

# AU InforMed

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

**New Drug ... pramlintide acetate** (Symlin<sup>®</sup> by Amylin Pharmaceuticals) was approved by the FDA on March 17, 2005. It is a parenteral medication indicated for type I and type II diabetes. It is the only drug approved for type I diabetes besides insulin. Areas of concern include the risk of hypoglycemia, gastroparesis patients, mixing with insulin in the same syringe (can alter insulin activity) and the inappropriate off-label uses of the drug.

FDA. FDA approves new drug to treat type 1 and type 2 diabetes. *FDA Talk Paper* 2005 Mar 17;T05-08.

<http://www.fda.gov/bbs/topics/ANSWERS/2005/ANS01345.html>

**New Drug ... micafungin** (Mycamine<sup>™</sup> for injection by Fujisawa Healthcare) is a new antifungal agent indicated for treatment of patients with esophageal candidiasis and prophylaxis of *Candida* infections in patients undergoing hematopoietic stem cell transplantation.

<http://www.accessdata.fda.gov/scripts/cder/drugsatfda/index.cfm?fuseaction=Search.SearchAction&ApplNo=021506&SearchType=AddlSearch&SEARCHOPTION=B>

**New Indication ... temozolomide** (Temodar<sup>®</sup> by Schering-Plough) received approval from the FDA for a new indication, glioblastoma multiforme the most common form of malignant brain cancer. It is indicated in conjunction with radiotherapy and with such, extends the lives of patients an additional 2.5 months.

FDA. Temodar approved for glioblastoma multiforme. *FDA Talk Paper* 2005 March 16;T05-07.

<http://www.fda.gov/bbs/topics/ANSWERS/2005/ANS01344.html>

**MedWatch ...** Public health advisory from the FDA ... a potential cancer risk exists from use of Elidel<sup>®</sup> (**pimecrolimus**) and Protopic<sup>®</sup> (**tacrolimus**). This is based on information from animal studies, case reports in a small number of patients, and how these drugs work. It may take human studies of ten years or longer to determine if these drugs are linked to cancer. Since this risk is uncertain the FDA advises that Elidel<sup>®</sup> and Protopic<sup>®</sup> should be used only as labeled, for patients who have failed treatment with other therapies. Read the complete MedWatch 2005 Safety summary, including links to the Public Health Advisory, Talk Paper and Drug Information pages, at:

[www.fda.gov/medwatch/SAFETY/2005/safety05.htm#Elidel](http://www.fda.gov/medwatch/SAFETY/2005/safety05.htm#Elidel)

**MedWatch ...** The FDA and Biogen notified healthcare professionals of revisions to the WARNINGS, PRECAUTIONS/Drug Interactions and ADVERSE REACTIONS/Post-Marketing Experience sections and Medication Guide of **Avonex<sup>®</sup>** (interferon beta-1a). Severe hepatic injury, including cases of hepatic failure, has been reported in patients taking Avonex<sup>®</sup> as well as asymptomatic elevation of hepatic transaminases; in some patients this has recurred upon rechallenge. The potential risk of Avonex<sup>®</sup> used in combination with known hepatotoxic drugs or other products (e.g. alcohol) should be considered prior to Avonex<sup>®</sup> administration, or when

adding new agents to the regimen of patients already on Avonex<sup>®</sup>. Read the complete MedWatch 2005 Safety Summary, with links to the Dear Healthcare Professional letter and revised label, at: <http://www.fda.gov/medwatch/SAFETY/2005/safety05.htm#Avonex>

**Recall** ... FDA has issued a nationwide alert against the use of PharMEDium Services **Magnesium Sulfate** 1 gram in 50mL D5W (piggyback) IV solution, lot number 100504900049 and expiration date 4/4/05. This product is manufactured by PharMEDium Services of Houston, Texas and may be contaminated with *Serratia marcescens* bacteria that can cause serious, life-threatening illness in patients with compromised immune systems. This product is frequently administered intravenously to patients undergoing cardiac surgery and was apparently distributed to several hospitals around the country. It has been associated with at least 5 cases of *Serratia marcescens* infection in a New Jersey hospital. The firm has notified FDA that it is in the process of withdrawing this lot from hospitals. Hospitals with questions may contact the company at 1-847-457-2300. Persons wanting to report anything to the Food and Drug Administration regarding this product may contact FDA's MedWatch office at 1 800-FDA-1088. FDA Issues nationwide alert on ONE lot of Pharmedium Services magnesium sulfate solution. *FDA Statement* 2005 Mar 18. <http://www.fda.gov/bbs/topics/news/2005/NEW01166.html>

**Denied** ... **Petition to withdraw Crestor<sup>®</sup> (rosuvastatin** by Astra Zeneca)... was submitted March 4, 2004 by the Health Research Group of Washington, DC due to its concerns about the drug's adverse effects, particularly rhabdomyolysis and kidney failure or kidney damage. The FDA responded to the petition March 11, 2005 in a 35-page document and, as expected, did not agree with the petition. Lots of good data if you care to read through it. [http://www.fda.gov/cder/drug/infopage/rosuvastatin/crestor\\_CP.pdf](http://www.fda.gov/cder/drug/infopage/rosuvastatin/crestor_CP.pdf) (Docket No. 2004P-0113/CP1)

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



**Boy or girl, your choice** ... A survey was recently published, according to WebMD, that shows that 41% of women, given the choice (and free, though one-half of these would pay) would choose to select the gender of their baby. In this study of 561 women, 38% would select a male and 61% would select a female. Lots of other demographic information included.

Warner J, Nazario B. Gender selection in demand. WebMD 2005 Mar 16.

<http://www.cbsnews.com/stories/2005/03/16/health/webmd/main680702.shtml>



**Short finger, bad temper?** ... Here's some party conversation. According to a recent study, the finger length ratio of the second (index) and fourth (ring) fingers of men correlates to their likelihood of having higher physical aggression scores. The finger length ratio is smaller ("more masculine") in men and is correlated better performance in sports and having higher physical aggression scores. This is also hypothesized to be subject to levels of testosterone. These ratios do not apply to females.

Bailey AA, Hurd PL. Finger length ration (2D:4D) correlates with physical aggression in men but not in women. *Biol Psychology* 2005;68:215-22.

**Guideline** ... The Pre-eclampsia Community Guideline (PRECOG) has been published. It provides information and advice for the screening and early detection of pre-eclampsia in the community. The rationale is that in the United Kingdom, 46% of maternal deaths and 65% of fetal deaths are due to pre-eclampsia.

Milne F, Redman C, Walker J, Baker P, Bradley J, Cooper C, et al. The pre-eclampsia community guideline (PRECOG): how to screen for and detect onset of pre-eclampsia in the community. *BMJ* 2005;330:576-80.



**TB Trends** ... New surveillance report release by the Centers for Disease Control and Prevention (CDC) detailing tuberculosis infections in the U.S. While the incidence continues to decline in the U.S. since 1993, the rate of decline has significantly slowed, raising concerns that the pattern may reverse without additional attention.

CDC. Trends in tuberculosis-United States, 2004. *MMWR* 2005 Mar 18;54(10):245-49.

<http://www.cdc.gov/mmwr/preview/mmwrhtml/mm5410a2.htm>

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

- Top 200 Brand-name Drugs by Units in 2004. *Drug Topics* 2005 Mar 7;149(5):25.
- Top 200 Generic Drugs by Units in 2004. *Drug Topics* 2005 Mar 7;149(5):26.
- Boyer EW, Shannon M. The serotonin syndrome. *N Engl J Med* 2005 Mar 17;352(11):1112-20.

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



**Protecting tiny fingers** ... a study in *Annals of Emergency Medicine*, as reported in the *Los Angeles Times*, found that 19 of every 100,000 children <4 years old lost all or part of a finger in accidents each year. Doors were the most common cause and household doors were the culprit 85% of the time. This is nearly twice the rate of older men (most common cause being power tools).

Singer E. Protecting tiny fingers. *Los Angeles Times.com* 2005 Mar 14.

<http://www.latimes.com/features/health/la-he-capsule14mar14,1,3830044.story?coll=la-headlines-health>



**Shock Therapy** ... Interesting “review article” from *Business Week* that covers a number of new uses of “pacemakers” or something similar. Various devices are being tested and used that deliver small shocks that are benefiting such diverse problems as epilepsy, depression, bladder incontinence, chronic pain, migraine headaches, post-stroke paralysis, Parkinson’s disease, and obesity. The cardiac pacemaker has come a long way.

Arndt M. Rewiring the body. *Business Week* 2005 Mar 7; p. 74-82.

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

- Williams Cori. The Auburn University Academy of Student Pharmacists. *Alabama Pharmacy* 2005 Feb/Mar; 11.
- Besong Besem. The common cold. *Alabama Pharmacy* 2005 Feb/Mar; 24.
- Berger BA. Moral and ethical courage. *Alabama Pharmacy* 2005 Feb/Mar; 18.

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

- Standring S, ed. *Gray’s Anatomy: The Anatomical Basis of Clinical Practice*. 39<sup>th</sup> ed. Edinburgh: Elsevier Churchill Livingstone, 2005.

 The last “dose” ...

“There are some remedies worse than the disease.”

--Publilius Syrus, 1<sup>st</sup> century B.C., in *Maxim* 301.



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