase the probability of cure.

¹CDC. Emergence of *Mycobacterium tuberculosis* with extensive resistance to second-line drugs – Worldwide, 2000-2004. *MMWR*. 2006 Mar 24;55(11):301-305.

<http://www.cdc.gov/mmwr/preview/mmwrhtml/mm5511a2.htm>

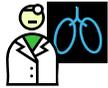
²CDC. Trends in tuberculosis – United States, 2005. *MMWR*. 2006 Mar 24;55(11):305-308.

<http://www.cdc.gov/mmwr/preview/mmwrhtml/mm5511a3.htm>

Reviews of Note ...

- Meadows M. Taking care of your feet. *FDA Consumer*. 2006 Mar-Apr;40(2):16-24.
- Top 200 Brand-name drugs by retail dollars in 2005. *Drug Topics*. 2006 Mar 6;150(5):26. [#1 is Lipitor ...]
- Top 200 generic drugs by retail dollars in 2005. *Drug Topics*. 2006 Mar 6;150(5):29. [#1 is hydrocodone/APAP ...]
- Top 200 Brand-name drugs by units in 2005. *Drug Topics*. 2006 Mar 6;150(6):25. [#1 is Lipitor ...]
- Top 200 generic drugs by units in 2005. *Drug Topics*. 2006 Mar 6;150(6):26. [#1 is hydrocodone/APAP ...]
- CDC. Preventing tetanus, diphtheria, and pertussis among adolescents: Use of tetanus toxoid, reduced diphtheria toxoid and acellular pertussis vaccines. Recommendations of the Advisory Committee on Immunization Practices (ACIP). *MMWR*. 2006 Mar 24;55(RR-3):1-43.

FROM THE LAY LITERATURE about medicine ...



Health care careers – most excellent ... Yet another justification to show your mother that your chosen career path is a “healthy” one. Some of the highlighted careers are physician assistants, nurses, and of course, pharmacists. In addition, there is a lot of peripheral growth in related fields, particularly technicians. There are also new specialties emerging such as emergency and disaster planning. While shortages are widespread, the concentration of need is in California, New York, Florida, Texas and Pennsylvania.

Armour S, Appleby J. Pronosis for health care jobs: Excellent. *USA Today* 2006 Mar 9.

http://www.usatoday.com/news/health/2006-03-09-health-jobs-usat_x.htm



A rose by any other name ... and you thought conceiving, testing and producing a new drug was tough; the next big hurdle is what to name it!? There are a couple of divisions of FDA that look and rule on such things. The Division of Drug Marketing, Advertising and Communications takes a shot as does the Division of Medication Errors and Technical Support. These divisions have numerous procedures and databases that are combed looking for any look-alike or sound-alike drug names that could cause confusion and result in the wrong drug being orders, delivered or taken. Yet another valuable use of your tax dollars, not to mention your health care dollar.

Mathews AW. When a drug maker creates a new pill, Uncle Sam vets name. *Wall Street Journal* 2006 Mar 17; p. A1.



Boomer’s: It may not be so bad after all ... A new report from the United States Census Bureau on the aging population “65+ in the United States: 2005,” was drawn from existing data in several other government agencies. The basic conclusion seems to be that the Boomer generation is significantly healthier, has less disability, is better educated and more prosperous than previous generations. Thus, the strain on health care may not be as great as once believed. However, there is always a downside: the growing obesity rate may cut into these gains; in addition divorce seems to be rising in this group and there are still segments of society where poverty is very significant. Lots of good data.

Lyman R. Census report foresees no crisis over aging generation’s health. *New York Times.com* 2006 Mar 10.

<http://www.nytimes.com/2006/03/10/national/10aging.html?pagewanted=all>

Kids going crazy ... No, not Spring Break 2006, but more disturbing. According to a report (based on a study in Ambulatory Pediatrics), antipsychotic drugs are being commonly prescribed for children with a variety of behavioral problems, such as attention deficit disorder. While some of this use of such powerful drugs may be justified, is all of it? Between 1995 and 2002 the number of children prescribed antipsychotic agents increase five-fold. Heavy marketing by pharmaceutical companies was one reason, yet many of these agents do not have labeled uses for children.

Associated Press. Kids’ prescriptions for anti-psychotic drugs skyrockets. *USA Today* 2006 Mar 16.

http://www.usatoday.com/news/health/2006-03-16-kids-drugs_x.htm

AUBURN HSOP FACULTY in the literature ...

- AU research focused on using the contact lens for effective drug delivery. *AU Research News* Feb-Mar 2006; p. 4.

A researcher from AU's Dept. of Chemical Engineering, Mark Byrne, is highlighted for his research improving the contact lens for drug delivery.

<http://www.auburn.edu/research/vpr/communications/resnews/feb-march06.html#contacts>

TIMELY TOP TECH TIP ...



Personal health information in an emergency? Store it on your cellphone or hand-held device. Critical information such as physicians, emergency contacts, insurance, prescriptions, allergies can be stored in your phone's memo function, which will save it in your address book. Medical personnel are increasingly trained to check a cellphone's address book for contact information.

Some companies are even offering products to more easily retrieve such information. Juke Systems Inc. has a new software program called *ICE First* that links your information to an icon installed on your cellphone/hand-held device. It costs \$9.95 and is available at icefirst.com. MedicTag provides a similar service for your laptop or PC. Pricing and other information can be found at www.medictag.com or www.bytes4life.com.

Ali S. Storing medical information. *Wall Street Journal* 2006 Mar 21; p. D1.



The last "dose" ...

"The ultimate result of protecting men from the results of their own folly is to fill the world with fools."

-- Herbert Spencer [1820-1903]



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

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