

# AU InforMed

Volume 3 Number 33 (Issue 96)

Wednesday, December 14, 2005



## Key Inforbits

- A couple of MedWatches
- Two serious drug alerts!
- Pharmacists are #2 (try harder?)
- Government drug fight over turf!
- Say it isn't so, ghostwriting for journals?!
- The way drug ads should be ...

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

**MedWatch** ... Safety-related drug labeling changes for September 2005 have been posted on the MedWatch website. The September 2005 posting includes 37 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/sep05\\_quickview.htm](http://www.fda.gov/medwatch/SAFETY/2005/sep05_quickview.htm)

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

The Detailed view -- <http://www.fda.gov/medwatch/SAFETY/2005/sep05.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** ... FDA and Bedford Laboratories, a division of Ben Venue Laboratories, Inc., Bedford, Ohio, announced that it is voluntarily recalling one lot of **Methotrexate for Injection (preservative free)**, USP 1 gram per vial (NDC 55390-143-01), Lot # 859142, exp 09/07, because the active drug substance contained low levels of ethylene glycol. Preservative-free Methotrexate is the only formulation that is acceptable for intrathecal administration. Do not distribute these vials and contact Bedford Laboratories for return instructions. Consumers that have received this product and have questions should contact their physicians.

Read complete MedWatch 2005 Safety summary, including a link to the firm press release, at:


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


## FROM THE MEDICAL LITERATURE ...




**Life expectancy** ... A couple of huge reports are published concerning life expectancy and related data. The good news is that life expectancy continues to rise, from 75.4 years in 1990 to 77.6 years in 2003. This is largely attributable to strides made in health care (drugs in particular) and actually some positive changes in lifestyle, such as smoking cessation. There are also the continuing warnings of the aging baby boomers. On the other end, infant mortality continues to decrease.

<http://www.cdc.gov/nchs/fastats/lifexpec.htm>

 **Biaxin (clarithromycin) FDA Alert** ...A placebo controlled study of patients in Denmark with heart disease (the CLARICOR Study), reporting increased mortality in patients treated with clarithromycin for 14 days. (<http://bmj.bmjournals.com/cgi/rapidpdf/bmj.38666.653600.55v1>). The observed difference in mortality became apparent after patients had been followed for one year or longer; a mechanism by which two-weeks of clarithromycin could cause increased mortality measured after one year or longer is not clear. Previous trials of antibacterial drugs to prevent heart disease and other trials of clarithromycin have not shown a statistically significant effect on mortality. The FDA is not recommending any specific changes to the use of clarithromycin at this time. For more information, go to the web site below.  
<http://www.fda.gov/cder/drug/infopage/clarithromycin/default.htm>

 **Public Health Advisory ... Paroxetine** ... December 8, 2005. The FDA has determined that exposure to paroxetine (Paxil<sup>®</sup>, Paxil CR<sup>®</sup>, Pexeva<sup>®</sup>) in the first trimester of pregnancy may increase the risk for congenital malformations, particularly cardiac malformations. At the FDA's request, the manufacturer has changed paroxetine's pregnancy category from C to D and added new data and recommendations to the prescribing information. This is based on preliminary analyses of two recent unpublished epidemiology studies; one using Swedish national registry data, and the other from a United States insurance claims database. It is of note that the data in these studies was limited to first trimester exposures only. In the interim of waiting for more data, FDA recommends the following: **Physicians who are caring for women receiving paroxetine** should alert them to the potential risk to the fetus if they plan to become pregnant or are currently in their first trimester of pregnancy. Discontinuing paroxetine therapy should be considered. In individual cases, the benefits of continuing paroxetine may outweigh the potential risk to the fetus. Paroxetine should generally not be initiated in women who are in their first trimester of pregnancy or in women who plan to become pregnant in the near future. **Women who are pregnant, or planning a pregnancy**, and currently taking paroxetine should consult with their physician about whether to continue taking it. Women should not stop the drug without discussing the best way to do that with their physician.  
<http://www.fda.gov/cder/drug/advisory/paroxetine200512.htm>

 **No. 2 is still pretty good** ... According to the latest Gallup poll on honesty and ethics of professions, pharmacists rank only behind nurses as the most trusted health professional. As most of us know, pharmacists have been at the top or very near the top since 1988. Do we need to try harder?  
[http://www.pharmacist.com/articles/h\\_ts\\_0988.cfm](http://www.pharmacist.com/articles/h_ts_0988.cfm)

### Reviews of Note ...

- Brown J. Zygomycosis: An emerging fungal infection. *Am J Health-Syst Pharm* 2005 Dec 15;62:2593-6.
- Rosenfield RL. Hirsutism. *N Engl J Med* 2005 Dec 15;353:2578-88.
- Tejpratap T, Murphy TV, Moran J. Recommended antimicrobial agents for the treatment and postexposure prophylaxis of Pertussis. *MMWR* 2005 Dec 9;54(RR14):1-16.  
<http://www.cdc.gov/mmwr/preview/mmwrhtml/rr5414a1.htm>

## FROM THE LAY LITERATURE about medicine ...



**Dry eyes crying ...** Informative article in *USA Today* about the prevalence of “dry eye” in the U.S. population (very common; 8% of women and 4% of men >50 years old, or nearly 5 million people). It covers a fair amount of information such as prevalence, mechanisms, usual and unusual causes, associated problems, lifestyle modifications and therapy. **Pharmacists**, this may be good reading, as you will likely be among the first to see these patients.

Painter K. Eye’s lament: How dry I am. *USA Today* 2005 Nov 27.

[http://www.usatoday.com/news/health/2005-11-27-dry-eye\\_x.htm](http://www.usatoday.com/news/health/2005-11-27-dry-eye_x.htm)



**Kava ...** A dangerous sign post is up: Kava is trendy! Kava bars are sprouting up, serving drinks that taste like mud. Yet, it is touted as a natural tranquilizer/stress reducer. It can be powerful enough to impair motor abilities and DUI citations have been given to drivers under the influence. Links to liver failure have been published for several years and Germany (which regulates herbs more like drugs) and several other European countries have banned kava due to safety concerns. In the U.S. of course, it’s a food supplement.

Leinwand D. FDA concerned about trendy brew. *USA Today* 2005 Dec 8.

[http://www.usatoday.com/news/health/2005-12-08-kava-concerns\\_x.htm](http://www.usatoday.com/news/health/2005-12-08-kava-concerns_x.htm)



**Drug fight!! ...** Did you know that the federal government is the only [legal] producer and supplier of marijuana in the U.S.? Through one facility at the University of Mississippi where the plants are grown, the National Institute on Drug Abuse (NIDA) controls the quality of output and its distribution for medical research. A facility at the University of Massachusetts is challenging that monopoly in court. Needless to say, the DEA is not happy. Interestingly, even if UMass wins the DEA is under no obligation to grant a license. Can you say “legislation?”

Kaufman M. Federal marijuana monopoly challenged: Researchers want to grow more plants and find more medicinal uses. *Washington Post.com* 2005 Dec 12; p. A02.

<http://www.washingtonpost.com/wp-dyn/content/article/2005/12/11/AR2005121100825.html?referrer=email>

**Hoodia Gordonii ...** Another herbal product that is “weighing in” is Hoodia. It is an African plant that earned a reputation as an appetite suppressant based on use by a South African tribe that supposedly used the plant to stave off hunger during crossings of the Kalahari Desert (some trivia for those Christmas parties). Companies as big as Pfizer were studying it, but it was dropped in 2003 due to manufacturing problems. Several other companies are pursuing it. However, as with many such botanicals, published trials are lacking. So far, no particular problems have been reported, but then again, neither has efficacy.

Johannes L. Hoodia’s hunger claims. *Wall Street Journal* 2005 Dec 13; p. D5.



**Ghostwriting, really!?!? ...** Another page one exposé from the *Wall Street Journal*. Described in the article as an “open secret in medicine” many pharmaceutical companies hire medical writers to put together articles to submit for publication to medical journals. The journals include many very prestigious publications such as *JAMA*. Several issues with the practice are involved such as often there is no disclosure of the actual author; when the sponsoring company hires its own writers, is there a biased slant (eg, “spin”) given to the piece. The listed authors, commonly respected physicians, claim to have reviewed and signed-off on

everything, even rewriting much of it. Yet, irregularities continue to surface; a couple of early Vioxx® articles are cited as examples. While even the most critical readers can't spot fraud (which is not the main issue here), a jaundiced eye can spot inappropriate conclusions or "spin" or glossing over not-so-positive results.

Mathews AW. At medical journals, writers paid by industry play big role: Articles appear under name of academic researchers, but they often get help. J&J receives a positive 'spin.' *Wall Street Journal* 2005 Dec 13; p. A1.

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

- Reile DM, Nickols JL. *Survival Strategies for Your New Career*. Bethesda, MD: American Society of Health-System Pharmacists, 2002.
- Rowe C, Sheskey PJ, Owen SC. *Handbook of Pharmaceutical Excipients*. 5<sup>th</sup> ed. London: The Pharmaceutical Press, 2006.
- Hendler SS, Rorvik D, eds. *PDR for Nutritional Supplements*. Montvale, NJ: Thomson PDR, 2001.
- USPC. *USP/NF: The Official Compendia of Standards 2006*. Rockville, MD: United States Pharmacopeial Convention, 2006.
- AMCP. *2005-2006 Membership Directory: Who's Who in Managed Care Pharmacy*. Alexandria, VA: Academy of Managed Card Pharmacy, 2005.
- NPC. *Pharmaceutical Benefits Under State Medical Assistance Programs 2004*. Reston, VA: National Pharmaceutical Council, 2005.
- Tice B, Chair, et al. *Medication Therapy Management Services in Community Pharmacy: Planning for Successful Implementation. A Practical Guide for Community Pharmacists*. Washington, DC: American Pharmacists Association and National Association of Chain Drug Stores Foundation, 2005.



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

### **Panexa**

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

A bit of a spoof on pharmaceutical ads. Go to the web site for a few chuckles. Just what you need before that big holiday push!



*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>

*Bernie R. Olin, Pharm.D., Director*