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Key Inforbits

- Pemoline off the market 
- Vending machines again
- Another Asheville project coming
- Warning, about labels, to pharmacists
- Bird flu watch
- National Epilepsy Awareness Month

NEW DRUGS, and other related stuff ...

MedWatch ... FDA has concluded that the overall risk of liver toxicity from Cylert[®] and generic pemoline products outweighs the benefits of this drug. In May 2005, Abbott chose to stop sales and marketing of Cylert[®] in the U.S. All generic companies have also agreed to stop sales and marketing of this product. Pemoline, a CNS stimulant indicated for the treatment of Attention Deficit Hyperactivity Disorder (ADHD), is considered second line therapy for ADHD because of its association with life-threatening hepatic failure. Healthcare professionals should transition their patients to an alternative therapy. Cylert[®] will remain available through pharmacies and wholesalers until supplies are exhausted. No additional product will be available. Read the complete MedWatch 2005 Safety Summary, including links to the Cylert[®]/generic pemoline drug information page, at:

<http://www.fda.gov/medwatch/safety/2005/safety05.htm#Cylert>

MedWatch ... Safety-related drug labeling changes for August 2005 have been posted on the MedWatch website. The posting includes 60 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/aug05_quickview.htm -- provides drug names and a listing of the sections changed.

The Detailed view -- <http://www.fda.gov/medwatch/SAFETY/2005/aug05.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 ... Biogen Idec and FDA notified healthcare professionals of revision to Boxed Warnings, Warnings, and Adverse Reactions sections of the Prescribing Information to describe severe cutaneous or mucocutaneous reactions, some with fatal outcome, that have been reported in association with the Zevalin[®] (ibritumomab tiuxetan) therapeutic regimen in the post-marketing experience. Patients experiencing a severe cutaneous or mucocutaneous reaction should not receive any further components of the Zevalin[®] therapeutic regimen and should seek prompt medical evaluation. 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/2005/safety05.htm#Zevalin>

FROM THE MEDICAL LITERATURE ...



Replaced by a vending machine? ... Drug vending machines have been covered in previous issues of *AU InforMed* [2005 Feb 7;3(4):13. 2005 Jun 22;3(16):61. 2005 Aug 18;3(21):81]. Now there is a cover story in *Drug Topics* that gives a decidedly pharmacist's perspective and at least raises the issues that most nonpharmacist-oriented publications seem to gloss over. The hot spot of the moment is in California, where the State Board of Pharmacy has granted waivers for the use of the machines.

Sipkoff M. Will ATMs replace you? *Drug Topics* 2005 Oct 10;149(19):42-49.

<http://www.drugtopics.com/drugtopics/article/articleDetail.jsp?id=184114>

Preliminary Births Data for 2004 ... A new report from CDC's National Center for Health Statistics summarizes the 2004 birth data for the United States. Some of the key findings show:

- Number of births up; fertility rate up slightly in 2004.
- Childbearing by unmarried women reached a record high of almost 1.5 million births in 2004, up 4 percent from 2003.
- Childbearing by women in their early 20's showed a decline.
- Births to older women continue to increase.

For the full report on "Preliminary Births for 2004" go to the CDC website at:

www.cdc.gov/nchs.

CDC National Center for Health Statistics, October 28, 2005.

<http://www.cdc.gov/od/oc/media/pressrel/fs051028.htm>

Reviews of Note ...

- Mann JJ. The medical management of depression. *N Engl J Med* 2005 Oct 27;353(17):1819-34.

FROM THE LAY LITERATURE about medicine ...



Another Asheville ... The American Pharmacist's Association and GlaxoSmithKline are teaming up to conduct a nationwide project to demonstrate the value of pharmacist intervention in diabetes patients. They are seeking participation from 10 large employers in the U.S. Co-pays would be waived and the pharmacist would be paid \$350 to \$450 per patient in the first year for their counseling and monitoring. The concept is simple according to a Glaxo representative, "Healthier workers cost less."

Hensley S. Cutting costs for diabetes patients. *Wall Street Journal.com* 2005 Oct 25; p. D4.



Generic drugs save money ... not exactly ground-breaking news, but that is a conclusion of a recent report from Express Scripts. According to the report, consumers, employers and health plans could have saved over \$20 billion by using generics "appropriately." Without action, these losses are likely to increase. The other side of the coin however, is that the Pharmaceutical Research and Manufacturers of America (PhRMA) claims that much of the "savings" would have to come by actually switching to a different drug in the same class that is available as a generic, which they of course, oppose.

Associated Press. Generic drugs could have saved us \$20 billion. *USA Today* 2005 Oct 25.

http://www.usatoday.com/news/health/2005-10-25-generic-drugs_x.htm



Warning (label) to pharmacists ... Warning labels are inconsistent! In a lengthy article, an unpublished study by three physicians is described where the warning labels placed on prescription bottles (the little colored stickers) were tested against several hundred English-speaking patients with a variety of reading levels. The variety and number of misinterpretations were amazing. One of the more common labels “For External Use Only” was misinterpreted by 25% to 90% of patients! Several points were made in the article including: These labels are not officially sanctioned by any official group (FDA, etc); there are a wide variety available; pictograms (pictures) are often confusing rather than helpful; sometimes the color of the label is the determinant of patient action; application of labels both intra- and interpharmacy is very inconsistent. This one is a must-read.

Franklin D. And now, a warning about labels. *New York Times.com* 2005 Oct 25.

<http://www.nytimes.com/2005/10/25/health/policy/25cons.html> (free but registration may be required)

Antidepressant use down in kids ... and probably not because of a new happy pill. Two reports show antidepressant use in children down 20% to 25% over the last 2 to 3 years. This is thought largely due to the black box warning added to package labeling and even more likely due to the publicity from several reports and studies. While probably good news, there are some concerns that some patients who should be so treated are not getting the medication.

Elias M. After suicide link, kids taking fewer antidepressants. *USA Today.com* 2005 Oct 24.

http://www.usatoday.com/news/health/2005-10-24-kids-antidepressants_x.htm

Flu Watch ... Tamiflu[®], the new must have ... Over the last several weeks, there have been many reports of stockpiling of Tamiflu[®] (oseltamivir by Roche), the antiviral drug thought to be effective against avian influenza (bird flu). While this has been recommended by the World Health Organization for nations to prepare for a possible pandemic, the message has been so well publicized that many are worried about a shortage. Many patients have been requesting the drug “just in case” and many physicians, as well as corporations, are building their own stockpile; demand for the drug is way up. Now there is word that the manufacturer, Roche, a Swiss company, is suspending shipments to the U.S., primarily to pharmacies and wholesalers. This is due to Roche’s inability to manufacture enough drug for the unprecedented demand and their reluctance to allow other manufacturers to produce the drug. The company’s reason for the suspended shipments is to ensure enough supply for the “regular” flu season coming upon us. A lot of the drug is likely to go to waste and one can expect a price increase. The black market for the drugs is probably in motion. Do you have yours?

Brown D. Run on drug for avian flu has physicians worried. *Washington Post.com* 2005 Oct 22; p. A01.

<http://www.washingtonpost.com/wp-dyn/content/article/2005/10/21/AR2005102102141.html?referrer=email>

Pollack A. Hoarding prompts halt in flu drug shipping. *New York Times.com* 2005 Oct 27.

<http://www.nytimes.com/2005/10/27/health/27flu.html>

Update ...

Summer Internship opportunity ... The Academy of Managed Care Pharmacy (AMCP) and Pfizer are offering 12 managed care internships for the summer of 2006. The goal of the program is to enhance students’ awareness of career options in managed care pharmacy practice settings or within the Department of Veterans Affairs (VA) by direct hands-on involvement. Ten

managed care organizations and two VA medical centers will each host an intern for this program. Eligibility is limited to students enrolled full-time in an ACPE accredited school of pharmacy during the 2005-2006 school year, with anticipated graduation in 2007 or 2008 with a PharmD degree. More information is available on the AMCP website at:

<http://www.amcp.org/amcp.ark?c=stu&sc=x3D8AAC6BC473A5C15EE593FA724C1A0C>.

An on-line version of the application is available at:

http://www.amcp.org/amcp.ark?c=stu&sc=internship_app.

Also, with additional questions or for additional application forms, please contact Mark Brueckl, RPh, MBA, AMCP's Pharmacy Affairs Manager at 1-(800) 827-2627, ext. 609.

AUBURN HSOP FACULTY in the literature ...

- DeRuiter J, Holston PL. New drug review. *US Pharmacist* 2005 Oct;30(10):75-84.

The last “dose” ...

National Epilepsy Awareness Month ---- November 2005

Epilepsy affects approximately 2.7 million persons in the United States and is characterized by unprovoked seizures. Delayed recognition of seizures and inadequate treatment greatly increase the risk for subsequent seizures, brain damage, disability, decreased health-related quality of life, and death from injuries incurred during a seizure. Epilepsy most often affects young children and older adults, although persons can have epilepsy at any age. The effects of epilepsy on children can be especially burdensome as they transition into adulthood (e.g., driving and working). The Epilepsy Foundation seeks to improve social acceptance and understanding of epilepsy and to increase support for persons living with it. Information about epilepsy and the campaign is available from the Epilepsy Foundation, telephone 800-332-1000, or at

<http://www.epilepsyfoundation.org> and in Spanish at telephone 866-748-8008 or at <http://www.fundacionparalaepilepsia.org>.

MMWR 2005 Oct 28;54(42):1083-84.



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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