

AU InforMed

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Key Inforbits

- New vaccine and a new combination product
- New stroke guidelines
- A drug for gambling addiction?
- Generic drug reviews backlogged at FDA
- Too many sleeping pills?
- Residency and career information

NEW DRUGS, and other related stuff ...

New Vaccine ... The FDA announced, on February 3, 2006 the approval of **RotaTeq™** (by Merck & Co., Inc.), a live, oral, vaccine to prevent rotavirus gastroenteritis in infants. The rotavirus may cause diarrhea, vomiting, fever, and dehydration. Infection with rotavirus is a leading cause of severe diarrhea in infants and young children in the U.S. and worldwide. In the U.S. rotavirus infection results in approximately 55,000 hospitalizations annually of infants and young children, but death is rare. In 1998, FDA approved a different live vaccine against rotavirus that was later withdrawn from the market because of its association with an increased risk of intussusception, a rare, life-threatening type of blockage or twisting of the intestine. The manufacturer has committed to conducting a large post-licensure study, as has the CDC.

RotaTeq™ is a liquid given by mouth in three doses, between the ages of 6 and 32 weeks.

FDA. FDA approves new vaccine to prevent rotavirus gastroenteritis in infants. *FDA News* 2006 Feb 3; P06-16.

[Additional information regarding the approval of RotaTeq](#)

<http://www.fda.gov/bbs/topics/news/2006/NEW01307.html>

New Combo ... In case you missed it, a new fixed-dose combination for type 2 diabetes was approved by the FDA on November 23, 2005. Rosiglitazone maleate and glimepiride (**Avandaryl™** by GlaxoSmithKline). As an adjunct to diet and exercise, Avandaryl™ is indicated to improve blood sugar control in patients with type 2 diabetes who are already treated with a combination of rosiglitazone and sulfonylurea or who are not adequately controlled on a sulfonylurea alone or for those patients who have initially responded to rosiglitazone alone and require additional blood sugar control. For more information and prescribing information:

http://www.avandia.com/about_avandaryl/avandaryl.html?a=238

MedWatch ... Safety-related drug labeling changes for November 2005 have been posted on the MedWatch website. The November 2005 posting includes 48 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/nov05_quickview.htm

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

The Detailed view -- <http://www.fda.gov/medwatch/SAFETY/2005/nov05.htm>

-- The full labeling may be accessed by clicking on the drug name in the detailed view.

FROM THE MEDICAL LITERATURE ...

Stroke Guidelines ... The American Heart Association/American Stroke Association along with the Council on Cardiovascular Radiology and Intervention: The American Academy of Neurology, have developed new evidence-based guidelines for prevention of second stroke in patients who have had an ischemic stroke or transient ischemic attack. The guidelines address a variety of modifiable risk factors and circumstances, therapeutic interventions including medical or surgical treatments, and recommendations for special populations.

Sacco RL, Adams R, Albers G, Benavente O, Furie K, Goldstein LB, et al. AHA/ASA Guidelines: Guidelines for prevention of stroke in patients with ischemic stroke or transient ischemic attack. *Stroke*. 2006;37:577-617.(abst.)
<http://stroke.ahajournals.org/cgi/content/abstract/37/2/577> (abstract)

Hospital pharmacy survey ... In the second installment of ASHP's national survey of the six steps of the medication use process, dispensing and administration are covered. A 43.5% response was received from mailed surveys to 1173 general hospitals randomly selected. There is a lot of data to peruse, so get to it! However, the conclusions state that most hospitals have safe systems and -pause for effect- technology is affecting the process!

Pedersen CA, Schneider PJ, Scheckelhoff DJ. ASHP national survey of pharmacy practice in hospital settings: Dispensing and administration – 2005. *Am J Health-Syst Pharm*. 2006 Feb 15;63:327-45.



AHRQ Comparative report on GERD management ... The Agency for Healthcare Research and Quality (AHRQ) has issued a very large report (>200 pages) on their evaluation of managements for gastroesophageal reflux disease (GERD). They compared several management strategies including surgery, endoscopic procedures, and medical treatments. Perhaps the most interesting conclusion was that proton pump inhibitors (PPIs) were judged superior to H2 receptor antagonists, based on three meta-analyses. For the whole enchilada, go to:
Effective Health Care: Comparative effectiveness of management strategies for gastroesophageal reflux disease. AHRQ Pub. No. 06-EHC003-1, 2005 Dec.

<http://effectivehealthcare.ahrq.gov/aboutUs/index.cfm>

Reviews of Note ...

- Hankey GJ, Norman PE, Eikelboom JW. Medical treatment of peripheral arterial disease. *JAMA*. 2006 Feb 1;295(5):547-553.
- Serebruany VL. Selective serotonin reuptake inhibitors and increased bleeding risk: Are we missing something? *Am J Med*. 2006 Feb;119(2):113-116.
- Casey C, Vellozzi C, Mootrey GT, Chapman LE, McCauley M, Roper MH, et al. Surveillance guidelines for smallpox vaccine (vaccinia) adverse reactions. *MMWR*. 2006 Feb 3;55(RR-1):1-16.
- Næsdal J, Brown K. NSAID-Associated adverse effects and acid control aids to prevent them: A review of current treatment options. *Drug Safety* 2006;29(2):119-132.

FROM THE LAY LITERATURE about medicine ...



And that's a winner! ... We generally think of treating drug addictions with various agonists or antagonists; now that may be possible for gambling addiction. Based on an article from the *American Journal of Psychiatry*, researchers are testing the effectiveness of a drug, nalmefene (Revex®, an opioid antagonist approved since 1995), to treat compulsive gambling, of which there are an estimated 6 million such patients in the U.S. The pleasure aspect of gambling

is associated with the brain opiate circuits and the drug interferes with these pathways. Getting the “patient” to admit to the problem is often one of the biggest challenges.

Hotz RL. Drug shows promise in curbing compulsive gambling, study says. *Los Angeles Times* 2006 Feb 1.
<http://www.latimes.com/news/science/la-sci-gamble1feb01,0,2645620.story?coll=la-home-headlines>

 **Milk, eggs, bread, physical exam** ... We've covered this topic before, but here is another article covering retail-based health clinics who unabashedly tout their convenience. More clinics are popping up, mostly in grocery stores from mid-size to mega, across the country. Big money investors are backing the concept and store chains as large as Wal-Mart are testing them out. These clinics are typically staffed by nurses or physician assistants and have a limit as to the range of illnesses that they may address. However, compared to the expense of an emergency room visit, particularly for the numbers of uninsured, this could be a welcome addition.

Associated Press. Grocery list: Milk, detergent, strep test. *CNN.com* 2006 Feb 3.

<http://www.cnn.com/2006/HEALTH/02/03/clinics.instores.ap/index.html>



Generics backlogged at FDA ... After so many exhortations regarding the use of generic drugs to cut medication expenses, particularly for Medicaid and Medicare, now comes word that the FDA has over 800 applications pending to bring generics to the market. This number continues to grow, with no end in sight. In addition, it now takes over 20 months to review an application vs. the 6 months required by law. Politics (*big surprise*) seem to play a large role, as the FDA is requesting no additional money to apply to the problem. Another ostrich approach? Kaufman M. Generic drugs hit backlog at FDA: No plans to expand review capabilities. *Washington Post.com* 2006 Feb 4; p. A01.

<http://www.washingtonpost.com/wp-dyn/content/article/2006/02/03/AR2006020302598.html?referrer=email>

Influence comes in different forms ... A story about the supposed “independence” of advocate groups, specifically named were the American Diabetes Association and the National Osteoporosis Foundation. Although the article seems a bit slanted against the pharmaceutical industry, many questions are raised as to their monetary influence. Large pharmaceutical companies often donate very large sums (eg, hundreds of thousands of dollars) and while they are listed as corporate sponsors, the amounts are not. The content of the sites were sometimes judged to read more like an advertisement rather than independently informative, and significant adverse information was often difficult, if not impossible, to find.

Ready T. Divided loyalties? Nonprofit health advocacy groups like to portray themselves as patients' allies. Can they serve corporate benefactors at the same time? *Washington Post.com* 2006 Feb 7; p. HE01.

<http://www.washingtonpost.com/wp-dyn/content/article/2006/02/06/AR2006020601180.html?referrer=email>



Sleep well ... a little exposé on the “sleeping pill” industry, particularly over the last few years. According to the article, money spent on advertising for sleeping aids has, in some cases, increased four-fold over 2004, nearly topping \$300 million; how often have you seen that little blue luna moth fluttering about? Prescriptions have increased 60% since 2000 to 42 million in 2005. Two of the more popular ones, zolpidem (Ambien[®]) and eszopiclone (Lunesta[®]) are known as the “Z” drugs. There is also concern about adverse reactions. Short term amnesia was mentioned, although this is well-known with some of the earlier drugs.

Saul S. Record sales of sleeping pills are causing worries. *New York Times.com* 2006 Feb 7.

<http://www.nytimes.com/2006/02/07/business/07sleep.html?r=1&pagewanted=all&oref=slogin>

Update ... Students

Drug Information Residency ... The Dept. of Pharmacy Practice at Purdue University, in conjunction with Clarian Health Partners and Eli Lilly and Company in Indianapolis, IN is offering a 1-year, ASHP-accredited residency in drug information. Information about our program can be found at: http://www.lilly.com/careers/programs/drug_information/index.html Consideration continues for interested and qualified candidates for the 2006-7 academic year. You may call JiHyun Lee, Pharm.D., Sr. Medical Information Associate, Purdue/Lilly Residency Co-coordinator, at 317-433-0235 to further discuss the details of the program.

Going back ... Its not uncommon for student's considering a residency to think – I'll work a couple of years, pay off some debt, then go back and do a residency. Here is a perspective on that very topic, from someone who has been there. According to this author, approximately 7% of those seeking residencies in 2005 had graduated prior to 2005. The primary message of this article is, once you are out in practice and are dissatisfied, it's not too late to go back. However, there are special challenges you may not have considered ...

Sommer KS. Backtracking: Pursuing residency training after working. *Am J Health-Syst Pharm.* 2006 Feb 15;63:313-14.

Careers in pharmacy ... In the latest issue of *Student Pharmacist* (copy in the DIC) there is a web site given for "2005 Full Preparation: The Pfizer Guide to Careers in Pharmacy." It is good to scan through to gather a better picture of the scope of potential pharmacy practice.

www.pfizercareerguides.com

AUBURN HSOP FACULTY in the literature ...

- Clark DB, Andrus MR, Byrd DC. Drug interactions between linezolid and selective serotonin reuptake inhibitors: Case report involving sertraline and review of the literature. *Pharmacotherapy.* 2006 Feb;26(2):269-76.



The last “dose” ...



Did you know ???

"vitamins" began their journey of discovery in the early 1900's. Before they were chemically characterized, they were assigned letters of the alphabet, eg, A, B, C, etc, except for vitamin K. In this case, the "K" stands for "Koagulation" so named by its discoverer, Henrik Dam, a Danish investigator.

- Haubrich WS. *Medical Meanings: A Glossary of Word Origins.* 2nd ed. Philadelphia: American College of Physicians, 2004, p. 261.

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

Auburn University, Harrison School of Pharmacy, Drug Information Center

• Phone 334-844-4400 • Fax 334-844-8366 • <http://www.pharmacy.auburn.edu/dilrc/dilrc.htm>

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