

# AU InforMed

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

**Public Health Advisory** ... FDA issued a public health advisory on April 11, 2005 regarding the **use of antipsychotic drugs in the elderly** for the treatment of behavioral disorders. Antipsychotics are approved for the treatment of schizophrenia and mania, however, they are not approved for the treatment of behavioral disorders in elderly patients with dementia. This issue is of concern because these medications have been shown to have a higher death rate associated with their use in elderly patients compared to those receiving placebo. The FDA has asked the manufacturers of these medications to place a boxed warning describing the risk and highlighting that these medications are not approved for the treatment of behavioral disorders in elderly with dementia. For more information go to the FDA website:

<http://www.fda.gov/cder/drug/infopage/antipsychotics/default.htm>

<http://www.fda.gov/cder/drug/advisory/antipsychotics.htm>

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

**Name Change** ... Ortho McNeil Neurologics, Inc announced April 11, 2005 that it would be changing galantamine (**Reminyl**<sup>®</sup>) to **Razadyne**<sup>®</sup> and Razadyne ER<sup>®</sup> in efforts to decrease confusion with the diabetes drug Amaryl<sup>®</sup>. The manufacturer hopes to have the extended release form available in May and the immediate release form available in July. For information regarding this change visit: <http://www.razadyne.com/>

**New Formulation** ... **Mometasone furoate** (Asmanex<sup>®</sup> Twisthaler<sup>®</sup> 220mg by Schering-Plough Corporation) for first line maintenance treatment of asthma in patients 12 years of age and older was approved by the FDA on March 31, 2005. Asmanex is currently the only inhaled therapy approved for once daily initiation and management of asthma.

For more information and product labeling go to: <http://www.spfiles.com/piasmanex.pdf>

**New Medication** ... **Alendronate Sodium/Cholecalciferol** (Fosamax Plus D<sup>®</sup> by Merck & Co., Inc.) is a once weekly combination tablet that contains 70mg of alendronate sodium and 2800 IU vitamin D3 (seven days worth of 400 IU vitamin D). Fosamax Plus D is a bisphosphonate approved for the treatment osteoporosis in postmenopausal women and to increase bone mass in males. For more information and product labeling go to:

[http://www.fosamax.com/alendronate\\_sodium/fosamax/hcp/plus/index.jsp](http://www.fosamax.com/alendronate_sodium/fosamax/hcp/plus/index.jsp)

**New Device** ... The FDA approved on April 11, 2005, the single-indication orphan drug **Retisert**<sup>™</sup> (**fluocinolone acetonide intravitreal implant** by Bausch & Lomb), 0.59 mg, for the treatment of chronic non-infectious uveitis affecting the posterior segment of the eye, a sight-threatening inflammatory disease that primarily afflicts people between the ages 20 and 50.

It is the world's first intravitreal drug implant for the treatment of this condition that affects an estimated 175,000 people in the U.S. and an estimated 800,000 people worldwide. The product is targeted for a mid-year launch.

[http://www.bausch.com/us/vision/about/news/pressrelease.jsp?pressRelease=2005\\_04\\_11\\_retimer.html](http://www.bausch.com/us/vision/about/news/pressrelease.jsp?pressRelease=2005_04_11_retimer.html)

**New Device**...Hypoguard has introduced **Advanced Micro-Draw™**, a blood glucose monitoring system that allows for alternate site testing on the palm of a hand in addition to the traditional fingertip site. A few more benefits of this meter include results in 15 seconds, small amount of blood required (1.5 µL), and a 250 test memory. For more information on this meter visit Hypoguards website at: [http://www.hypoguard.com/advance\\_micro\\_draw.html](http://www.hypoguard.com/advance_micro_draw.html)

**Recall**...GlaxoSmithKline Plc has recalled **Lamictal® starter kits** because of incorrect dosing. Lamotrigine (Lamictal®) is used for the treatment of epilepsy and bipolar disorder. The starter kits contain 5-week blister packs and are designed for treatment initiation. GSK informed the FDA of the voluntary recall and will not produce any more starter kits until the problem is resolved. For more information visit: <http://www.medscape.com/viewarticle/502707>

**Medwatch**...PharMEDium Services has announced a recall of all strengths of 50ml admixtures of Magnesium Sulfate in 5% Dextrose solution. This recall was issued because of the potential lack of sterility assurance for these products. The company has also voluntarily stopped production and distribution of the product until this issue can be corrected. For more information regarding this recall go to the FDA website:

[http://www.fda.gov/oc/po/firmrecalls/pharmedium04\\_05.html](http://www.fda.gov/oc/po/firmrecalls/pharmedium04_05.html)

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



**Regulatory Issue**... The DEA has placed zopiclone, its salts, isomers and salts of isomers into Schedule IV of the Controlled Substances Act (CSA). Eszopiclone (Lunesta®), the S isomer of zopiclone, is a CNS depressant currently available for the treatment of insomnia. For more information regarding this issue go to:

<http://a257.g.akamaitech.net/7/257/2422/01jan20051800/edocket.access.gpo.gov/2005/pdf/05-6703.pdf>



**New Guideline** ... A new guideline on the **pharmacologic and surgical management of obesity in primary care**. This guideline comes from American College of Physicians and is published in the *Annals of Internal Medicine*.

Snow V, et al. Pharmacologic and surgical management of obesity in primary care: a clinical practice guideline from the American college of physicians. *Ann Intern Med*. 2005; 142: 525-531.



**Computers and Resistant Bacteria**... Computers are a vital part of the healthcare system in today's information age and are becoming more important with the introduction of CPOE and electronic medical records, but could these same computers be spreading bacteria? According to an abstract presented at Society for Healthcare Epidemiology of America 15<sup>th</sup> Annual Scientific Meeting, contact with computer keyboards and keyboard covers allows transmission of bacteria to gloved and ungloved hands. In order to prevent transmission, it is important to keep the keyboard disinfected on a daily basis and to make hand washing a ritual.

[http://www.medscape.com/viewarticle/502836\\_print](http://www.medscape.com/viewarticle/502836_print)

### Reviews of Note ...

- Phillips DP, Jarvinen JR, Phillips RR. A spike in fatal medication errors at the beginning of each month. *Pharmacotherapy* 2005; 25(1):1-9.
- Sears EL, Generali JA. Adverse drug reaction and medication error reporting by pharmacy students. *Ann Pharmacother* 2005; 39: 452-9.
- Angelo LB, Ferreri SD. Assessment of workflow redesign in community pharmacy. *JAPhA* 2005; 45(2): 145-51.
- Licata AA. Discovery, clinical development, and therapeutic uses of bisphosphonates. *Ann Pharmacother* 2005; 39: 668-77.
- Richard CL, Jurgens TM. Effects of natural health products on blood pressure. *Ann Pharmacother* 2005; 39: 712-20.
- Hussar DA. New drugs of 2004. *JAPhA* 2005; 45(2): 185-218.

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

**Silicone or Saline...** The FDA is considering if the ban on silicone breast implants should be lifted after thirteen years. A panel of representatives met April 11 – 13<sup>th</sup> to discuss this issue and on April 12<sup>th</sup> voted 5 to 4 against recommending approval of silicone breast implants. This meeting was held after two manufacturers of silicone breast implants have requested to re-enter the market. This issue is confounded by patients who prefer silicone implants to saline because of the aesthetics. On the other hand, there are women who have strong feelings about the silicone implants re-entering the market because of the pain and suffering caused by implants. Arguments for silicone implants state that the woman should be able to choose whether or not they prefer silicone or saline.

Rubin Rita. FDA panel rejects silicone implants. *USA Today.com* 2005 Apr 12.

[http://www.usatoday.com/news/washington/2005-04-12-breast-implants\\_x.htm](http://www.usatoday.com/news/washington/2005-04-12-breast-implants_x.htm)



**Patient Privacy Floating in the Wind...** Approximately 3,000 detailed patient hospital statements were “floating in the wind” after a box fell off a delivery trunk in Cleveland, Ohio. The records were from two members of the Cleveland Hospital System and they have set up a hotline for records that were found. Hospital system officials contacted each patient to inform them of the situation.

<http://www.msnbc.msn.com/id/7403750/>



**Abnormal CT...Encourage Smoking Cessation...** Research shows that smokers are more likely to abstain from smoking if abnormal findings are present on a chest CT compared to normal findings. This information will appear in the online issue of *Cancer*, and is based on a study of 926 current smokers and 594 former smokers who were screened for lung cancer with a chest CT.

<http://www.medscape.com/viewarticle/502800>

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

- Wargo KA, Eiland EH III. Appropriate antimicrobial therapy for community-acquired methicillin-resistant *Staphylococcus aureus* carrying the Panton-Valentine Leukocidin genes. *Clin Infect Dis* 2005 May 1;40:1376-78.

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

- Physician's Desk Reference. 59<sup>th</sup> ed. Montvale, NJ: Thomson PDR, 2005
- USP-DI Volume I. Drug Information for the Health Care Professional. 25<sup>th</sup> ed. Greenwood, CO: Thomson Micromedex, 2005.
- USP-DI Volume II. Advice for the Patient: Drug Information in Lay Language. 25<sup>th</sup> ed. Greenwood, CO: Thomson Micromedex, 2005.

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

"Hope lies in dreams, in imagination and in the courage of those who dare to make dreams into reality."  
Jonas Salk