

AU InforMed

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Key Inforbits

- New sleep aid
- Lots of MedWatches
- Surveys on hospital quality and chemicals
- New flu vaccine recommendations
- Heat wave!
- On the moon!

NEW DRUGS, and other related stuff ...

New Drug ... Ramelteon (Rozerem™ by Takeda Pharmaceuticals) was approved by the FDA on July 22, 2005. It is indicated for treatment of insomnia characterized by difficulty with sleep onset. It is described as a melatonin receptor agonist and is not a controlled substance. It is primarily metabolized by the CYP1A2 isozymes and thus drug interactions are possible (fluvoxamine is listed). It will be supplied as 8mg tablets and will be available in September.

<http://www.rozerem.com/>

<http://www.cnn.com/2005/HEALTH/conditions/07/25/sleep.drug.ap/index.html>

New Product ... Dapsone gel, 5% (Aczone™ by QLT, Inc) was approved by the FDA on July 7, 2005 for the topical treatment of acne vulgaris. It represents a new class of treatment, but patients with Glucose 6-phosphate dehydrogenase (G6PD) deficiency will need to be monitored for development of hemolytic anemia.

<http://press.arrivenet.com/pro/article.php/665384.html>

Removal ... Palladone® (hydromorphone HCl by Purdue Pharma L.P.) is the subject of an FDA withdrawal request, due to potentially fatal adverse reactions can occur when Palladone® extended release capsules are taken together with alcohol. When Palladone® is taken with alcohol the extended release mechanism is harmed which can lead to dose-dumping, ie, the rapid release of the active ingredient from an extended release product into the blood stream. Patients currently taking Palladone® should consult with their physicians for alternative treatments. For additional information, go to: <http://www.fda.gov/cder/drug/infopage/palladone/default.htm>

FDA. FDA asks Purdue Pharma to withdraw Palladone for safety reasons. *FDA News* 2005 Jul 13; P05-42.

<http://www.fda.gov/bbs/topics/NEWS/2005/NEW01205.html>

Discontinued ... Eli Lilly and Co. has announced that it will stop making Humulin U Ultralente and Humulin L Lente recombinant insulin products. The company will continue shipping the two products through at least mid-August 2005.

<http://www.fda.gov/cder/drug/shortages/HumulinDr.pdf>

Warnings ... Reiterated ... FDA is investigating reports of death and other serious side effects from overdoses of fentanyl in patients using fentanyl transdermal (skin) patches for pain control. Deaths and overdoses have occurred in patients using both the brand name product Duragesic® and the generics. The primary problem appears to be that patients (or caregivers) do

not appreciate the dangers of the drug and may be unintentionally overdosing. Important safety information has been highlighted. [product label and patient package insert](#).
The Duragesic[®] product label was updated in June 2005 and a “Dear Healthcare Professional” letter about these changes was issued by the manufacturer and is available at this link (http://www.fda.gov/medwatch/SAFETY/2005/duragesic_ddl.pdf).

FDA Public Health Advisory: Safety warnings regarding use of fentanyl transdermal (skin) patches. July 15, 2005. <http://www.fda.gov/cder/drug/advisory/fentanyl.htm>

MedWatches ... Updated labeling for **Cialis, Levitra and Viagra** to reflect a small number of post-marketing reports of sudden vision loss, attributed to NAION (non arteritic ischemic optic neuropathy), a condition where blood flow is blocked to the optic nerve. FDA advises patients to stop taking these medicines, and call a doctor or healthcare provider right away if they experience sudden or decreased vision loss in one or both eyes. For complete MedWatch 2005 Safety summary, go to: <http://www.fda.gov/medwatch/SAFETY/2005/safety05.htm#ED>

Worsened renal function and mortality with nesiritide (Natrecor by Scios). For complete MedWatch 2005 Safety summary, go to: <http://www.fda.gov/medwatch/safety/2005/safety05.htm#Natrecor2>

Septic deaths reported in women following medical abortion with mifepristone (Mifeprex by Danco Labs) and misoprostol, all in California. The bacteria causing sepsis has been identified in two of the cases as *Clostridium sordellii*. Read the complete MedWatch 2005 Safety summary, including links to other documents, at: <http://www.fda.gov/medwatch/safety/2005/safety05.htm#Mifeprex>

Labeling changes for efalizumab (Raptiva by Genentech). Healthcare professionals and patients were informed about reports of immune-mediated hemolytic anemia and postmarketing reports of thrombocytopenia and serious infections including necrotizing fasciitis, tuberculous pneumonia, bacterial sepsis with seeding of distant sites, severe pneumonia with neutropenia, and worsening of infection (e.g. cellulitis, pneumonia) despite antimicrobial treatment. Complete MedWatch 2005 Safety summary, at: <http://www.fda.gov/medwatch/safety/2005/safety05.htm#Raptiva>

FROM THE MEDICAL LITERATURE ...

2005 update for CDC’s influenza recommendations ... that include five principal changes:
1) persons with any condition (e.g., cognitive or neuromuscular disorders) that can compromise respiratory function or the handling of respiratory secretions or that can increase the risk for aspiration be vaccinated. 2) ALL health-care workers should be vaccinated against influenza annually. 3) Use of both available vaccines (inactivated and LAIV) is encouraged for eligible persons every flu season. During periods when inactivated vaccine is in short supply, use of LAIV is especially encouraged when feasible for eligible persons (including health-care workers). 4) The 2005--06 trivalent vaccine virus strains are A/California/7/2004 (H3N2)-like, A/New Caledonia/20/99 (H1N1)-like, and B/Shanghai/361/2002-like antigens. For the A/California/7/2004 (H3N2)-like antigen, manufacturers may use the antigenically equivalent A/New York/55/2004 virus, and for the B/Shanghai/361/2002-like antigen, manufacturers may use the antigenically equivalent B/Jilin/20/2003 virus or B/Jiangsu/10/2003 virus. 5) CDC and other agencies will continually assess the vaccine supply and will make recommendations preceding the 2005--06 influenza season.

CDC. Prevention and Control of Influenza: Recommendations of the Advisory Committee on Immunization Practices (ACIP). *MMWR*. 2005 Jul 13;54:1-40.

<http://www.cdc.gov/mmwr/preview/mmwrhtml/rr54e713a1.htm>

Hospital Quality? ... Two studies just published, one from the Joint Commission on Accreditation of Healthcare Organizations (JCAHO) and another from Harvard School of Public Health, report on aspects of hospital quality. In general, there has been a steady improvement in rated standards of care, largely from the JCAHO's "core measures" program. However, the second study shows discrepancies in regions. The Northeast and Midwest rate the highest where (unfortunately) the Southeast and West rate lowest. There is also an accompanying editorial to provide some perspective.

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

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

Romano PS. Improving the quality of hospital care in America. *N Engl J Med*. 2005 Jul 21;353(3):302-4.

Pesticide poisoning from a prescription bottle? ... A brief report describes a case of an 11-month old child who presented with confusing symptoms. Eventually it was deduced that the child had ingested rivastigmine (Exelon[®] by Novartis), a reversible acetylcholinesterase inhibitor. The exposure produced predominantly nicotinic cholinergic symptoms. The patient recovered with supportive therapy.

Lai MW, Moen M, Ewald MB. Pesticide-like poisoning from a prescription drug. *N Engl J Med*. 2005 Jul 21;353(3):317-8.



Chemicals down ... The Third national report on human exposure to environmental chemicals was released July 21, and among many other things, reports that Americans have lower levels of lead, secondhand-smoke byproducts and various other potentially dangerous substances in their bodies than 10 years ago. The data is based on taking blood and urine samples from about 2,400 people in 2001 and 2002 and testing for 148 environmental chemicals, including metals, pesticides, insect repellants and disinfectants. There is much more data in the 475 page report that is available at the web site below.

CDC. Third national report on human exposure to environmental chemicals. Atlanta: National Center for Environmental health Division of Laboratory Sciences. NCEH Pub. No. 05-0570, 2005 July. (475 pgs.)

<http://www.cdc.gov/exposurereport/>



Heat illness ... Prevention is the key in avoiding heat related illnesses. If you need a review on what to do to prevent or treat the heat related maladies, visit the CDC's web site below.

<http://www.bt.cdc.gov/disasters/extremeheat/index.asp>

Reviews of Note ...

- Pochop S. Pharmacy practice residency programs. *Am J Health-Syst Pharm*. 2005 Aug 1;62:1562, 1564.
- Lichtenstein AH, Russell RM. Essential nutrients: Food or supplements? Where should the emphasis be? *JAMA* 2005 Jul 20;294(3):351-8.
- White WB. Update on the drug treatment of hypertension in patients with cardiovascular disease. *Am J Med* 2005 Jul;118(7):695-705.
- Basaria S, Cooper DS. Amiodarone and the thyroid. *Am J Med* 2005 Jul;118(7):706-14.

- OTC Products: 2005 Survey of Pharmacist Recommendations. *Pharmacy Times* 2005 Jun;Suppl:1-52.
- Abramowicz M, ed. CYP3A and drug interactions. *Med Lett Drugs Ther* 2005 Jul 4;47(1212):54-5.
- Abramowicz M, ed. Vitamin supplements. *Med Lett Drugs Ther* 2005 Jul 18;47(1213):57-9.
- Raisz LG. Screening for osteoporosis. *N Engl J Med* 2005 Jul 14;353(2):164-71.
- Abramowicz M,ed. Drugs for diabetes. *Treat Guidelins Med Lett* 2005 Aug;3(36):57-62.

FROM THE LAY LITERATURE about medicine ...

Abortion Data ... A new report shows that the rate of abortion continues to decline. In 2002, approximately 1.29 million women received abortions compared to 1.61 million in 1990. There is a variety of data in the report as to those most likely to seek abortions, including by age and race, and gestational age. Links to the recent Guttmacher report and the last report from the CDC, considered the two most reliable for this data, are available at the web site below.

Sowti N. Abortion: Just the data. *Washington Post.com* 2005 Jul 19; p. HE01.

<http://www.washingtonpost.com/wp-dyn/content/article/2005/07/18/AR2005071801164.html>



Well-being assessment of America's children ... is in a report released July 20, 2005. As with most such reports, there is good news and bad. The report covers the areas of health, behavior and social environment, economic security, education, and population and family characteristics. For public access to the report, go to the web site: <http://childstats.gov/>

Free electronic medical records (EMR) ... being given away by Medicare, starting next month. The software package, Vista, used by the Dept. of Veterans Affairs for 20 years, will be given to any physician who wants it. The lack of an electronic medical record is recognized by Medicare as one of the biggest stumbling blocks to improved health care, so they are doing something about it. Apart from filing insurance claims, only about 25% of physicians use an EMR. The software has its own problems so the success of the program remains to be seen.

Kolata G. U.S. will offer doctors free electronic records system. *New York Times.com* 2005 Jul 21.

<http://www.nytimes.com/2005/07/21/health/21records.html?>

The last "dose" ...

July 20, 1969 Men first landed on the moon.

"That's one small step for [a] man, one giant leap for mankind."

Neil Alden Armstrong [1930 -]



Neil Armstrong works at the LM in one of the few photos taken of him from the lunar surface. NASA photo AS11-40-5886 [from Wikipedia, accessed 7/20/05, http://en.wikipedia.org/wiki/Neil_Armstrong]

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

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