# **AU InforMed**

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# NEW DRUGS, and other related stuff ...

**New Drug** ... The FDA gave approval on February 18, 2005 for DynPort Vaccine Company LLC to manufacture and distribute vaccinia immune globulin intravenous (VIGIV) as a treatment for some of the rare complications of smallpox vaccination. It may also help in those exposed to smallpox in a bioterror attack.

FDA. FDA approves new plasma-derived product to treat complications of smallpox vaccination. *FDA Talk Paper* T05-04; 2005 Feb 18.

http://www.fda.gov/bbs/topics/ANSWERS/2005/ANS01341.html

**New Product**.....FDA approved a new Bausch and Lomb combination ophthalmic suspension Zylet<sup>®</sup>. The active ingredients are the steroid loteprednol etabonate 0.5% and antibiotic tobramycin 0.3%. This product is indicated in patients who require corticosteroid ocular therapy but have a high risk of bacterial infection. Zylet<sup>®</sup> is available in 2.5mL, 5mL, and 10mL bottles. Product showcase. Latner AW, editor. Pharmacy Times 2005;11(2):6.

**New Indication**.....Aripiprazole (Abilify<sup>®</sup>) now carries a third FDA approved indication for maintaining efficacy in patients with bipolar I disorder with a recent manic or mixed episode who had been stabilized and then maintained for at least 6 weeks. This indication is added to those of treatment of schizophrenia and treatment of acute bipolar mania. For those patients who have difficulty swallowing, Abilify<sup>®</sup> is now also available in an oral 1mg/ml solution. http://www.pharmacist.com/articles/h\_ts\_0748.cfm

**Public Health Advisory** ... The FDA issued a public health advisory February 28, 2005 about the suspended marketing of natalizumab (Tysabri<sup>®</sup> by Biogen Idec) due to two serious adverse events reported. There is one confirmed, fatal case and one possible case of progressive multifocal leukoencephalopathy (PML) in patients receiving Tysabri<sup>®</sup> for multiple sclerosis (MS). The FDA is announcing the following, effective immediately: 1)Biogen Idec is voluntarily suspending marketing of Tysabri<sup>®</sup>. 2)Biogen Idec is suspending dosing of Tysabri<sup>®</sup> in clinical trials and is notifying patients and investigators of the possible association between Tysabri<sup>®</sup> and PML. For more information go to the FDA document: http://www.fda.gov/cder/drug/advisory/natalizumab.htm

**Reminyl/Amaryl Confusion ...** Johnson and Johnson has announced that it will be renaming its Alzheimer's product Reminyl<sup>®</sup> (galantamine HBr). This change was prompted by two patient deaths resulting from a sound-alike medication error where the diabetes agent Amaryl<sup>®</sup> (glimepiride) was dispensed instead of Reminyl<sup>®</sup>. The final name is expected to be announced at the end of this month.

Pharmacy news briefs. Eckel FM, editor. Pharmacy Times 2005 February: p.2.

# FROM THE MEDICAL LITERATURE ...

CPOE...friend or foe?......A three article section in *JAMA* discusses a few of the pitfalls of computerized physician order entry (CPOE) and computerized clinical decision support systems (CDSS). CPOE has been hailed as the innovative solution to the numerous medication order errors found in hospitals. Some manufacturers of these products quote a reduction in errors of more than 80%. Unfortunately, a recent review of a tertiary-care teaching hospital CPOE system found that 22 different types of medication errors were produced by the use of this system. A review of a CDSS system showed an improvement in physician performance in areas such as disease state management and drug dosing and prescribing of approximately 60% but, little impact on patient outcomes resulted.

Koppel R, Metlay JP, Cohen A, Abaluck B, Localio AR, Kimmel SE, et al. Role of Computerized Physician Order Entry Systems in Facilitating Medication Errors. *JAMA* 2005;293:1197-1203.

Wears RL, Berg M. Computer Technology and Clinical Work: Still Waiting for Godot. *JAMA* 2005;293:1261-1263. Garg AX, Adhikari NKJ, McDonald H, Rosas-Arellano MP, Devereaux PJ, Beyene J, et al. Effects of Computerized Clinical Decision Support Systems on Practitioner Performance and Patient Outcomes: A Systematic Review. *JAMA* 2005;293:1223-1238.

**Livin' longer** ... The Centers for Disease Control and Prevention (CDC) have just released their annual "State of the CDC" report. Among much more data, the report indicates that life expectancy has increased. Those born in 2002 can expect to live 77.6 years, up 0.3 year; death rates are at record lows. Infant mortality remained approximately the same. To view the 72 page report, go to:

CDC. CDC: Protecting Health for Life. The State of the CDC, Fiscal Year 2004. <a href="www.cdc.gov/od/oc/media/pressrel/ProtectingHealth\_ForLife\_04.pdf">www.cdc.gov/od/oc/media/pressrel/ProtectingHealth\_ForLife\_04.pdf</a>

Contraception stats ... In 2002, the most frequent contraceptive method among women 15 to 44 years old was oral contraception. Other leading methods were female sterilization and the male condom. A smaller, but significant, number of women were using the newer, long-acting hormonal methods, including injectables, implants, and the patch. Additional information is available at http://www.cdc.gov/nchs/nsfg.htm.

CDC. QuickStats: Primary contraceptive methods among women aged 15-44 years – United States, 2002. MMWR 2005 Feb 18:54(6):152.

http://www.cdc.gov/mmwr/preview/mmwrhtml/mm5406a5.htm

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

- Weiss G, Goodnough LT. Anemia of chronic disease. N Engl J Med 2005;352:1011-23.
- Fedutes BA, Donihi AC, Culley CM, McCreery BJ, Ansani NT. An evidence-based summary of insulin analogues. *P&T Journal* 2005;30(2):112-20.
- Padwal R, Majumdar SR, Johnson JA, Varney J, McAlister FA. A systematic review of drug therapy to delay or prevent type 2 diabetes. *Diabetes Care* 2005;28:736-44.
- Kelton JG. The pathophysiology of heparin induced thrombocytopenia: biological basis for treatment. *Chest* 2005;127(2):9S-20S.
- Ghali WA, Wasil BI, Brant R, Exner DV, Cornuz J. Atrial flutter and the risk of thromboembolism: A systematic review and meta-anylysis. *Am J Med* 2005 Feb;118(2):101-7.
- Call SA, Vollenweider MA, Hornung CA, Simel DL, McKinney WP. Does this patient have influenza? *JAMA* 2005 Feb 23;293(8):987-97.
- Top 200 brand-name drugs by retail dollars in 2004. *Drug Topics* 2005 Feb 21;149(4):18.
- Top 200 generic drugs by retail dollars in 2004. *Drug Topics* 2005 Feb 21;149(4):21.

# FROM THE LAY LITERATURE about medicine ...

Hypertension...More Than Just A Headache?... Elevated systolic blood pressure and elevated or low diastolic blood pressure have been linked to a decline in cognitive function in older adults according to the most recent data from the Baltimore Longitudinal Study of Aging. The relationship between blood pressure and cognitive function does not appear to be linear, and age, educational level, and use of blood pressure drugs may have greatly impacted the results of this study. For more information see the March issue of *Hypertension*. http://www.reuters.com/newsArticle.ihtml?type=healthNews&storyID=7856353

Laughter May Indeed Be The Best Medicine....A research presentation at this month's American College of Cardiology meeting reports that laughter may in fact cause physiologic vasodilatation with a resulting increase in blood flow. Study participants were shown two different movies two days apart and received baseline readings of blood pressure and blood vessel dilation with follow-up readings every 15 to 30 minutes thereafter. Saving Private Ryan was emotionally stressful to the patients causing vasoconstriction and an approximate decrease in blood flow of 35%. King Pin produced laughter in most patients resulting in vasodilatation and an increase in blood flow of 22% or greater. The benefits from laughter on the endothelium are similar to those from aerobic exercise. So, what's the final prescription? Thirty minutes of exercise 3 times a week, and 15 minutes of laughter on a daily basis, is probably good for you. <a href="http://www.usnews.com/usnews/health/briefs/heart/hb050310a.htm">http://www.usnews.com/usnews/health/briefs/heart/hb050310a.htm</a>

Pharmaceutical Care to the Rescue....Recent studies indicate that roughly half of all Americans do not follow physician's instructions or take their medication appropriately. The top three reasons for non-adherence are misunderstanding of instructions, forgetfulness, and denial of the significance of the illness. A new trend in the third party market is that of "pay for performance" where physician reimbursement is linked to direct patient outcomes. Some physicians are concerned that they will be penalized for behaviors that are not in his or her direct control. Margaret O'Kane, president of the National Committee for Quality Assurance, admits, "we still do not know much about how to motivate patients." As a result, a small number of physicians are turning to the help of disease state management companies who monitor patients via telephone calls. The companies are paid under separate contract with the hope that patient outcomes are improved and the physicians' are looked upon more favorably by the third party companies. Does anyone see a huge potential for pharmacists in this area?

Landro L. Enforcing treatment vexes doctors. The Wall Street Journal 2005 March 9;Sect. D:9 (col. 1)

#### **Update** ...

**Job Security**....A recent review suggests that the national pharmacist shortage continues but, investigators have recently noticed a slight downward trend in the severity. For more detailed information about your state's current status see the article below.

Knapp KK, Quist RM, Walton SM, Miller L. Update on the pharmacist shortage: National and state data through 2003. *Am J Health-Syst Pharm* 2005;62:492-9.

**Chiron Back in Business**....British regulators have finally lifted the ban on Chiron Corporation to allow the company to resume production of flu vaccines. It remains to be determined if Chiron will be able to supply products to the United States. Industry experts hope that the wrinkles will be ironed out prior to the next flu season in order to avoid the shortage madness of last year.

**Mucinex**<sup>®</sup> ... by Adams, is a long-acting guaifenesin product. It is being promoted by implying it is a new drug when in fact, it is not and is also in a GRAS category. What is new is that the company applied for, and received FDA approval (although it was not required) and now the FDA has removed all single-ingredient, extended release guaifenesin products from the market until manufacturers apply for, and receive FDA approval. It does not require a prescription. For the moment, Adams has an exclusive market.

Abramowicz M, ed. Mucinex. Med Lett Drugs Ther 2005 Feb 14;47:16.

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

Doorenbos NJ. Antimicrobial Desoxy-azasteroids. 2004 AOCS Virtual Annual Meeting Tape. May 9 - 12 Meeting, American Oil Chemists Society, 1-30 (June, 2004).

#### TIMELY TOP TECH TIP ...

Even Cell Phones are getting the Flu....A new virus called the Commwarrior. A virus has been spreading this week through cell phones that run on the operating software Symbian (especially Bluetooth compatible phones). This little bug is sent through multimedia messages, and when downloaded, constantly replicates itself by sending messages to every person in your contact list until the battery is completely drained! Representatives from Nokia say that the cell phone industry is ready to fight these little critters since they tend to spread much slower than computer viruses. For all of you tech savvy pharmacists with PDA/cell phone combos beware of any messages from unknown sources!

http://money.cnn.com/2005/03/08/technology/personaltech/mobile\_virus.reut/index.htm?cnn=yes

# <u> The last "dose" ...POLI-TICKS???</u>

An article in *The Lancet* reports a similarity between the patterns of distribution of Lyme disease cases in the United States in 2002 and the states voting for John Kerry in the 2004 Presidential election. The 19 states voting for Kerry account for over 95% of the Lyme disease cases caused by the spirochete *Borrelia burgdorferi*. Another interesting difference, in most southern states (Bush supporters), Lyme disease is transmitted through an entirely different vector, the "Lone Star tick" which produces a unique rash on the bite victims known as southern-tick-associated rash illness (STARI). One editorial suggests that high incidences of Lyme disease in a patient population may be "protective against the hazards of being a Republican". What is the author's conclusion? Further study is needed in both STARI and Presidential Elections. *Our conclusion*....No matter what your political preference, Spring is fast approaching, and be sure to take special precautions when outside to minimize your exposure to tick-borne illnesses! Nadelman RB, Wormser GP. Poly-ticks: Blue state versus red state for Lyme disease. *Lancet* 2005;365(956):280.