

# AU InforMed

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## Key Inforbits

- Lots of MedWatches
- New AHA CPR guidelines
- Tylenol<sup>®</sup> toxicity very common!
- *C. difficile* is becoming an epidemic
- Drug reps as cheerleaders? No, the other way ..
- Drunk and Drugged Driving Prevention Month

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

**MedWatch** ...Boehringer Ingelheim and the FDA notified healthcare professionals of revisions to PRECAUTIONS and ADVERSE REACTIONS sections of the prescribing information for **Flomax<sup>®</sup>**, indicated for benign prostatic hyperplasia (BPH). A surgical condition, Intraoperative Floppy Iris Syndrome (IFIS) has been observed during phacoemulsification cataract surgery in some patients treated with alpha-1 blockers including Flomax<sup>®</sup>. Most of these reports were in patients taking the alpha-1 blocker when IFIS occurred, but in some cases alpha-1 blocker had been stopped prior to surgery. Male patients being considered for cataract surgery should be specifically questioned to ascertain whether they have taken Flomax<sup>®</sup> or other alpha-1 blockers. If so, the patient's ophthalmologist should be prepared for possible modifications to their surgical technique that may be warranted should IFIS be observed during the procedure. Read the complete MedWatch 2005 Safety summary, including links to the Dear Healthcare Professional letter and revised prescribing information, at:

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

**MedWatch** ... FDA announced that MBI Distributing, Inc. (MBI or Molecular Biologics), an OTC manufacturer of eye drops and other products will **cease manufacturing and distribution** until it corrects manufacturing deficiencies and other violations. MBI's product line includes eye drops sold under the brand names Oxydrops, Bright Eyes, Bright Eyes II, Clarity Vision for Life, Visitein, and Can-C, as well as several OTC pain relieving drugs. These products are sold nationwide. FDA determined that the firm lacked manufacturing controls to ensure sterility. FDA has also determined that two of the firm's eye drop brands, Visitein and Clarity Vision for Life, are unapproved drugs. In addition, three of the firm's OTC pain relieving drugs, Biogesic, Bio-Ice, and Bio-Heat, do not provide adequate warnings for their safe use. FDA recommends that consumers, health care providers, and caregivers dispose of the Oxydrops, Bright Eyes, Bright Eyes II, Clarity Vision for Life, Visitein, and Can-C brands of eye drops and the Biogesic, Bio-Ice, and Bio-Heat pain relieving drugs.

Read the complete MedWatch 2005 Safety summary, including links to the FDA Press Release, at: <http://www.fda.gov/medwatch/safety/2005/safety05.htm#MBI>

**MedWatch** ... Novo Nordisk and FDA notified healthcare professionals of revisions to the WARNINGS and ADVERSE REACTIONS sections of the prescribing information for NovoSeven, to provide updated safety information on thrombotic and thromboembolic adverse events, based on clinical studies in non-hemophilia patients and on post-marketing safety

surveillance. Read the complete MedWatch 2005 Safety summary, including links to the Dear Healthcare Professional letter and revised prescribing information, at: <http://www.fda.gov/medwatch/safety/2005/safety05.htm#NovoSeven>

**MedWatch** ... Amgen, Ortho Biotech and FDA notified healthcare professionals of revision to the prescribing information for **Aranesp**<sup>®</sup>, **Epogen**<sup>®</sup>, and **Procrit**<sup>®</sup>. The revised labeling provides updated safety information on reports of pure red cell aplasia and severe anemia, with or without other cytopenias, associated with neutralizing antibodies to erythropoietin in patients treated with these products. This has been reported predominantly in patients with CRF receiving these products by subcutaneous administration. Read the complete MedWatch 2005 Safety summary, including links to the Dear Healthcare Professional letters and revised prescribing information at: <http://www.fda.gov/medwatch/safety/2005/safety05.htm#aranesp2> and <http://www.fda.gov/medwatch/safety/2005/safety05.htm#epoetin>

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



**New CPR Guidelines just published** ... Major updates to several sections of the CPR (cardiopulmonary resuscitation) and ECC (emergency cardiovascular care) guidelines by the American Heart Association. The one that is receiving the most attention is the change of recommendations for the compression/ventilation ratio for adults from 15:2 to 30:2. There are a variety of other changes, too.

American Heart Association. *Circulation* 2005 Nov 28; vol. 112.

All of the guidelines are available free at: <http://www.circulationaha.org> 



**Tylenol<sup>®</sup> toxicity .. deadly** ... Liver toxicity is a well known problem with acetaminophen, but how common is it? A recent survey of 22 tertiary care centers in the U.S. found 662 cases of acute liver failure over six years. Of these cases of liver injury, 42% were due to acetaminophen and approximately one-half of these were unintentional; and many of these were taking multiple acetaminophen-containing products. Of all of the acetaminophen overdoses, 35% either died or underwent liver transplantation. This is serious stuff.

Larson AM, Polson J, Fontana RJ, Davern TJ, Lalani E, Hynan LS, et al. Acetaminophen-induced acute liver failure: Results of a United States multicenter, prospective study. *Hepatology* 2005 Dec;42(6):1364-72.



**Antipsychotics** ... it doesn't matter how old they are ... A retrospective cohort study of over 22,000 patients drawn from an elderly indigent pharmaceutical assistance program between 1994 and 2003, analyzed mortality rates based on receipt of an atypical or conventional antipsychotic medication. Results showed a significantly higher risk of death with conventional antipsychotics. Despite an FDA warning earlier this year for atypical antipsychotics, the conventional agents appear to be at least as dangerous in the elderly population.

Wang PS, Schneeweiss S, Avorn J, Fischer MA, Mogun H, Solomon, et al. Risk of death in elderly users of conventional vs. atypical antipsychotic medications. *N Engl J Med* 2005 Dec 1;353(22):2335-41.

**Early release** ... The *New England Journal of Medicine* has published three articles as an early release, online. These two articles and one editorial concern an apparently new strain of *Clostridium difficile* with a high morbidity and mortality. The articles are available free at the general web site, until published in the December 8 issue. [www.nejm.org](http://www.nejm.org)

A similar report is available this week from the Centers of Disease Control and Prevention. CDC. Severe *Clostridium difficile*-Associated Disease in Populations Previously at Low Risk-Four States, 2005. *MMWR* 2005 Dec 2;54(47):1201-1205.

<http://www.cdc.gov/mmwr/preview/mmwrhtml/mm5447a1.htm>

## **Reviews of Note ...**

- Patrono C, Rodriguez LAG, Landolfi R, Baigent C. Low-dose aspirin for the prevention of atherothrombosis. *N Engl J Med* 2005 Dec 1;353(22):2373-83.

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



**Oh, my aching joints ...** A new National Institutes of Health (NIH) study presented as an abstract at the American College of Rheumatology's annual scientific meeting a few weeks ago showed mixed results with the combination product of glucosamine and chondroitin sulfate. There were apparently mixed signals from the study. On one hand it was shown to be no better than placebo, up to 60% reporting pain relief. However, a subgroup analysis indicated there may be some benefit in those with moderate to severe knee pain. The authors are quick to point out that these are preliminary results and have yet to go through the rigors of peer-review.

Agnvall E. Joint dispute: Early results of arthritis trial show little benefit for glucosamine; but the industry is already spinning. *Washington Post.com* 2005 Nov 22; p. HE01.

<http://www.washingtonpost.com/wp-dyn/content/article/2005/11/21/AR2005112101144.html?referrer=email>



**Rah – Rah – Rah, Sis Boom Rx ...** Our little girls are graduating from cheerleading and selling school spirit to selling drugs. An enlightening story about the legions of cheerleaders as fertile recruitment populations for pharmaceutical company sales reps. The demand from various companies is significant enough to have spawned an employment firm just for former cheerleaders. There are a variety of subplots to this story as well (professional cheerleaders, Miss USA, restraining orders); it almost reads like a soap opera.

Saul S. Gimme an Rx! Cheerleaders pep up drug sales. *New York Times.com* 2005 Nov 28.

<http://www.nytimes.com/2005/11/28/business/28cheer.html>

## **AUBURN HSOP FACULTY and STUDENTS in the literature ...**

- Kelly, Emmy. Atopic dermatitis: The itch that rashes. *Alabama Pharmacy* 2005 Fall;38:25-6.
- Doorenbos NJ. Herbicide control of *Cannabis Sativa* L. and *Papaver Somniferum* L. *J Ala Acad Sci* 2005;76:100.
- Doorenbos NJ, Horner R. Brine shrimp as test animals. *J Ala Acad Sci* 2005;76:113.
- Doorenbos NJ. Air pollution rainbows in photographic prints. *J Ala Acad Sci* 2005;76:120.
- Doorenbos NJ. Tidbits of nutritional supplement therapies. *J Ala Acad Sci* 2005;76:132.
- Doorenbos NJ. Governor George Wallace, Harvard University, Marihuana and the maximizer. *J Ala Acad Sci* 2005;76:137.
- Doorenbos NJ, Varricchio F, Jacobs B, Ortiz G. Effect of an azasteroid on Leydig cells in vitro. *J Ala Acad Sci* 2005;76:141.
- Doorenbos NJ. Early adventures with marihuana. *J Ala Acad Sci* 2005;76:161.

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

- Committee on Infectious Diseases, American Academy of Pediatrics. *Red Book: 2003 Report of the Committee on Infectious Diseases*. 26<sup>th</sup> ed. Elk Grove Village, IL: American Academy of Pediatrics, 2003.

## **TIMELY TOP TECH TIP ...**

**Drug Interaction Skeptic ...** A short article from drug interaction experts reminds us of some simple rules when communicating information about a drug interaction, perhaps especially true if the drug interaction is caught by your pharmacy system, but provides minimal information:

- Call prescribers only about *real* drug interactions. Not all drug interaction alerts are clinically important, and prescribers may be correct in being skeptical when the drug interaction is bogus.
- It is natural for prescribers to be skeptical. Therefore, before discussing a drug interaction with prescribers, plan for the "I don't see it in my practice" line.
- Before discussing drug interactions with prescribers, try to determine how often the interaction produces an adverse effect. If adverse effects from the interaction are rare, prescribers may better understand why they have not seen them.
- **Be ready to offer management options.** They are more likely to be responsive if a viable option is available.

Horn JR, Hansten P. Dealing with the drug interaction skeptic. *Pharm Times*. 2005 Nov;71(11):20, 49.



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



**National Drunk and Drugged Driving Prevention Month** 

December is National Drunk and Drugged Driving Prevention Month (3D Month). During 2004, alcohol-related motor-vehicle crashes resulted in 16,694 deaths in the United States, accounting for 39% of all traffic fatalities; or one alcohol-related death every 31 minutes (1). Moreover, approximately 21% of all crashes that killed children aged  $\leq 14$  years in 2004 were alcohol-related (1), and nearly two thirds of children killed in alcohol-related crashes were in the same car as the drinking driver (2). To decrease alcohol-related traffic fatalities, communities must implement and enforce strategies that are known to be effective, such as sobriety checkpoints, 0.08% blood alcohol concentration laws, minimum legal drinking age laws, and "zero tolerance" laws for young drivers. Information about such interventions is available at

<http://www.thecommunityguide.org/mvoi>.

Information about National 3D Month is available at <http://www.nhtsa.dot.gov> and <http://www.stopimpaireddriving.org/holidayplanner2005/planner/index.cfm>.

<sup>1</sup>National Highway Traffic Safety Administration. Traffic safety facts 2004, alcohol. Washington, DC: US Department of Transportation, National Highway Traffic Safety Administration; 2004. Publication no. DOT-HS-809-905.

<sup>2</sup>Quinlan KP, Brewer RD, Sleet DA, Dellinger AM. Characteristics of child passenger deaths and injuries involving drinking drivers. *JAMA* 2000;283:2249--52.

From: *MMWR* 2005 Dec 2;54(47):1214.

<http://www.cdc.gov/mmwr/preview/mmwrhtml/mm5447a5.htm>

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