



Family Medicine Clinical Pharmacy Forum

Vol. 2, Issue 5 (September/October 2006)

Family Medicine Clinical Pharmacy Forum is a brief bi-monthly publication from the Family Medicine clinical pharmacists distributed to faculty and residents of the Department of Family Medicine. Our intent is to provide timely information on broad-based issues of pharmacotherapy, as well as regulatory and practiced-based issues affecting you as a prescriber. If you have suggestions for things you would like to see, please contact us.

Pharmacotherapy Issues.

Wal-mart promotes \$4 per month generics

- Wal-Mart stores are piloting a list of close to 300 generic medications for a monthly fee of \$4. The program is targeting the uninsured offering cheaper options to expensive medications. Wal-Mart plans to expand the program to other states in 2007 but may do so earlier if the program in Tampa is successful. <http://www.walmartfacts.com/articles/4464.aspx>
- K-Mart also has a discount generic plan which has been in place since May of 2006. This plan offers a list of generics for \$5 per month and has close to 1,100 pharmacies participating

LDL lowering for high risk patients being questioned

- The science behind recommendations of LDL goals of <70 mg/dL in high risk patients has recently been questioned
 - Use of dichotomous comparisons, aggregate analysis, accounting for confounders, and assumption that the only mechanism of action for statins is tied into LDL lowering has led to recommendations that have questionable validity
 - In addition, the burden to the patient, costs of treatment, and potential risks of combining treatments needs further study
- Current guidelines are still recommended by the NCEP; these authors are not suggesting that current recommendations are not valid but rather they wish to see evidence that combining treatments other than statins is safe and effective

Annals of Internal Medicine 2006;145:520-530.

Plan B moved to OTC status

- The FDA has approved Plan B (levonorgestrel) emergency contraception to over-the-counter status for women 18 years of age and older; it will remain prescription status for girls 17 years of age and younger
- The medication will be kept behind the pharmacy counter and proof of age will be required before it can be dispensed; appropriate labeling and education are required

Authored by:

John M. Swegle, Pharm.D.; BCPS, Cindy Buys, Pharm.D., BCPS, Michael Ernst, Pharm.D., BCPS, Jim Hoehns, Pharm.D, BCPS, CoraLynn Trewet, MS, Pharm.D.,



- In addition, the product will only be sold through retail operations with pharmacy services or through clinics with licensed healthcare practitioners
<http://www.fda.gov/bbs/topics/NEWS/2006/NEW01436.html>

New Drug: Exubera® (inhaled insulin)

- This is a new formulation of insulin designed to be administered via inhalation. The onset of action is similar to lispro insulin with a slightly longer duration of effect. It is intended to be used as a bolus insulin. Availability will be as blister packets labeled as milligrams of insulin potentially requiring conversion from units of regular insulin
- Contraindicated in those who are current smokers or those who have discontinued smoking < 6 months prior to starting Exubera and in those with unstable or poorly controlled lung disease
 - Recommended that all patients have spirometry assessed prior to initiation of therapy, after the first 6 months of therapy, and annually thereafter
 - Exubera should be discontinued if there is a decline of $\geq 20\%$ from baseline
- Available as a 1- and 3 mg blister packs given 10 minutes before meals; the individual packs are designed for inhalation and should not be swallowed
 - 1 mg = 3 units of regular insulin
 - 3 mg = 8 units of regular insulin
 - Three of the 1 mg capsules may not be substituted for one 3 mg capsule

-Exubera® Prescribing Information. Pfizer Labs, 2006

New Drug: Implanon® (etonorgestrel)

- This is a single rod implantable contraceptive containing 68 mg of etonorgestrel
 - Rod is the size of a matchstick and implanted under the skin in the inner upper arm
 - Etonorgestrel is released over a period of 3 years upon which time the rod is removed
- Implantation must occur between days 1 and 5 of the cycle even if the female is menstruating
- Common side effects include menstrual irregularities, headache, vaginitis, and weight gain
- Cost for the product is ~\$525

-The Medical Letter on Drugs and Therapeutics 2006;48:83-84

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Practice-Based Issues.

- **2006 guidelines for prevention and treatment of sexually transmitted diseases**
 - New guidelines have been published for prevention and treatment of STDs replacing the 2002 version
 - The new guidelines may be obtained through the CDC at <http://www.cdc.gov/mmwr/preview/mmwrhtml/rr5511a1.htm>
- **Wait and see approach to treatment of acute otitis media**
 - A recent study randomized children aged 6 months to 12 years with AOM to one of two groups: standard prescription or “wait and see prescription” (WASP) whereby parents were instructed to have the prescription filled if the child was not better within 48 hours
 - 62% of those in the WASP group did not fill the prescription versus 13% in the standard prescription group (P<0.001)
 - No significant differences between the groups in the frequency of subsequent fever, otalgia, of unscheduled follow-up visits
 - Fever and otalgia were associated with filling the prescription in the WASP group

-JAMA 2006;296:1235-1241.
- **ADHD update**
 - Warnings have been increased concerning cardiovascular risk (sudden death, heart attacks, strokes) with use of stimulant medications
 - The majority of these events occur in people with pre-existing cardiovascular disease
 - Concerning numbers:
 - ~10% of students grades 7-12 have used non-prescription stimulants
 - ~1/3 of young ADHD patients have been asked to sell their medications with 7-15% doing so
 - ~11% of adolescent and adult ADHD patients have sold their drugs at some point in time; 22% have taken more than prescribed; and 10% have used the drugs to get high
 - The vast majority of these abuses have previous diagnosis of conduct disorder or substance abuse

-Harvard Mental Health Letter October 2006:3-5.

Regulatory Issues.

Makers of Enzyte facing federal charges of fraud, conspiracy, and money laundering

- Berkeley Premium Nutraceuticals, makers of Enzyte, has been accused of attracting customers with free trials and money back guarantees followed by unauthorized billing of credit cards. In addition, the company has been accused of using false advertising and has a history of questionable business practices.

<http://www.cnn.com/2006/LAW/09/21/enzyte.indictment.ap/index.html>

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**Clinical Pearl.**

Tips for handling drug reps:

- Make rules that are applicable to your clinic
 - Create the rules that are acceptable to everyone in the practice
 - Inform all new representatives of the rules and provide them with a copy
 - If they are broken, ban the rep from your clinic for a period of time and call their supervisor to inform them of the violation
- Place one person in charge as the contact person for the visiting rep
- Avoid allowing reps access to clinic areas
 - Slows physicians down
 - Violates HIPAA regulations concerning patient confidentiality
- Avoid allowing reps access to the sample closet
 - Designate someone to put the drugs away and maintain the sample closet
- Minimize advertising in your clinic
 - This includes pens, clocks, clipboards or any other paraphernalia that is visible to patients

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