

# AU InforMed

Volume 4 Number 32 (Issue 129)

Wednesday, October 25, 2006



## Key Inforbits

- 2 new drugs and 2 MedWatches
- Pharmaceutical industry “ethics” in the news
- Huge study on serious adverse drug reactions
- Sizzurp, a not-so-pleasant cocktail
- Therapeutic harmonica
- **Happy Pharmacy Month!**

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

**New Drug** ... The FDA announced October 23, 2006 the approval of **ciclesonide nasal spray (Omnaris™** by Altana Pharma US), a new corticosteroid drug. It is indicated for the treatment of nasal symptoms associated with seasonal and perennial allergic rhinitis, commonly known as hay fever, in adults and children 12 years of age and older.

FDA approves new treatment of allergies. *FDA News*. 2006 Oct 23; P06-172.

<http://www.fda.gov/bbs/topics/NEWS/2006/NEW01495.html>

**New Drug** ... The FDA announced approval of **sitagliptin phosphate (Januvia™** by Merck and Co., Inc.) tablets, on October 17, 2006. It is the first in a new class of drugs known as DDP-4 inhibitors that enhances the body's ability to lower elevated blood sugar. Sitagliptin is approved for use in addition to diet and exercise in patients with type 2 diabetes, alone or in combination with metformin or a PPAR (peroxisome proliferator-activated receptor gamma) agonist. Sitagliptin prolongs the activity of proteins that increase the release of insulin after blood sugar rises by blocking an enzyme (dipeptidyl peptidase IV or DPP-IV) which breaks down these proteins, leading to better blood sugar control. It may also be an expensive drug, estimated cost of \$3 to \$6 per day. A combination tablet (sitagliptin and metformin) is being readied for approval, possibly next Spring. In addition, the second drug of this class (by Novartis) may be approved soon.

FDA approves new treatment for diabetes. *FDA News*. 2006 Oct 17; P06-169.

<http://www.fda.gov/bbs/topics/NEWS/2006/NEW01492.html>

Associated Press. Merck diabetes drug wins federal approval. *USA Today*. 2006 Oct 17.

[http://www.usatoday.com/news/health/2006-10-17-diabetes\\_x.htm](http://www.usatoday.com/news/health/2006-10-17-diabetes_x.htm)

**MedWatch** ... Novartis and FDA announced revisions to the Precautions section of the prescribing information, describing the occasional occurrence of severe congestive heart failure and left ventricular dysfunction in patients taking **Gleevec® (imatinib)**. Most of the patients with reported cardiac events had other co-morbidities and risk factors, including advanced age and previous medical history of cardiac disease. Patients with cardiac disease or risk factors for cardiac failure should be monitored carefully and any patients with signs or symptoms consistent with cardiac failure should be evaluated and treated.

Read the complete MedWatch 2006 Safety summary, including links to the Sponsor's Dear Healthcare Professional Letter and updated prescribing information regarding this issue at:

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

**MedWatch** ... The FDA and CDC have updated an October 2005 alert regarding reports of **Guillain-Barré Syndrome (GBS) following administration of Meningococcal Conjugate Vaccine A, C, Y, and W135, manufactured by Sanofi Pasteur**. To date a total of 15 confirmed cases of GBS among individuals 11-19 years of age occurring within six weeks of vaccination with Menactra® have been reported to the Vaccine Adverse Event Reporting System (VAERS). Two additional cases have been confirmed in persons 20 years of age and older. All individuals are reported to be recovering or have recovered. While the cases reported suggest a small increased risk of GBS following immunization with Menactra®, the limitations in VAERS, and the uncertainty regarding background incidence rates for GBS require that these findings be viewed with caution. At this time, CDC and FDA cannot determine with certainty whether Menactra® does increase the risk of GBS or to what degree. Currently, there are no changes in recommendations for vaccination; individuals should continue to follow their doctors' advice. FDA asks any persons with knowledge of possible GBS cases occurring after receiving Menactra® to report them to VAERS at <http://www.vaers.hhs.gov> or at 1-800-822-7967. Read the complete MedWatch 2006 Safety summary, including links to the FDA and CDC update documents, at: <http://www.fda.gov/medwatch/safety/2006/safety06.htm#Menactra> Update: Guillain-Barré syndrome among recipients of Menactra® meningococcal conjugate vaccine – United States, June 2005 – September 2006. *MMWR*. 2006 Oct 20;55(41):1120-1124. <http://www.cdc.gov/mmwr/preview/mmwrhtml/mm5541a2.htm>

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

**Practice guidelines or marketing brochure** ... In a rather straightforward “Perspective” article in the *New England Journal of Medicine*, the authors have harsh words concerning pharmaceutical company involvement in practice guideline development. They make the case that Eli Lilly unduly influenced practice guidelines for treatment of sepsis in favor of their new (and expensive) product drotrecogin alfa (Xigris®) by heavily funding several efforts in that direction and making the guidelines a part of a comprehensive marketing plan. References and timelines are offered in support.

Eichacker PQ, Natanson C, Danner RL. Surviving sepsis – Practice guidelines, marketing campaigns, and Eli Lilly. *N Engl J Med*. 2006 Oct 19;355(16):1640-42.

**Grassroots professionalism** ... In an unrelated, but very applicable article, a medical school professor makes the case that medicine has not done well against the rise of the healthcare corporation and that an instillation of professionalism as a core medical competency should be used as a primary weapon. In addition, this must be reinforced by community-based peer-review including state review boards. To paraphrase an old adage, “if a profession doesn’t police itself, someone will step in and do it for them.”

Hafferty F. The elephant in medical professionalism’s kitchen. *Acad Med*. 2006 Oct;81(10):906-14.

**More on ADR’s** ... A large, active surveillance study was designed to describe the frequency and characteristics of adverse drug events (ADE’s) that resulted in an Emergency Room (ER) visit. The study spanned two years and resulted in 21,298 reports of ADE’s. The author’s then extrapolated population estimates from the data. It was estimated that ADE’s accounted for 2.5% of ER visits for unintentional injuries and 0.6% of ER visits for all causes. The elderly were more likely to have suffered an ADE; insulins, warfarin and amoxicillin were the most commonly implicated drugs. There is a lot more data in this study. Budnitz DS, Pollock DA, Weidenbach KN, Mendelsohn, Schroeder TJ, Annest JL. National surveillance of emergency department visits for outpatient adverse drug events. *JAMA*. 2006 Oct 18;296(15):1858-66.



**Too many, too few ...** In a study of 194 patients, investigators looked at both overuse and under use of medications in an elderly, VA Medical Center population (mean age, 74.6 years). Some of the data uncovered included 65% of patients taking inappropriate medications; 37% taking a



“Beers drugs-to-avoid” and 57% taking a drug that was ineffective, not indicated or duplicative. Medication under use was seen in 64% of patients; 13% were taking all appropriate medications. Also, the more drugs being taken, the more likely there would be inappropriate drug therapy; under use was not correlated with total drugs taken. Is this a message?? 87% of patients need help with medications!

Steinman MA, Landefeld CS, Rosenthal GE, Berthenthal D, Sen S, Kaboli PJ. Polypharmacy and prescribing quality in older people. *J Am Geriatr Soc.* 2006 Oct;54(10):1516-23.

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

- Mozaffarian D, Rimm EB. Fish intake, contaminants, and human health. *JAMA.* 2006 Oct 18;296(15):1885-1899.
- Russell JA. Management of sepsis. *N Engl J Med.* 2006 Oct 19;355(16):1699-1713.
- Donaldson M, Goodchild JH. Oral health of the methamphetamine abuser. *Am J Health-Syst Pharm.* 2006 Nov 1;63:2078-82,

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

**Downside of diabetes ...** Although the new drug, sitagliptin, and for most other drugs for diabetes, diet and exercise is a coprescription. It is often first prescribed, then drugs next. A recent article gives voice to common clinician frustration that most patients just will not change and that drug therapy is inevitable. Therapists make the case that just telling a patient to “lose weight and exercise” will not influence behavior and there should be specific programs to help the patients. However, when a pill is available, incentive decreases dramatically...

Kolata G. When advice is sound, but ignored. *New York Times.* 2006 Oct 17.

[http://www.nytimes.com/2006/10/17/health/17pros.html?\\_r=1&ref=health&oref=slogin](http://www.nytimes.com/2006/10/17/health/17pros.html?_r=1&ref=health&oref=slogin)

**Sizzurp, Lean, Purple Drank ...** are just some of the names of an apparently popular “cocktail” of a codeine-containing syrup (Rx), mixed with Sprite® or similar soft drink, a Jolly Rancher®, and poured over ice. A popular rap music DJ died from a codeine overdose. This mixture seems to be spreading across the south. A pint of syrup may wholesale to a pharmacy for \$12, sold to dealers for about \$300 and by the time it gets to users, usually sold by the ounce, the price may be up to \$640 to \$1360 per pint. Strangely enough, there is a common misperception that prescription drugs are medicine and therefore safe. How many kids will pay the ultimate price to discover the fallacy of that argument!



DEA warns of soft drink-cough syrup mix. *USA Today.* 2006 Oct 19.

[http://www.usatoday.com/news/health/2006-10-18-lean\\_x.htm](http://www.usatoday.com/news/health/2006-10-18-lean_x.htm)

**Rx for lung capacity = Harmonica ...** In part an effort to keep the harmonica from extinction, but several enthusiasts are touting harmonica playing as a way to increase lung function, mostly in the elderly, but also in patients with asthma, emphysema and chronic bronchitis. Due to the inhalation and exhalation through pursed lips, as required to play the instrument, it is thought more effective than other wind instruments, and is of course, easy to do. While little research exists in support, the American Lung Association and some pulmonologists at least support the concept. Who knows, it could be beautiful music!



Begley S. One more reason to play harmonica: It's good for the pipes. *Wall Street Journal.* 2006 Oct 19; p. A1.

## Update ...

**Freshman 15 is on a diet ...** Good news, more or less. The dreaded “freshman 15” or those 15lbs gained during the first year of college, has lost weight. Now the average gain is estimated around 8lbs. While most of this heavy research concerns college freshman, most college students are still susceptible to the same environments and pressures. If you have gained some wisdom concerning healthy eating and exercise, that’s good! Getting older has its own problems! Some good, basic advice on diet and exercise are also in this article.

Hellmich N. Freshman 15 drops some pounds. *USA Today*. 2006 Oct 23.

[http://www.usatoday.com/news/health/2006-10-22-freshman-weight\\_x.htm](http://www.usatoday.com/news/health/2006-10-22-freshman-weight_x.htm)

## NEW RESOURCES in the DILRC ...

**New Journal.** *Pharmacy Education* is in its 6<sup>th</sup> volume and is primarily a European-based journal. It is relatively pricy so your feedback will determine whether or not we keep it. Hard copy issues are in the DIC; it is also available online, so mark it in your Favorites.



<http://www.metapress.com/link.asp?id=300275>

- Drug Facts and Comparisons. 61<sup>st</sup> ed. St. Louis: Facts and Comparison/Wolters Kluwer Health, 2007.

## TIMELY TOP TECH TIP ...

**Cell phone traps ...** So what do you do with that old cell phone when you upgrade to the latest model? Erase and resell, right? Might want to rethink that! A recent article details just how easy it is for those of nefarious intent to extract data from the phone you just sold them on the internet. With so much data “smart phones” with addresses, willingly handing over the keys erase, and perhaps better, talk to someone who knows what they are doing!



Nakashima E. Used cellphones hold trove of secrets that can be hard to erase. *Washington Post*. 2006 Oct 21; p. A01. <http://www.washingtonpost.com/wp-dyn/content/article/2006/10/20/AR2006102001647.html?referrer=email>



## The last “dose” ...

October is ...



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