

# FYDI

FOR YOUR DRUG INFORMATION



October 5, 2009

Greetings from the Drug Information Center at the University of Louisiana at Monroe College of Pharmacy!

We hope you find this newsletter helpful in keeping you well-informed.

Please contact us and let us assist you with any drug information needs.

## ULM COLLEGE OF PHARMACY

### Drug Information Center



PhongPhu Dang, PharmD Candidate 2010  
Jessica Robinson, PharmD Candidate 2010  
Gregory W. Smith, PharmD

Drug Information Services  
318.342.5501  
[druginfo@ulm.edu](mailto:druginfo@ulm.edu)

#### In this issue...

Special—Flu  
FDA MedWatch Alerts  
News Items  
Drug Approvals  
Drug Information Center

#### All About the Flu

##### H1N1 Vaccinations Expected to start October 6

Of the first 6 million doses of swine flu vaccine, most will be the live virus, nasal spray vaccine. By mid-October, another 45 million doses, including traditional flu shots, will be distributed to states based on population.

[View Article](#)

##### Live versus Inactivated Flu Vaccines

A review of the 2007-2008 flu season concluded that both the inactivated vaccine and the live attenuated virus were effective in preventing symptomatic influenza, with the inactivated being superior.

[View Summary](#)

[View Article \(N Engl J Med\)](#)

##### Vaccines may Offer More than Just Flu Prevention for Cardiac Patients

With a review of cases, a prediction was made that influenza virus may trigger cardiac arrest; therefore, the H1N1 and seasonal flu vaccines are expected to offer protection for cardiac patients.

[View Summary](#)

[View Article \(Lancet Infect Dis\)](#)

##### Use of Influenza A (H1N1) 2009 Monovalent Vaccine

[View Recommendation](#)

##### Have Additional Questions about the H1N1 Flu?

[View Questions & Answers 2009 H1N1 Influenza Vaccine](#)

#### FDA MedWatch Alerts

##### Changes to Reference Standard for Heparin Unit Dose

The USP has modified the reference standard for heparin's unit dose to correspond with the World Health Organization's International Standard, which is about 10% less potent than the former USP unit dose. "Although the FDA-approved labeling for heparin has not changed, including the recommended doses, it is essential that health care professionals be aware of the potential difference in potency between the old and new vials of heparin when administering the drug," stated John Jenkins, M.D. director of the Office of New Drugs in the FDA's Center for Drug Evaluation and Research.

[View Alert](#)

##### Boxed Warning for Promethazine Hydrochloride Injection

The FDA now requires a boxed warning to emphasize the risk for severe tissue damage when injected into the artery or under the skin. The preferred route of administration is deep intramuscular.

[View Alert](#)

##### Reports of Acute Pancreatitis associated with Sitagliptin

Acute pancreatitis has been reported in a large number of people who received sitagliptin (Januvia, Janumet). The prescribing information will be revised to highlight the warning and recommend monitoring for pancreatitis with initiation or dose changes of sitagliptin.

[View Alert](#)

##### Tylenol Oral Suspension Products Recalled

Several lots of Tylenol oral suspension have been recalled due to possible contamination of bacteria during the manufacturing process. No reports of subsequent illness have been made.

[View Alert](#)

[View Recalled Lots](#)

##### Increased adverse effects with Exjade (deferasirox)

Reports of increased adverse reactions have occurred in patients using Exjade (deferasirox) who have myelodysplastic syndrome (MDS) and are over sixty years old.

[View Alert](#)

##### New Warnings and Precautions for Intelence (etravirine)

Intelence (etravirine) has been reported to cause severe skin or hypersensitivity reactions, which could lead to death or organ dysfunction.

[View Alert](#)

[View Letter](#)

##### Graduated Oral Syringe should Match Oseltamivir Instructions

Tamiflu suspension prescriptions should be written in milligrams, not milliliters or teaspoons. Pharmacists should ensure that the correct measuring device is given to patients if the prescription has instructions for administration in milliliters.

[View Alert](#)

[View Manufacturer Letter](#)

#### News Items

##### Decrease in Heart attacks with Smoke-free Zones

The number of heart attacks have decreased by 17% in just one year after the smoking ban in North America and Europe. A large study published in *Circulation* projects this number to reach 36% by a three-year period.

[View Article](#)

##### SSRIs Linked to Heart Defects in Newborns

The risk of heart defects in the newborn is increased with administration of antidepressants during the first trimester. These effects were primarily seen with sertraline and citalopram, both of the SSRI group. A study concluded the birth defect may be a class effect of all SSRIs.

[View Article](#)

[View Article \(BMJ\)](#)

##### New, Improved Way for CPR without Mouth-to-Mouth

As concluded by a study presented in *Circulation*, the outcomes were substantially better for the cardiac arrest patient who received chest compressions 60 to 80 percent of the time during CPR compared to those who received fewer chest compressions. The American Heart Association updated the CPR guidelines in 2008 recommending the bystanders to only conduct uninterrupted chest compressions. With the new implementation, the "germs" from mouth-to-mouth are not an issue.

[View Article](#)

##### Some Good News with the AIDS Vaccine

More than 16,000 adult volunteers in Thailand were part of the Phase III clinical trial demonstrating the safety and somewhat effectiveness of the investigational HIV vaccines, ALVAC<sup>®</sup> HIV and AIDSVAX<sup>®</sup> B/E. The final results concluded a decreased rate of the HIV infection by 31.2% with the combination vaccine as compared to the placebo.

[View Article](#)

[View Press Release](#)

##### Angiotensin-Receptor Blockers not effective for Microalbuminuria

Two studies with telmisartan and candesartan concluded the ARBs are no better than placebo in preventing microalbuminuria. ACE inhibitors, that are known to prevent microalbuminuria in people with diabetes, are still considered superior to ARBs.

[View Article](#)

[View Article I \(Ann Intern Med\)](#)

[View Article II \(Ann Intern Med\)](#)

##### Statins may be in the Future for COPD Treatment

Statins have anti-inflammatory and pleiotropic effects in addition to the lipid lowering effects, which have been proven beneficial in numerous studies. The evidence is not considered strong enough and more studies are needed to determine if a place for statins exists in the COPD treatment regimen.

[View Article](#)

##### Confusion for Diabetics with Phenergan Elixir

The statements 'sugar-free' and 'not suitable for diabetics' are both printed on the label of Sanofi-aventis' Phenergan Elixir 5mg/5ml, 100ml. The product does not contain sucrose, glucose or fructose, so technically it is sugar-free and there is no risk of dental caries. But, it does contain hydrogenated glucose, which is not suitable for diabetic patients.

[View Drug Safety Information Letter](#)

##### Use Of Diabetes Drug Linked To Higher Risk Of Bone Fractures

The study concluded that fracture risk is increased during periods of exposure to thiazolidinediones (rosiglitazone and pioglitazone) compared with unexposed periods. The increased risk is observed in both men and women and at a range of fracture sites. The risk also increases with longer duration of use.

[View Article](#)

#### Drug Approvals

##### FDA Approves First Drug for Treatment of Peripheral T-cell Lymphoma

The FDA has approved Folutyn (pralatrexate), the first treatment for a form of cancer known as Peripheral T-cell Lymphoma (PTCL). It is approved for patients who have relapsed, or have not responded well to other forms of chemotherapy.

[View FDA News Release](#)

##### FDA Approves New Drug to Treat Psoriasis

The FDA approved Stelara (ustekinumab), a biologic product for adults who have a moderate to severe form of psoriasis.

[View FDA News Release](#)

##### Combo antihypertensive Valtorna approved by the FDA

The FDA has approved Valtorna (aliskiren and valsartan) tablets. Valtorna is indicated for the treatment of high blood pressure in patients not adequately controlled on aliskiren or angiotensin receptor blocker monotherapy and as initial therapy in patients likely to need multiple drugs to achieve their blood pressure goals.

[View Novartis News Release](#)

##### Safer Colchicine Dosing Regimen Approved

The FDA has approved the first single-ingredient oral colchicine product, Colcrys, for the treatment of Familial Mediterranean fever and acute gout flares. The FDA-approved label includes more detailed drug interaction warnings and recommended dosing adjustments.

[View Article](#)

[View Alert](#)

[View Prescribing Information](#)

## ULM COLLEGE OF PHARMACY Drug Information Center

The Louisiana Drug Information Center (DIC), which became operational in 1995, is located on the first floor of the College of Pharmacy (COP) Bienville Building of the University of Louisiana at Monroe (ULM). The operation objectives of the DIC are centered around the three core components of the University mission of service, teaching and scholarship, with a primary focus on service. These objectives are as follows:

- ◆ To provide current, comprehensive, objective and need-specific information to the healthcare professional community of the State of Louisiana for clinical decision making and for the delivery of quality patient care.
- ◆ To serve as an information resource center for faculty, students, and healthcare professionals.
- ◆ To teach pharmacy students, pharmacists, and other healthcare providers the skills of efficient literature retrieval, critical evaluation of the information, and accurate communication of a response.
- ◆ To conduct research for the advancement of drug information and pharmacy practice.

The service component makes up the largest portion of the DIC operation and includes providing assistance with areas such as literature retrieval, evidence-based recommendations and off-label use of medications. We respond to drug information requests from healthcare professionals regarding the following areas:

Adverse Drug Events  
Availability of Products  
Complimentary and Alternative Medicine  
Clinical Kinetics  
Drug Dosage and Scheduling  
Drug Identification  
Drug Interactions  
Drug Regulations/Laws  
Drug Use Evaluation Support  
Institutional Review Board Support  
Investigational/Foreign Drugs  
IV Compatibility  
Laboratory Interpretation  
Pharmacoeconomics  
Pharmacy and Therapeutics Committee Support  
Pregnancy and Lactation  
Product Compounding  
Therapeutic Drug Monitoring  
Therapeutic Uses/Drugs of Choice  
Toxicology  
Travel/Health Information

Currently, the DIC has a new phone number and a healthcare provider-focused service for the State of Louisiana. As of September 2007, the DIC discontinued public services and provides information services exclusively to healthcare professionals. Additionally, this service is available to Medicaid providers through support from the Louisiana Medicaid Pharmacy Benefits Management Program.

Please contact us and let us assist you with any drug information needs at our new number for Healthcare Professionals Drug Information Service:

**318-342-5501**

[University of Louisiana at Monroe College of Pharmacy  
Drug Information Center](#)

View [previous issues](#) of the FYDI newsletter.

For comments and suggestions please email [druginfo@ulm.edu](mailto:druginfo@ulm.edu).

Please click on the following link to unsubscribe or reply to this newsletter with [CANCEL FYDI](#) as the subject.

Disclaimer: No information source can replace clinical judgment applied to a specific case. Some of the drug therapy we write about will be outside the labeled indications for specific products. References will be provided when possible. Consult these references, product labeling, and/or give us a call if we can help with specific cases. This newsletter is supported by the University of Louisiana at Monroe College of Pharmacy and is not intended for commercial promotion.