

# AU InforMed

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## Key Inforbits

- Nolvadex<sup>®</sup> off the market
- MedWatches
- New guidelines for Parkinson's Disease
- New database for drugs and lactation
- Too much prevention?
- More sources of potential bias

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

**Discontinued** ... Nolvadex<sup>®</sup> (tamoxifen citrate by AstraZeneca Pharmaceuticals LP) is being discontinued by the company by the end of June 2006. This was announced to healthcare professionals in a letter from the company on March 15, 2006. This will affect AstraZeneca's patient assistance program. It should not affect the availability of tamoxifen citrate, as it is manufactured by several generic companies. AstraZeneca is discontinuing the trade name product due to declining market share. The full text of the letter is available at:

<http://www.fda.gov/cder/drug/shortages/default.htm#disc>

**MedWatch** ... Pfizer Pharmaceuticals notified healthcare professionals of important changes in the approved product labeling for Macugen<sup>®</sup> (pegaptanib sodium injection), including changes to the Contraindications, Precautions, Adverse Events post-marketing, and Dosage and Administration sections. Rare reports of anaphylaxis/anaphylactoid reactions, including angioedema following the administration of pegaptanib sodium along with various medications administered as part of the injection preparation, were described. Pegaptanib sodium is indicated for the treatment of neovascular (wet) age-related macular degeneration, and is administered once every six weeks by intravitreal injection. Healthcare professionals should evaluate the patient's medical history for hypersensitivity reactions to pegaptanib prior to using this product. Read the complete MedWatch 2006 Safety Summary, including links to the Dear Healthcare Professional Letter and the updated approved product labeling at:

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

## **MedWatch ... Fungal Keratitis Infections Related to Contact Lens Use**

The FDA and CDC notified all healthcare practitioners and consumers of an increase in the number of reports in the United States of a rare but serious fungal infection of the eye in soft contact lens wearers. The infection, a fungal keratitis caused by the *Fusarium* fungus, may cause vision loss requiring corneal transplants. The CDC received reports of 109 cases of suspected fungal keratitis in 17 different States; 28 of the 30 cases reported wearing soft contact lenses. The majority of the individuals (26) reported using a Bausch & Lomb ReNu brand contact lens solution in the month prior to the onset of infection. Healthcare practitioners should refer patients presenting with a microbial keratitis immediately to an ophthalmologist for immediate treatment and report cases of fungal keratitis in contact lens wearers to FDA. Contact lens wearers should use good hygiene practices, e.g., wash hands with soap and water, and dry (lint

free method) before handling lenses; wear and replace lenses according to the prescribed schedule; follow the specific lens cleaning and storage guidelines from the doctor and the solution manufacturer; keep the contact lens case clean and replace every 3-6 months; and remove lens immediately if the wearer experiences symptoms such as redness, pain, tearing, increased light sensitivity, blurry vision, discharge or swelling.

Read the complete MedWatch 2006 Safety summary, including links to the FDA Preliminary Public Health Notification, Advice to Patients, and Press Release at:

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

**MedWatch** ... Boca Medical Products and FDA notified consumers and healthcare professionals of a recall of **Ultilet Insulin Syringe 30g 1/2cc** (Lot # - 5GEXI, NDC # - 08326-3002-50) because of possible bacterial presence of *Bacillus Cereus* and *Staphylococcus Intermedius*. This presents a risk of local infection due to soft tissue injection, as well a risk of introduction of contaminating organisms into a previously sterile vial. The introduced contamination may degrade the insulin, which could lead to problems maintaining insulin levels. This product has been distributed to the following states: FL, NY, MA, AL, SC, NC, CO, TX, MI, AR. For any question related to the case consumers should call 1-800-354-8460.

Read complete MedWatch 2006 Safety summary, including link to the firm's press release, at: <http://www.fda.gov/medwatch/safety/2006/safety06.htm#boca>

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

**New Clinical Practice Guidelines for Parkinson's Disease** ... The American Academy of Neurology has published new clinical practice guidelines on Parkinson's disease (PD) that address diagnosis and prognosis of new-onset disease; effective treatments and alternative therapies; medical and surgical management of PD with motor fluctuations and dyskinesia; and evaluation and management of PD-associated depression, psychosis, and dementia. The guidelines and helpful information for physicians, patients, and caregivers can be found at:

<http://www.aan.com/professionals/practice/guideline/index.cfm>

Also, some more specific segments include:

[http://aan.com/professionals/practice/guidelines/Eval\\_Treatment\\_PD.pdf](http://aan.com/professionals/practice/guidelines/Eval_Treatment_PD.pdf)

(PD with depression, psychosis, and dementia)

[http://aan.com/professionals/practice/guidelines/PD\\_Motor\\_Fluctuations.pdf](http://aan.com/professionals/practice/guidelines/PD_Motor_Fluctuations.pdf)

(PD with levodopa-induced motor fluctuations and dyskinesia)

**Peer review bias** ... Investigators analyzed the effect of blinding to the peer reviewers, the authors (and their institutions). Their hypothesis was that peer reviewers could be influenced by familiarity with the authors (or reputations), institutions, etc. They proved their case. Taking advantage of a change in procedure for the American Heart Association's annual Scientific Session, they looked at acceptance rates of over 67,000 abstracts submitted for acceptance over 5 years that were unblinded and blinded to the reviewers. They found that when reviewers were not blinded, acceptance rates favored authors from the U.S., English-speaking countries outside the U.S., and prestigious institutions.

Ross JS, Gross CP, Desai MM, Hong Y, Grant AO, Daniels SR, et al. Effect of blinded peer review on abstract acceptance. *JAMA*. 2006 Apr 12;295(14):1675-80.



**Pandemic Plan** ... or more appropriately, public health strategies. Apart from vaccinations and drugs to combat flu, what are the “non-drug” measures that may be effective should a pandemic flu strike the U.S., or other countries? This article presents a discussion of some of the methods that have been used in the past and their ethical/legal considerations in today’s world. The strategies include public health surveillance, limitation of animal-human pathogen exchange, community hygiene, hospital infection control, “social distancing”, border controls, and finally isolation and quarantine.

Gostin L. Public health strategies for pandemic influenza: Ethics and the law. *JAMA*. 2006 Apr 12;295(14):1700-04.

**Drugs and Lactation** ... **LactMed**, from the National Library of Medicine, is a Web-based collection of 450 drug records on maternal drug levels in breast milk, drug levels in infants' blood, potential effects of drug ingestion on breastfeeding infants, and alternate drugs to consider. The database was developed by Philip O. Anderson, Pharm.D., FASHP, under the guidance of a scientific review panel. It is fully referenced and indicates the date last updated. <http://toxnet.nlm.nih.gov/cgi-bin/sis/htmlgen?LACT>

### Reviews of Note ...

- Mozaffarian D, Katan MB, Ascherio A, Stampfer MJ, Willett WC. Trans fatty acids and cardiovascular disease. *N Engl J Med*. 2006 Apr 13;354(15):1601-13.
- Arnold RM, Han PKJ, Seltzer D. Opioid contracts in chronic nonmalignant pain management: Objectives and uncertainties. *Am J Med*. 2006 Apr;119(4):292-6.
- Wirbelauer C. Management of the red eye for the primary care physician. *Am J Med*. 2006 Apr;119(4):302-6.

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



**Prevention a step too far** ... Particularly for those in, or contemplating, community pharmacy, an article from our nation’s capitol, prophylactic barriers for prophylactic measures!? Personal accounts of the difficulty of purchasing condoms in community pharmacies in Washington, DC. CVS stores were highlighted, but a number of other establishments were also named. While theft is the main reason given for locking up condoms in glass cabinets, the problems it causes, which is usually the consumer walking out, deterred from using condoms, but not necessarily deterred from having sex.

Redfearn S. Prophylactic measures. *Washington Post* 2006 Apr 11; p. HE01.

<http://www.washingtonpost.com/wp-dyn/content/article/2006/04/10/AR2006041001312.html?referrer=email>



**Dog Lover’s beware** ... There may be surgery in your future – for your dog! Apparently the rate of anterior cruciate ligament repair (ACL – in dogs it’s the cranial ligament) in dogs is rising fast; it is now the most common surgery for diseased or injured dogs. Veterinarians are at a loss to explain this sudden rise, other than that pet owners are more willing to fork over the average \$3000 for the surgery. Which at least partly explains the doubling in the number of veterinary surgeons over the last 10 years. It’s no longer unconditional love for just dog food! Helliker K. This joint problem makes dogs, owners, weak in the knees. *Wall Street Journal* 2006 Apr 11; p. A1.

**Funding bias???** ... An article argues that if the funding source for a clinical trial is a pharmaceutical company, 90% of the time, the study will favor that drug! This is based on a review published in February. The article goes on to indict the pharmaceutical industry for cleverly manipulating trial designs and interpretations to get desired results. Independently funded trials (eg, by the government) often find that older, much less expensive drugs are just as effective. Some of the “manipulations” include doses and dose escalation, inclusion/exclusion criteria, statistical methods and interpretation of results. Both articles are a worthy read. A quote at the end of the *Washington Post* article from Uwe Reinhardt says a lot: “I have come to believe a lot of inefficiency is quite deliberate and supported by Congress. One person’s inefficiency is another person’s income.”

Vedantam S. Comparison of schizophrenia drugs often favors firm funding study. *Washington Post* 2006 Apr 12; p. A01. <http://www.washingtonpost.com/wp-dyn/content/article/2006/04/11/AR2006041101478.html?referrer=email>  
Heres S, Davis J, Maino K, Jetzinger E, Kissling W, Leucht S. Why olanzapine beats risperidone, risperidone beats quetiapine, and quetiapine beats olanzapine: An exploratory analysis of head-to-head comparison studies of second-generation antipsychotics. *Am J Psychiat.* 2006 Feb;163:185-194.

**Top 50 jobs in America** ... Of the top 50 jobs, **pharmacist ranks number 9!** This *Money* poll assessed factors such as those jobs with significant growth rates over the last 10 years, those paying over \$50,000 per year, and also stress, flexible hours, working environment, creativity and ease of entry/advancement. Read also about the best job in America. <http://money.cnn.com/magazines/moneymag/bestjobs/?cnn=yes>

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

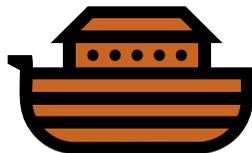
Dumas, Katie. Migraine prevention. *Alabama Pharmacy* 2005 Winter;38:22-3.



#### **The last “dose” ...**

“Never be afraid to try something new. Remember that a lone amateur built the Ark. A large group of professionals built the Titanic.”

-- Dave Barry [1947 - ], *16 Things That it Took Me Over 50 Years to Learn*



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*Bernie R. Olin, Pharm.D., Director*