

# AU InforMed

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## Key Inforbits

- New drug - **paliperidone (Invega®)**
- 3 MedWatches
- 2 vaccine administration updates (Hep B, Tdap)
- Presenteeism defined
- Malware is getting better
- Ancient wisdom ...

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

**New Drug** ... The FDA approved **paliperidone (Invega®)** manufactured by ALZA Corp. for Janssen) extended-release tablets for the treatment of schizophrenia December 20, 2006. Paliperidone is the principal active metabolite of risperidone (Risperdal®), a marketed drug for treating schizophrenia. The effectiveness of paliperidone in the acute treatment of schizophrenia was established in three 6-week, placebo-controlled trials conducted in North America, Europe and Asia, with 1665 adults. In the three studies the doses ranged from 3 mg to 15 mg a day. The recommended dose range for paliperidone is 3 mg to 12 mg a day. Among the commonly reported adverse events were restlessness, extrapyramidal symptoms (movement disorders), rapid heart beat and sleepiness. Paliperidone is an atypical antipsychotic and these agents have an increased rate of death compared with placebo in elderly patients with dementia-related psychosis; although paliperidone is not approved for dementia-related psychosis.

FDA approves new drug for schizophrenia. *FDA News*. 2006 Dec 20; P06-208.

<http://www.fda.gov/bbs/topics/NEWS/2006/NEW01534.html>

<http://www.invega.com/> (Manufacturer web site with prescribing information)

**MedWatch** ... (12/15//2006) The FDA and Bayer Pharmaceuticals notified healthcare professionals of revisions to the prescribing information for Trasylol. The new labeling has a more focused indication, a new Warning that **Trasylol administration increases the risk of renal dysfunction** and may increase the need for dialysis in the perioperative period, and stronger warnings about anaphylactic reactions. In addition, due to the higher risk for anaphylactic reactions, re-administration of Trasylol to patients with a known or suspected exposure during the past 12 months is contraindicated.

Read the complete MedWatch Safety summary, including links to prescribing information for Trasylol, a Healthcare Professional Sheet and a Drug Information Page regarding this issue at: <http://www.fda.gov/medwatch/safety/2006/safety06.htm#Trasylol>

**MedWatch** ... (12/18/2006) The FDA and Genentech informed healthcare professionals of important emerging safety information about Rituxan. **Two patients died after being treated with Rituxan** for systemic lupus erythematosus (SLE). The cause of death was a **viral infection of the brain called progressive multifocal leukoencephalopathy (PML)** that is caused by reactivated JC virus which is present in about 80 percent of adults. Physicians should maintain a high index of suspicion for the development of PML in patients under treatment with Rituxan.

Read the complete MedWatch Safety summary, including links to the FDA's Public Health Advisory, Healthcare Professional Sheet and Drug Information Page at:

<http://www.fda.gov/medwatch/safety/2006/safety06.htm#Rituxan>

**MedWatch** ... (12/22/2006) The FDA issued a Public Health Advisory to notify healthcare professionals that it has received additional information about a **new disease, known as Nephrogenic Systemic Fibrosis or Nephrogenic Fibrosing Dermopathy (NSF/NFD)**, which may occur in patients with moderate to end-stage kidney disease after they have had a Magnetic Resonance Imaging (MRI) or Magnetic Resonance Angiography (MRA) scan with a **gadolinium-based contrast agent**. FDA has received reports of 90 patients with moderate to end-stage kidney disease who developed NSF/NFD after they had an MRI or MRA with a gadolinium-based contrast agent. FDA is notifying health care providers and patients that: 1] Patients with moderate to end-stage kidney disease who receive an MRI or MRA with a gadolinium-based contrast agent may get NSF/NFD which is debilitating and may cause death, 2] Patients who believe they may have NSF/NFD should contact their doctor, 3] When a patient with moderate to end-stage kidney disease needs an imaging study, select imaging methods other than MRI or MRA with a gadolinium-based contrast agent for the study whenever possible, and 4] FDA asks health care professionals and patients to report possible cases of NSF/NFD to the FDA through the MedWatch program.

Read the complete MedWatch 2006 Safety summary, including links to the updated information page, Public Health Advisory, and previous June 2006 alert, at:

<http://www.fda.gov/medwatch/safety/2006/safety06.htm#Gadolinium>

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

**Hepatitis B Immunization Strategy** ... The CDC has released the recommendations of their Advisory Committee on Immunization Practices (ACIP) for Hepatitis B immunization in adults. Since a large adult segment of the population are vulnerable to Hepatitis B infection and its long term consequences, the ACIP recommends vaccination for all unvaccinated adults. A similar report was issued last year for infants, children and adolescents.

Mast E, Weinbaum CM, Fiore AE, Alter MJ, Bell BP, Finelli L, et al. A comprehensive immunization strategy to eliminate transmission of hepatitis B virus infection in the United States: Recommendations of the Advisory Committee on immunization practices (ACIP) Part II: Immunization of adults. *MMWR*. 2006 Dec 8;55(RR-16):1-33. <http://www.cdc.gov/mmwr/preview/mmwrhtml/rr5516a1.htm>



**Black Cohosh to the Rescue .. NOT** ... In another example of what seems to be a general rule: when herbal therapies are subjected to the rigors of clinical investigation, they often fail to live up to expectations. In this case, black cohosh was compared to multi-herbal + soy, placebo and conjugated estrogens in 351 women with vasomotor symptoms of menopause. Black cohosh, and other therapies could not show benefit beyond placebo.

Newton KM, Reed SD, LaCroix AZ, Gothaus LC, Ehrlich K, Guiltinan J. Treatment of vasomotor symptoms of menopause with black cohosh, multibotanicals, soy, hormone therapy, or placebo: A randomized trial. *Ann Intern Med*. 2006 Dec 19;145(12):869-79.

**It's not bad, its worse** ... Several U.S. and Australian researchers have analyzed data from the 1918 Spanish Flu pandemic and applied the analysis to the world of 2004, should a similar influenza outbreak occur (eg, avian flu). The researchers were motivated by their feeling that current estimates of 50 million deaths were exaggerated. As it turns out, their estimates are significantly worse, ranging from 51 million to 81 million deaths (median of 62 million). The

majority (96%) of these deaths would occur in developing countries. This indicates that, among other things, the virulence of the virus would be only one contributing factor to overall mortality. Also, there is an over 30-fold variation in mortality. Wow!

Murray CJL, Lopez AD, Chin B, Feehan D, Hill KH. Estimation of potential global pandemic influenza mortality on the basis of vital registry data from the 1918-20 pandemic: A quantitative analysis. *Lancet*. 2006 Dec 23/30;368:2211-18.

If the 1918 flu struck today, death toll could hit 81 million. *Wall Street Journal*. 2006 Dec 22.

**New Recommendations for Tdap ...** New recommendations for the prevention of tetanus, diphtheria and pertussis have been published, using the relatively new licensed vaccine for adults and adolescents (Adacel<sup>®</sup>).

Kretsinger K, Broder KR, Cortese MM, Joyce MP, Ortega-Sanchez I, Lee GM, et al. Preventing tetanus, diphtheria, and pertussis among adults: Use of tetanus toxoid, reduced diphtheria toxoid and acellular pertussis vaccine: Recommendations of the Advisory Committee on Immunization Practices (ACIP) and Recommendation of ACIP, supported by the Healthcare Infection Control Practices Advisory Committee (HICPAC), for use of Tdap among health-care personnel. *MMWR*. 2006 Dec 15;55(RR-17):1-36.

<http://www.cdc.gov/mmwr/preview/mmwrhtml/rr5517a1.htm>

**PPI's and hip fracture ...** A recent study has linked long term proton pump inhibitor (PPI) therapy with an increased risk of hip fractures in the elderly. A nested case-controlled study was done using patient records in the U.K. over a 15 year period. Based on 13,556 hip fracture cases and 135,386 controls, the investigators found an odds ratio for hip fracture following PPI therapy of more than one year, to be 1.44; the strength of association increased with length of therapy.

The two prevailing theories are an induced relative hypochlorhydria may decrease calcium absorption and/or an enzymatic pump for osteoclastic activity may be adversely affected.

Yang Y-X, Lewis JD, Epstein S, Metz DC. Long-term proton pump inhibitor therapy and risk of hip fracture. *JAMA*. 2006 Dec 27;296(24):2947-53.

### Reviews of Note ...

- Cremers S, Garnero P. Biochemical markers of bone turnover in the clinical development of drugs for osteoporosis and metastatic bone disease: Potential uses and pitfalls. *Drugs*. 2006;66(16):2031-58.
- Henness S, Robinson DM, Lyseng-Williamson KA. Rimonabant. *Drugs*. 2006;66(16):2109-19.
- McKeage K, Simpson D, Wagstaff AJ. Intravenous droperidol: A review of its use in the management of postoperative nausea and vomiting. *Drugs*. 2006;66(16):2123-47.

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

**Vocabulary ... Presenteeism ...** Roughly defined as “showing up to work when you should stay home sick.” There are several reasons for this phenomenon; altruism, exaggerated sense of self-importance, and less ‘backup’ due to downsizing. However, the more common reason appears to be a fear of retribution or simply no pay. Approximately one-half of workers have paid sick leave and many who do not are at a lower rung of the job ladder, and many of these are retail clerks who are face-to-face with the public. We all know better and should stay home when sick, but how many feel the obligation to slog through, regardless if paid sick time is available?

Mason M. Sniffing, sneezing and turning cubicles into sick bays. *New York Times*. 2006 Dec 26.

[http://www.nytimes.com/2006/12/26/health/26cons.html?\\_r=1&ref=health&oref=slogin](http://www.nytimes.com/2006/12/26/health/26cons.html?_r=1&ref=health&oref=slogin)

## Update ...

### ***The APhA Complete Review for Pharmacy and Companion Test CD ROM, 4th edition Coming in December 2006.*** Edited by Dick R. Gourley

APhA is again offering the NAPLEX<sup>®</sup> review book free of charge to eligible 2007 graduates (members of the local ASP chapter). In its 4th edition, the *Review* includes a test CD ROM containing over 900 questions from 36 chapters. The CD includes two test-taking modes: Learning Mode for practice and Certification Mode, which functions as a mock test; also includes study tips. The book is also available at reasonable prices. For full information, go to: [http://www.pharmacist.com/store\\_faculty/complete\\_review.cfm](http://www.pharmacist.com/store_faculty/complete_review.cfm)

## AUBURN HSOP FACULTY in the literature ...

- Braxton Lloyd K, Berger BA. Communication concerning sensitive issues: The depressed patient. *U.S. Pharm.* 2006 Nov;31(11):62-68.

## NEW RESOURCES in the DILRC ...

- Cohen MR, ed. *Medication Errors*. 2<sup>nd</sup> ed. Washington, DC: American Pharmacists Association, 2007.
- Pelton R, LaValle JB, Hawkins EB, Krinsky DL. *Drug-induced Nutrient Depletion Handbook*. 2<sup>nd</sup> ed. Hudson, OH: Lexi-Comp, Inc, 2001.

## TIMELY TOP TECH TIP ...

**Vocabulary ... malware ...** More of the same. Malware is a term for malicious software (eg, virus's, worms). The year 2006 was apparently a banner year for junk e-mail, sophisticated Internet attacks, 'phishing' schemes, etc. The bad news is that most experts look for 2007 to continue the trend. Much of it has turned from hobby to day-job thus increasing the frequency and sophistication. Until something better comes along, the same advice applies, be wary of Internet sources, particularly unsolicited email, never give personal information to unsolicited sources, and keep antivirus and antivirus software up-to-date. Some things don't change, ie, "*Caveat emptor*" and "if it sounds too good to be true, it probably is."

Krebs B. Cybercrooks deliver trouble. *Washington Post.com*. 2006 Dec 27; D01.

<http://www.washingtonpost.com/wp-dyn/content/article/2006/12/26/AR2006122600922.html?referrer=email>



## The last "dose" ...

"Study the past if you would define the future."

- Confucius [551-479 B.C.]



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