

# AU InforMed

Volume 3 Number 5 (Issue 68)

Wednesday, February 16, 2005

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

**MedWatch** ... **Look Alike/Sound Alike**...Eli Lilly and FDA notified healthcare professionals reports of medication dispensing or prescribing errors between the atypical antipsychotic **Zyprexa**<sup>®</sup> (olanzapine), and the antihistamine **Zyrtec**<sup>®</sup> (cetirizine HCl) marketed by Pfizer. These reports include instances where Zyprexa<sup>®</sup> was incorrectly dispensed for Zyrtec<sup>®</sup> and vice versa, leading to unnecessary adverse events or potential relapse in patients suffering from schizophrenia or bipolar disorder. For the complete MedWatch 2005 safety summary, and links to the Dear Healthcare Professional letter:

<http://www.fda.gov/medwatch/SAFETY/2005/safety05.htm#ZyPREXA>

**MedWatch** ... Roche and FDA announced an important **drug interaction warning**. Drug-induced hepatitis with marked transaminase elevations has been observed in healthy volunteers receiving rifampin 600 mg once daily in combination with ritonavir 100 mg/saquinavir 1000 mg twice daily (ritonavir boosted saquinavir). Rifampin should not be administered to patients also receiving saquinavir/ritonavir (ritonavir boosted saquinavir) as part of combination antiretroviral therapy (ART) for HIV infection. Read the complete MedWatch 2005 safety summary, including a link to the "Dear Healthcare Professional" letter, at:

<http://www.fda.gov/medwatch/SAFETY/2005/safety05.htm#Invirase>

**MedWatch** ... FDA issued a Public Health Advisory that Health Canada, the Canadian drug regulatory agency, has **suspended the sale of Adderall XR<sup>®</sup> in the Canadian market**. Adderall XR<sup>®</sup> is a controlled release amphetamine used to treat patients with Attention Deficit Hyperactivity Disorder (ADHD). The Canadian action was based on U.S. post-marketing reports of sudden deaths in pediatric patients. FDA continues to evaluate and monitor post-marketing reports of serious adverse events in children, adolescents, and adults being treated with Adderall<sup>®</sup> and related products. Read the complete MedWatch 2005 Safety Summary, including links to the Public Health Advisory, FDA Statement and other supporting information for healthcare professionals and patients, at:

<http://www.fda.gov/medwatch/SAFETY/2005/safety05.htm#Adderall>

**FDA ALERT** [February 14, 2005] ... **Elidel<sup>®</sup> Cream** (pimecrolimus) and **Protopic<sup>®</sup> Ointment** (tacrolimus) Information: FDA is investigating postmarketing reports of lymphoma and skin cancer in children and adults treated with these two topical therapies, but the causal relationship has not been clearly established. Reports are being analyzed to determine whether the occurrence of these adverse events affects the risk/benefit assessment of therapy. Neither product is approved for use in pediatric patients less than 2 years of age. For more information:

<http://www.fda.gov/cder/drug/infopage/elidel/default.htm> (Elidel)

<http://www.fda.gov/cder/drug/infopage/protopic/default.htm> (Protopic)

**Drug Safety Oversight Board ...** The FDA has announced its intent to create an independent board to more aggressively monitor the safety of drugs after approval and marketing as part of an effort to restore public confidence in the nation's prescription drug supply. This confidence has been seriously eroded with the ongoing "Vioxx" inquiry. The Board would essentially separate those who evaluate and approve new drugs, from those who would monitor for safety once they are on the market. Some have argued that this current dual role constitutes a conflict of interest.

<http://www.washingtonpost.com/wp-dyn/articles/A25893-2005Feb15.html?referrer=email>

(Washington Post)

[http://www.usatoday.com/news/washington/2005-02-15-fda-board\\_x.htm](http://www.usatoday.com/news/washington/2005-02-15-fda-board_x.htm) (USA Today)

## FROM THE MEDICAL LITERATURE ...



**Pregnancy and depression ...** A new study using a "data mining" technique on a WHO Collaborating Centre for International Drug Monitoring identified a neonatal withdrawal syndrome in infants born of mothers taking selective serotonin reuptake inhibitors (SSRI's) and four separate agents were identified. The withdrawal syndrome can include seizures and a version of the serotonin syndrome. See also the accompanying editorial.

Sanz E, De-las-Cuevas C, Kiuru A, Bate A, Edwards R. Selective serotonin reuptake inhibitors in pregnant women and neonatal withdrawal syndrome: A database analysis. *Lancet* 2005 Feb 5;365:482-87.

Ruchkin V, Martin A. SSRIs and the developing brain. *Lancet* 2005 Feb 5;365:451-53.

**ACPE discontinues CE accreditation for pharmaceutical manufacturers ...** The Accreditation Council for Pharmacy Education (ACPE) announced on January 15, 2005, that as of July 1, the organization will cease recognizing pharmaceutical and biomedical device manufacturers as accredited providers of continuing education (CE). This does not preclude pharmaceutical manufacturers from sponsorship of programs by other organizations with ACPE accreditation (eg, schools/colleges of pharmacy, pharmacy associations), but they will not be the sponsors and the ones providing CE credit. This will affect approximately 5% of the available CE programs.

<http://www.ashp.org/news/ShowArticle.cfm?id=9755>

## Reviews of Note ...

- American Academy of Pediatrics. Policy Statement: Breastfeeding and the use of human milk. *Pediatrics* 2005 Feb;115(2):496-506.
- Cappell MS, ed. Screening, prevention, and treatment of esophageal, gastric, and hepatic malignancies. *Med Clin N Am* 2005 Mar;89(2):219-418.

## FROM THE LAY LITERATURE about medicine ...

**Prilosec shortage?** ... a shortage of the over-the-counter Prilosec OTC<sup>®</sup> (omeprazole) for the last few months has some speculating that the shortage was intentional. AstraZeneca is the manufacturer, but partnered with Procter and Gamble to market the OTC product. However, AstraZeneca is also the manufacturer of the prescription proton pump inhibitor, Nexium<sup>®</sup>, an isomer of omeprazole. During the shortage, Nexium<sup>®</sup> sales rose 32%. There are denials all around, but is this another case of "follow the money?"

Ellison S, Whalen J. Prilosec scarcity puts spotlight on a P&G-AstraZeneca pact. *Wall Street Journal* online 2005 Feb 7; p. B2.

**Vocabulary ... Pharming ...** or today's drug abuse of choice, prescription drugs. In the 1970s it was LSD, cocaine in the 1980s, Ecstasy and heroin in the 1990s, now along with methamphetamine, prescription drugs appear to be the drugs of choice. It's easy to understand why, with dramatic increases of sales (up 400% since 1990) and easy availability (many coming from legitimate prescriptions found in the home). The more common ones are well known, Ritalin<sup>®</sup>, Vicodin<sup>®</sup>, Percocet<sup>®</sup> and Oxycontin<sup>®</sup>; benzodiazepines are in there, too. A lengthy article on the latest scourge of youth, is below.

Costello D. Their drugs of choice. *Los Angeles Times.com* 2005 Feb 7.

<http://www.latimes.com/features/health/la-he-rx7feb07,1,7192902.story?coll=la-headlines-health>



**Vocabulary ... Meth Mouth ...** A relatively new phenomenon, noticed mostly in prisons, are rotting teeth due to methamphetamine use. Apparently the chronic use of methamphetamine causes dry mouth which dramatically hastens natural bacterial activity. Dental bills in the nations prisons are rising significantly, along with toothless grins.

Associated Press. Methamphetamine users face growing problem of rotting, crumbling teeth. *Baltimore Sun.com* 2005 Feb 6.

<http://www.baltimoresun.com/news/health/bal-te.meth06feb06,1,580644.story?coll=bal-health-headlines>



**Behind the counter ... a good thing? ...** An article about the revived issue of creating a "third class" of drugs, available only behind the pharmacist's counter and under their control. Several recent examples include "Plan B" the emergency contraceptive, Mevacor<sup>®</sup> (lovastatin) recently rejected by the FDA for OTC availability, and for such things as pseudoephedrine products (eg, Sudafed<sup>®</sup>) due to its use as a precursor to manufacturing methamphetamine. Some discussion is also given to the value of pharmacist counseling services, both good and bad.

Rubin R. Pharmacies offer 'behind the counter' service. *USA Today.com* 2005 Feb 7.

[http://www.usatoday.com/news/health/2005-02-07-pharmacists\\_x.htm](http://www.usatoday.com/news/health/2005-02-07-pharmacists_x.htm)



**It's not your father's pharmacopeia ...** All hail pharmaceuticals! ... A special article from the *Washington Post* about the various innovative ways drugs are being delivered outside of the traditional tablet, capsule or needle. Briefly discussed are drugs delivered through the skin with electric current, ultrasound, and of course, the patch. Other delivery mechanisms include inhaler technology, and in a "double technology" jolt, microchip delivery where drugs could be delivered as a "smart" controlled release, or even by remote control!

Mishori R. Special delivery: Coming soon: New ways to take drugs, without needles or pills. *Washington Post.com* 2005 Feb 8; pg. HE01.

<http://www.washingtonpost.com/wp-dyn/articles/A5993-2005Feb7.html>



**Pay attention in Endocrine Module ...** The "metabolic syndrome" has now hit the popular press. Interviewing several leading physicians, the obesity epidemic has become the mother of the associated problems. Described as a fundamental malfunctioning of the body's energy storage system, it includes a cluster of risk factors such as hypertension, hyperglycemia and hypercholesterolemia. Probably the worst news of all, one of the initial therapies, and in fact a preventative prescription: DIET and EXERCISE!

Stein R. New diagnosis of overweight: Major risk factors add up to 'metabolic syndrome.' *Washington Post.com* 2005 Feb 8; pg. A01.

<http://www.washingtonpost.com/wp-dyn/articles/A6284-2005Feb7.html?referrer=email>



**Top 25 Medical Stories of the last 25 years ...** Yet another “top” list, but always entertaining to read. Most of the stories related to various advances in medical science. The “drug” list includes: 7. Prozac; 11. Phen-Fen; 17. Prescription drug advertising; 23. ADHD; 24. Tylenol tampering; and 25. Viagra.

CNN. Top 25: Medical stories: Human genome mapping ranks No. 1 in health news. *CNN.com* 2005 Feb 13.  
<http://www.cnn.com/2005/HEALTH/01/31/cnn25.top.medical/index.html>

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

- Roth MT, Andrus MR, Westman EC. Outcomes from an outpatient smoking-cessation clinic. *Pharmacotherapy* 2005 Feb;25(2):279-88.
- Marlowe KF, Woods DD. Evaluating a training program for pharmacist code blue response. *Hosp Pharm* 2005 Jan;40(1):49-53.

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

- McEvoy G, ed. *AHFS Drug Information 2005*. Bethesda, MD: American Society of Health-Systems Pharmacists, 2005.
- DiPiro JT, Spruill WJ, Blouin RA, Pruemer JM. *Concepts in Clinical Pharmacokinetics*. 3<sup>rd</sup> ed. Bethesda, MD: American Society of Health-Systems Pharmacists, 2004.
- Murphy JE, ed. *Clinical Pharmacokinetics*. 3<sup>rd</sup> ed. Bethesda, MD: American Society of Health-Systems Pharmacists, 2005.
- Barrett M, ed. *The Handbook of Clinically Tested Herbal Remedies*. 2 vol. New York: Haworth Press, 2004.
- Gehrman B, Koch W-G, Tschirch CO, Brinkmann H. *Medicinal Herbs: A Compendium*. New York: Haworth Press, 2005.
- Worthen DB, ed. *Dictionary of Pharmacy*. New York: Haworth Press, 2004.



### **The last “dose” ...**

“No families take so little medicine as those of doctors, except those of apothecaries.”

--Oliver Wendell Holmes [1800-1894], from *Medical Essays*, “Currents and Counter-Currents in Medical Science”

*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*