

# AU InforMed

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## Key Inforbits

- Attitudes on substance abuse: Teens / parents
- Rx drug abuse is very high – new survey
- Susceptibility to heat illness
- Sweatology

## **NEW DRUGS, and other related stuff ...**

**New Indications** ... (8/22/2007) The FDA has approved **risperidone (Risperdal®)** by Janssen, L.P. ) for the treatment of schizophrenia in adolescents, ages 13 to 17, and for the short-term treatment of manic or mixed episodes of bipolar I disorder in children and adolescents ages 10 to 17. This is the first FDA approval of an atypical antipsychotic drug to treat either disorder in these age groups. Until now, there has been no FDA-approved drug for the treatment of schizophrenia for pediatric use and only lithium is approved for the treatment of bipolar disorder in adolescents ages 12 and up. Drowsiness, fatigue, increase in appetite, anxiety, nausea, dizziness, dry mouth, tremor, and rash were among the most common side effects reported. FDA approves Risperdal for two psychiatric conditions in children and adolescents. *FDA News*. 2007 Aug 22. <http://www.fda.gov/bbs/topics/NEWS/2007/NEW01686.html>

**MedWatch** ... (8/15/2007) The FDA announced that on October 18 - 19, 2007, the **Nonprescription Drugs Advisory Committee will discuss the safety and effectiveness of cough and cold drug product use in children.** Questions have been raised about the safety of these products and whether the benefits justify any potential risks from the use of these products in children, especially in children under two years of age. Some reports of serious adverse events associated with the use of these products appear to be the result of giving too much of these medicines to children. Parents must carefully follow the directions for use in the "Drug Facts" box on the package label. The Public Health Advisory offers parents and caregivers of children recommendations when using cough and cold products in children. Read the complete MedWatch 2007 Safety summary, including a link to the FDA Public Health Advisory (also enumerates precautions in these situations) and Federal Register Meeting Notice regarding this issue at: <http://www.fda.gov/medwatch/safety/2007/safety07.htm#Cough>

**MedWatch** ... (8/16/2007) The FDA and Bristol-Myers Squibb notified healthcare professionals of **revisions to sections of the Baraclude® (entecavir) prescribing information:** Boxed Warnings, Microbiology/Antiviral Activity against HIV (human immunodeficiency virus), Warnings/Co-infection with HIV, Precautions/ Information for Patients, and Patient Package Insert. Entecavir therapy is not recommended for HIV/hepatitis B virus (HBV) co-infected patients who are not also receiving highly active antiretroviral therapy (HAART) due to the potential for the development of HIV resistance. Read the complete MedWatch 2007 safety summary including a link to the Bristol-Myers Squibb Dear Healthcare Professional Letter and Prescribing Information, at: <http://www.fda.gov/medwatch/safety/2007/safety07.htm#Baraclude>

**MedWatch** ... (8/16/2007) The FDA approved updated labeling to include **pharmacogenomics information** to the Clinical Pharmacology, Precautions, and Dosage and Administration sections of the prescribing information for the widely used blood-thinning drug, **Coumadin® (warfarin)**. This new information explains that people's genetic makeup may influence how they respond to the drug. The dosage and administration of warfarin must be individualized according to the patient's prothrombin time (PT)/International Normalized Ratio (INR) response to the drug. The specific dose recommendations are described in the warfarin product labeling, along with the new information regarding the impact of genetic information upon the initial dose and the response to warfarin. Ongoing warfarin therapy should be guided by continued INR monitoring.

Read the complete MedWatch 2007 Safety summary, including a link to the FDA Drug Information Page, at: <http://www.fda.gov/medwatch/safety/2007/safety07.htm#Warfarin>

**MedWatch** ... (8/17/2007) The FDA issued a Public Health Advisory about a very rare, but serious, side effect in nursing infants whose mothers are taking **codeine and are ultra-rapid metabolizers**. When codeine enters the body and is metabolized, it changes to morphine, which relieves pain. Some nursing mothers taking codeine may have higher morphine levels in their breast milk leading to life-threatening or fatal side effects in nursing babies. In most cases, it is unknown if someone is an ultra-rapid codeine metabolizer. When prescribing codeine-containing drugs to nursing mothers, physicians should choose the lowest effective dose for the shortest period of time and should closely monitor mother-infant pairs. There is an FDA cleared test for determining a patient's CYP2D6 genotype. The test is not routinely used in clinical practice but is available through a number of different laboratories. Read the complete MedWatch 2007 Safety summary, including a link to the FDA Public Health Advisory and Drug Information Page, at: <http://www.fda.gov/medwatch/safety/2007/safety07.htm#Codeine>

**MedWatch** ... (8/21/2007) Confidence Inc. is **recalling one lot of METABOLISM Apple Cider Vinegar Brand Dietary Supplement Capsules** (Lot: 3001006, Exp. 10/2009) because the product contains the undeclared drug ingredient sibutramine, an FDA approved drug used as an appetite suppressant for weight loss. The use of sibutramine may pose a threat to consumers because it is known to substantially increase blood pressure and/or pulse rate in some patients and may present a significant risk for patients with a history of coronary artery disease, congestive heart failure, arrhythmias or stroke. Consumers should return any unused product to the manufacturer.

Read the complete MedWatch 2007 Safety Summary including a link to the manufacturer's Recall notice at: <http://www.fda.gov/medwatch/safety/2007/safety07.htm#Confidence>

## **FROM THE MEDICAL LITERATURE ...**

**National Survey of American Attitudes on Substance Abuse XII: Teens and Parents ...** In its 12<sup>th</sup> year, the “back-to-school” survey shows a continuing upward trend of drug use in America’s teenagers, based on interviews with 1063 teens aged 12-17 years and 550 parents of teens. Although not a very large sample for a 16 million member group, it is estimated that 31% of middle schools and 61% of high schools are not “drug free.” Although not surprising, the survey confirms that attendance at these “drug-infested” schools greatly increases the chances of teens becoming involved in the drug using culture (including alcohol and tobacco). The survey also highlights some differences in the attitudes and perceptions of the teens versus their parents,

with the parents being “behind the curve” compared to the reality of their children’s perceptions. There is a lot of data in this 74-page report.

The National Center on Addiction and Substance Abuse at Columbia University (CASA). National survey of American attitudes on substance abuse XII: Teens and parents. August 2007.

[http://www.casacolumbia.org/absolutenm/articlefiles/380-2007%20Teen%20Survey%20XII%20\(2\).pdf](http://www.casacolumbia.org/absolutenm/articlefiles/380-2007%20Teen%20Survey%20XII%20(2).pdf)

**Heat Wave** – **Who is susceptible** ... Investigators conducted a meta-analysis of case-control or cohort studies related to descriptions of heat wave, heat stroke, sunstroke, heat stress, etc. The object was to discern the factors that may predict who in the population may be more susceptible to heat illness and also any identifying protective measures. They found that those with the highest risk of death during heat waves were those that were confined to bed, did not leave home daily and those who could not take care of themselves. Other factors included those with psychiatric, cardiovascular or pulmonary illness. Protective factors included: Working home air-conditioning, visiting cool environments, fans and social contacts.

Bouchama A, Dehbi M, Mohamed G, Matthies F, Shoukri M, Menne B. Prognostic factors in heat wave-related deaths: A meta-analysis. *Arch Intern Med.* 2007 Aug 13;167(20)©doi:10.1001/archinternmed.167.20.ira70009).

### Reviews of Note ...

- Singh IM, Shishehbor MH, Ansell BJ. High-density lipoprotein as a therapeutic target: A systematic review. *JAMA.* 2007 Aug 15;298(7):786-798.
- Mohamed Q, Gillies MC, Wong TY. Management of diabetic retinopathy: A systematic review. *JAMA.* 2007 Aug 22/29;298(8):902-916.

### FROM THE LAY LITERATURE about medicine ...

**“Non-medicine” in the curriculum** ... a report on four medical schools (University of Maryland, Johns Hopkins, UCLA, and University of Pennsylvania) and their proclivity to add complementary and alternative medicine (CAM) topics to their medical curriculum. Although far from widespread, the most “acceptable” topics covered are: Acupuncture, mind/body medicine (meditation, etc), herbal therapies, manipulative and body-based methods (eg, chiropractic), and energy medicine (eg, therapeutic touch, distant healing, prayer). It doesn’t appear that allopathic medicine is in any danger of giving ground.



Huget J. Earning a spot in the curriculum. *Washington Post.* 2007 Jul 17; p. HE01.

<http://www.washingtonpost.com/wp-dyn/content/article/2007/07/13/AR2007071301847.html?referrer=email>

**Rx drug abuse very high** ... An analysis by the Associated Press of Drug Enforcement Agency (DEA) data indicates that the amount of five major prescription analgesics sold has nearly doubled from 1997 to 2005. The single biggest culprit is oxycodone (OxyContin®). Some of the legitimate reasons cited are an increased need due to the aging population, aggressive marketing by pharmaceutical companies, and a change in pain management philosophy (trying to relieve pain rather than considering it part of healing) over the last couple of decades. However, there are many instances of “pill mills” and diversion of legitimate prescriptions and shipments. Physicians are more wary of prescribing narcotic agents and some physicians are simply refusing to do so.

Bass F (Associated Press). World of hurt: Painkiller use skyrockets. *USA Today.* 2007 Aug 21.

[http://www.usatoday.com/news/health/2007-08-19-painkillers\\_N.htm](http://www.usatoday.com/news/health/2007-08-19-painkillers_N.htm)

**Sweatology** ... If you haven't had enough of the heat, this article will imbue a bit more knowledge about our well-honed internal air-conditioner. It's not a medical description, but the author provides a readable perspective on sweating. It includes some discussion about acclimatization, value of clothing (less is not necessarily better), genetic variations, and adaptations over the millennia. So, don't sweat it!



Zuger A. Sweatology. *New York Times*. 2007 Aug 14.

<http://www.nytimes.com/2007/08/14/health/14swea.html?ref=health>

### **NEW RESOURCES in the DILRC ...**

- Kliegman RM, Behrman RE, Jenson HB, Stanton BF, eds. *Nelson Textbook of Pediatrics*. 18<sup>th</sup> ed. Philadelphia: Elsevier/Saunders, 2007.
- Levin BL, Hurd PD, Hanson A. *Introduction to Public Health in Pharmacy*. Sudbury, MA: Jones and Bartlett, 2008. USPC. *2007 USP Dictionary of USAN and International Drug Names*. Rockville, MD: United States Pharmacopeial Convention, 2007.
- Chiquette E, Posey LM. *Evidence-Based Pharmacotherapy*. Washington, DC: American Pharmacists Association, 2007.
- Hansten PD, Horn JR. *Drug Interactions Analysis and Management 2007*. St. Louis: Facts and Comparisons/Wolters Kluwer Health, 2007.
- Tatro DS, ed. *Drug Interaction Facts 2007*. St. Louis: Facts and Comparisons/Wolters Kluwer Health, 2007.



### **The last "dose" ...**

I view'd your urine, and the hypostasis  
Thick and obscure doth make your danger great,  
Your vaines are full of accidentall heat,  
Whereby the moisture of your blood is dried.

Christopher Marlowe [1564 - 1593] *Tamburlaine the Great*, Act V, Sc. iii



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