

AU InforMed

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Key Inforbits

- List of new drugs
- MedWatching
- Coffee good; smoking bad
- Exposé on drugs, medicine and big pharma
- Methamphetamine is #1
- Rx abuse is way up ↑

NEW DRUGS, and other related stuff ...

New Drugs ... The FDA keeps a running list of drugs approved in the current year that they update about quarterly. They have just updated their list and the web site is below. Thus far, there have only been seven drugs and one biologic approved this year; FDA is off of its usual pace. At this rate only 16 new drugs/biologicals will be approved this year.

<http://www.fda.gov/cder/rdmt/nmecy2005.htm>

MedWatch ... Safety-related labeling changes for April 2005 are posted on the MedWatch website. The April posting includes 22 drug products with safety labeling changes to the Contraindications, Boxed Warning, Warnings, Precautions, or Adverse Reactions sections.

The Summary page --

http://www.fda.gov/medwatch/SAFETY/2005/apr05_quickview.htm

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

The Detailed view --

<http://www.fda.gov/medwatch/SAFETY/2005/apr05.htm>

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

MedWatch ... In response to recent scientific publications that report the possibility of increased risk of suicidal behavior in adults treated with antidepressants, the FDA has issued a Public Health Advisory to update patients and healthcare providers. Even before the publication of these recent reports, the FDA had already begun the process of reviewing available data to determine if such a risk exists. The Agency has asked manufacturers to provide information from their trials using an approach similar to that used in the evaluation of the risk of suicidal behavior in the pediatric population taking antidepressants. This effort will involve hundreds of clinical trials and may take more than a year to complete.

Read the complete MedWatch 2005 Safety summary, including links to the FDA Talk Paper, Public Health Advisory and Drug Information Page, at:

<http://www.fda.gov/medwatch/SAFETY/2005/safety05.htm#antidepressant>

MedWatch ... FDA notified consumers and healthcare professionals about the risks of taking *Liqiang 4 Dietary Supplement Capsules* because they contain glyburide, an oral hypoglycemic agent. The product is manufactured by Liqiang Research Institute, China, and marketed throughout the US in herbal stores and through mail order by Bugle International of Northridge, CA. People who have low blood sugar or those with diabetes can receive dangerously high amounts of glyburide by consuming *Liqiang 4*. Consumers should immediately stop using these products and seek medical attention, especially if they are diabetic or if they have symptoms of fatigue, excessive hunger, profuse sweating, or numbness of the extremities. Read the complete MedWatch 2005 Safety summary, including a link to the FDA Talk Paper, at:
<http://www.fda.gov/medwatch/SAFETY/2005/safety05.htm#liqiang>

FROM THE MEDICAL LITERATURE ...



Finally, coffee may be good for you! ... A systematic review of coffee consumption and the risk of type 2 diabetes concludes that habitual coffee drinkers have a substantially lower risk of type 2 diabetes. The mechanism is not well understood, but hey, good news is good news!
van Dam RM, Hu FB. Coffee consumption and risk of type 2 diabetes. *JAMA* 2005 Jul 6;294(1):97-104.



but, smoking is bad for you ... in case you forgot ... The new “Annual Smoking-Attributable Mortality” report is published and hasn’t improved much. Smoking harms nearly every organ of the body, causing many diseases and reducing quality of life and life expectancy. This report assesses the health consequences and productivity losses attributable to smoking in the United States during 1997-2001. Cigarette smoking and exposure to tobacco smoke results in approximately \$92 billion in productivity losses annually. For more details see the web site.
CDC. Annual Smoking-Attributable Mortality, Years of Potential Life Lost, and Productivity Losses-United States, 1997-2001. *Morbidity and Mortality Weekly Report (MMWR)* 2005 Jul 1;54(25):625-28.
<http://www.cdc.gov/mmwr/preview/mmwrhtml/mm5425a1.htm>

Reviews of Note ...

- Abramowicz M, ed. Drugs for acne, rosacea and psoriasis. *Treatment Guidelines from Med Lett.* 2005 Jul;3(35):49-56.
- Gulseth MP. Ximelagatran: An orally active direct thrombin inhibitor. *Am J Health-Syst Pharm* 2005 Jul 15;62:1451-67.

FROM THE LAY LITERATURE about medicine ...



Exposé ... A series of articles in the *Seattle Times* takes aim at the pharmaceutical industry and it’s tremendous influence on the American public both up front and behind the scenes, in regards to disease, definition of disease and drug therapy. Nine articles over a span of five days detail “undue influence” on such diseases as hypertension, osteoporosis, deep vein thrombosis, female sexual dysfunction, obesity, and new drugs. It may raise some points you haven’t considered.

Submitted by Dr. Laura Smoot

Kelleher S, Wilson D. Suddenly sick: A special report. *Seattle Times.* 2005 Jun 26 to 30.

<http://seattletimes.nwsourc.com/news/health/suddenlysick/>



Bird Flu stockpiles ... Many governments of the world are stockpiling oseltamivir phosphate (Tamiflu[®] by Roche), an antiviral shown to be effective against the “bird flu” in accordance with World Health Organization (WHO) guidelines, in case of an influenza pandemic. The WHO recommends governments set aside enough drug to cover 20% to 40% of their population. So far the U.S. can cover about 2%. The drug is difficult to manufacture and to top it off, the inventor (Gilead Sciences) is attempting to discontinue their licensing agreement with the manufacturer, Roche.

Associated Press. Government short on bird flu drug. *CNN.com* 2005 Jul 1.

<http://www.cnn.com/2005/HEALTH/conditions/06/30/bird.flu.ap/index.html>



It's official, meth is #1 ... According to an article in *USA Today*, a recent survey of 500 counties in 45 states revealed that law enforcement agencies feel that methamphetamine “meth” is the number one drug problem in their area. The only exception was the northeast where heroin is still considered the main problem. It is as yet unknown how restricting access to pseudoephedrine may curb the problem.

Leinwand D. Counties say meth is top drug threat. *USA Today* 2005 Jul 5.

http://www.usatoday.com/news/nation/2005-07-04-meth-threat_x.htm



Rx abuse way up! ... A new survey by the National Center on Addiction and Substance Abuse at Columbia University (CASA) documents that controlled prescription drug abuse is increasing and now accounts for more cases (15.1 million Americans) than cocaine, hallucinogens, inhalants and heroin, combined. Much of the blame is placed on patients acquiring prescriptions by nefarious means, parents being unwitting suppliers by keeping these drugs in their easy-access medicine cabinet, and the ease of obtaining controlled substances over the Internet. In addition, approximately 1000 physicians and 1000 pharmacists were surveyed and, among other things, 40% to 50% of both groups say they received little or no training in recognizing prescription drug abuse or diversion. The press release/summary and the full report (226 pages) are available at the web site below.

Leshner AI (Chair). Under the counter: The diversion and abuse of controlled prescription drugs in the U.S.

National Center on Addiction and Substance Abuse at Columbia University (CASA). 2005 July, 226 pgs.

<http://www.casacolumbia.org/absolutenm/templates/article.asp?articleid=287&zoneid=32>



On Strike! ... A seamier side of pharmacy. Pharmacists at Chicago-area Walgreen's stores went on strike Wednesday evening at 10:00pm. Rival chains are already using ads to lure away the Walgreen's customers. The primary issues are working conditions and staffing policies that the pharmacist's union contends compromise patient safety. The action only affects the Chicago area and most people associated with the situation expect a rapid resolution.

Yerak B, Wischnowsky D. Walgreen's rival pounces: Special strike ads planned by Osco. *Chicago Tribune.com* 2005 Jul 7.

<http://www.chicagotribune.com/business/chi-0507070149jul07,1,1570268.story?coll=chi-news-hed>

NEW RESOURCES in the DILRC ...

- Manasse HR Jr, Thompson KK. *Medication Safety: A Guide for Health Care Facilities*. Bethesda, MD: American Society of Health-System Pharmacists, 2005.
- Gilbert DN, Moellering RC Jr, Eliopoulos GM, Sande MA. *The Sanford Guide to Antimicrobial Therapy 2005*. 35th ed. Hyde Park, VT: Antimicrobial Therapy, Inc. 2005.

The last “dose” ...

Some drugs have been appropriately called “wonder drugs” inasmuch as one wonders what they will do next.

--Samuel E. Stumpf [1918-]
Annals of Internal Medicine 1966;64:460.



Happy post-Independence Day!

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