FYDI

FOR YOUR DRUG INFORMATION

March 27, 2014

Greetings from the Drug Information Center at the University of Louisiana at Monroe College of Pharmacy!
We hope you find this newsletter helpful in staying well-informed.
Please contact us and let us assist you with any drug information needs, such as full-text article retrieval. In this issue, find out more about the services the DIC has to offer.

ULM COLLEGE OF PHARMACY Drug Information Center

Taiwo Aigberua and Dottie Shelton,
PharmD Candidates
Gregory W. Smith, PharmD, Director,
Drug Information Services
318.342.5501
druginfo@ulm.edu

In this issue…

FDA MedWatch and Other Safety Alerts

Access to full-text articles may require subscription. Contact the Drug Information Center for literature retrieval assistance.

Drug Recall: Pleo Homeopathic Drug Products
Tera Medica has announced a voluntary recall of some lots of Pleo Homeopathic drug products due to probable presence of penicillin.
View Recall

Product Recall: Freestyle and Freestyle Flash Glucometers
Abbott Diabetes Care has recalled Freestyle and Freestyle Flash glucose testing meters due to possible abnormal low readings when testing blood glucose with Abbott Freestyle test strips.
View Recall

Drug Recall: Reufoman Plus Tablets
The FDA has issued a warning stating some lots of Reufoman Plus tablets, marketed as dietary supplements for pain relief, contain undeclared active ingredients that are potentially harmful to patients.
View Alert

Drug Recall: Custom Procedural Tray/Kit, 1% Lidocaine HCl Injection, USP, 10 mg/mL
Hospira, Inc. has recalled one lot of lidocaine product due to confirmed customer reports of visible particulates.
View Recall

Drug Safety: Azithromycin/Levofloxacin
A recent study published by the Annals of Family Medicine suggests that azithromycin and levofloxacin are associated with cardiac arrhythmias and death.
View Alert

Drug Recall: Atorvastatin Calcium (Ranbaxy Product)
Ranbaxy Laboratories Ltd has recalled some batches of generic Lipitor due to product mislabeling that may result in possible overdose and serious side effects in patients.
View Alert

Drug Safety Alert: Doribax
The FDA issued a warning about the use of Doribax (doripenem) to treat pneumonia in mechanically ventilated patients.
View Alert

Drug Recall: Dianeal PD-2 Peritoneal Dialysis Solution
The FDA announced Baxter's voluntary recall of Dianeal PD solution with 1.5% Dextrose due to contamination with mold.
View Alert

Drug Recall: Pfizer's Effexor XR 150 mg and Greenstone's Venlafaxine HCL 150 mg ER Capsules
The FDA announced voluntary recall of two lots of Effexor XR 150 mg capsules by Pfizer and one lot of venlafaxine 150 mg capsules by Greenstone due to possible packaging adulteration with Tikosyn capsules.
View Alert

Drug Recall: Etomidate Injection by Pfizer-Mylan
The FDA has issued a voluntary recall for Etomidate injection due to presence of particulates and improper labeling.
View Alert

Drug Recall: L-citrulline by Medisaca
The FDA has announced that certain lots of L-citrulline have been recalled due to subpotency.
View Alert

Drug Recall: Weight Reducing Formulas by MyNicKnax
MyNicKnax and FDA announced the recall of Fruta Planta weight loss formula due to harmful active ingredients found in some manufactured lots.
View Alert

Drug Recall: Acetylcysteine Solution 10% by Roxane
The FDA announced a voluntary recall of acetylcysteine due to the presence of glass particles in the solution.
View Alert

Drug Safety Communication: Saxagliptin
The FDA is investigating the risk of developing heart failure in patients with type 2 diabetes taking saxagliptin, a DPP-4 inhibitor.
View Alert

Calcium Gluconate 10% Injections Made by Rx Formulations Recalled
Rx Formulations is recalling one lot of calcium gluconate injection due to microbial contamination.
View Alert

View All Medwatch Alerts
Sign Up to Receive Medwatch Alert Emails
Medwatch Voluntary Reporting Form

Back to Top

News Items

Hemoglobin A1c Offers No Significant Benefit in Cardiovascular Risk Outcomes
A new study suggests that additional assessment of HbA1c offers little or no benefits to cardiovascular risk prediction.
View Study

Widely Used Liquid Nicotine for E-Cigarettes Leads to Increased Adverse Events
The increased popularity of non-FDA regulated e-cigarettes for smoking cessation has led to an increase in accidental poisonings and adverse effects in children and adults due to the very potent e-liquid that can be harmful whether ingested or absorbed through the skin.
View Item

Ceftriaxone Linked to Acute Renal Failure in Pediatrics
Pediatrics Acute Renal Failure has been associated with the use of ceftriaxone according to recent study.
View Abstract

Phenylephrine and Acetaminophen Combo May Cause Serious Adverse Effects
According to a new study, acetaminophen increases phenylephrine blood levels four times higher and may lead to serious adverse effects including high blood pressure, dizziness, and tremors.
View Item

Statin May Help Slow Progression of Secondary Multiple Sclerosis
New research suggests that simvastatin slows brain atrophy in patients with secondary multiple sclerosis.
View Item
View Study

FDA Continues to Defend Zohydro Despite Lawmakers Disapproval
The FDA chief defends Zohydro, while lawmakers continue to introduce bills that will force the FDA to withdraw the drug and prevent approval of similar drugs that are not tamper resistant.
View Item

Low-Range Prehypertension May Predispose Patients to Stroke
A recent study demonstrated that people with low-range prehypertension are at an increased risk of stroke, although stroke is primarily associated with high-range prehypertension.
View Abstract

Nicotine Patches Yield No Better Result in Pregnant Women
New research shows that, despite adjustment of nicotine (patch) doses to suit actual dose in cigarettes, there are no benefits to pregnant women and newborn.
View Abstract

Study Suggests Glucosamine Provides No Benefit for Chronic Knee Pain
A study suggests there is no structural benefit or decrease in cartilage deterioration associated with glucosamine in patients taking the supplement for 6 months.
View Item

Pharmacy Provider Status Updates
The American Pharmacists Association announces the introduction of a bill in Congress that may grant pharmacists provider status and provide coverage for patient care services provided by pharmacists.
View Item

Women's Health Initiative Calcium and Vitamin D Trial
A new study shows that vitamin D supplementation may help lower bad cholesterol in post-menopausal women.
View Abstract

Oxytocin and HCG Hormone Combo May Benefit Patients with Intractable Pain
Researchers have determined that simultaneous use of two natural hormones, oxytocin and Human Chorionic Gonadotropin (HCG), which are normally released in large amounts during and after childbirth, may result in decreased need of opioid analgesics and relief for intractable pain.
View Item

New York City Health Department Reports Measles Outbreak and Encourages Vaccination
The Health Department in NYC reports identification of 16 cases of measles, four cases requiring hospitalization, and urges all residents to become vaccinated with MMR vaccine.
View Item

DEA One Step Closer to Rescheduling Hydrocodone Combination Products
A Notice of Proposed Rulemaking for rescheduling hydrocodone combination products from Schedule III to Schedule II has been published in the *Federal Register* by the DEA.
View Item

Study Shows CKD Patients with Atrial Fibrillation May Still Benefit From Warfarin Therapy
Research shows that patients with chronic kidney disease (CKD) on warfarin therapy for atrial fibrillation may be at increased risk of adverse bleeding events; however, a recent study discovered these patients benefited from warfarin therapy.
View Item

Spiriva Respimat Reduces Severe Exacerbations in Asthma Patients
Spiriva Respimat (tiotropium) was found to improve lung function and decrease severe exacerbations in asthma patients already on maximum doses of other medications.
View Item

Generic Plan B Available Over-the-Counter with No Age Restrictions
The FDA has lifted the 17 and older age restriction for over the counter generic Plan B (the morning-after pill).
View Item

Exposure to Secondhand Tobacco Smoke Linked to Adverse Pregnancy Outcomes
A recent study conducted by the Women's Health Initiative has determined secondhand tobacco exposure is associated with increased risk of adverse pregnancy outcomes including miscarriage, stillbirth, and ectopic pregnancy.
View Item

Appropriate MMR Vaccination Schedule Associated with Fewer Future Hospitalizations
Researchers have observed fewer rates of hospital admissions for other infections in children who received their measles, mumps, rubella (MMR) vaccine on schedule.
View Item

Emergence of Polio-Like Illness in California
Cases in a recent study included children with paralysis explained by abnormal spinal cord MRI scans, and there are between 20-25 reported cases to date of this polio-like syndrome.
View Item

Back to Top

Drug Approvals

FDA Approves ANDA for Atovaquone Oral Suspension
Amneal Pharmaceuticals' atovaquone, the generic version of GlaxoSmithKline's Mepron, which is used to prevent *Pneumocystis jiroveci* pneumonia in immunocompromised patients, has received FDA approval of the abbreviated new drug application for an oral suspension.
View Item

FDA Approves Otezla for Psoriatic Arthritis
Otezla (apremilast), a phosphodiesterase-4 inhibitor, has been approved for treatment of psoriatic arthritis and is currently being studied for a possible treatment option for psoriasis and ankylosing spondylitis.
View Item
View Approval

Impavido Receives FDA Approval in U.S.
Impavido is used to treat the three main types of leishmaniasis, a parasitic disease acquired while traveling overseas to tropical areas, and is the first FDA-approved drug for treatment of 2 specific types of leishmaniasis, cutaneous and mucosal.
View Item

FDA Approves Xartemis XR for Acute Pain Management
FDA approves new Schedule-II drug manufactured by Mallinckrodt, Xartemis XR (oxycodone and acetaminophen), for acute pain management.
View Item

Apixaban Receives FDA Approval for DVT Prophylaxis Following Hip or Knee Replacement
Apixaban (Eliquis) receives new FDA approved indication for deep vein thrombosis (DVT) prophylaxis in patients who have undergone surgery for hip or knee replacement.
View Item

Aveed Receives Approval from FDA
Aveed, a replacement therapy for testosterone, has been approved by the FDA for treatment of male hypogonadism after previously being rejected three times.
View Item

Teva Receives Generic Approval for Evista in U.S.
Teva receives approval for generic Evista (raloxifene) and will begin shipping raloxifene 60 mg tablets within the next 30 days.
View Item

FDA Approves Once-Weekly Bydureon Pen for Type 2 Diabetes
Bydureon (exenatide) Pen is a pre-filled device used once-weekly in patients with Type 2 diabetes along with diet and exercise for improved blood glucose control.
View Item

Myalept Approved for Generalized Lipodystrophy/Leptin Deficiency
Myalept (metreleptin) for injection has been approved to treat individuals with congenital or acquired generalized lypodystrophy leading to complications of leptin deficiency such as diabetes mellitus and hypertriglyceridemia.
View Approval

Drug Approval: Northera for Neurogenic Orthostatic Hypotension
FDA approves Northera (droxidopa) for the treatment of neurogenic orthostatic hypotension.
View Approval

FDA Approves Vimizim for Treatment of Morquio A Syndrome
Vimizim (elosulfase alfa) is the first drug approved for treatment of a rare disorder in which an individual lacks the enzyme N-acetylgalactosamine-6-sulfate sulfatase (GALNS) called Morquio A Syndrome.
View Approval

Imbruvica Approved for Chronic Lymphocytic Leukemia
FDA grants accelerated approval of Imbruvica for treatment of chronic lymphocytic leukemia.
View Approval

FDA Approves Hetlioz for Non-24 Hour Sleep-wake Disorder in Blind Individuals
Hetlioz (tasimelteon), a melatonin receptor agonist, is the first drug approved for treatment of non-24 hour sleep-wake disorder in blind individuals.
View Approval

Back to Top

New Guidelines

Updated Recommendations from CDC for Laboratory Diagnosis of Chlamydia and Gonorrhea
CDC provides updated recommendations for screening tests involved in the laboratory diagnosis of *C. trachomatis* and *N. gonorrhoeae* infections.
View Recommendation

New European Clinical Practice Guidelines on Hyponatremia
Europe has released new clinical practice guidelines on the diagnosis and treatment of hyponatremia.
View Guideline

New Practice Guidelines for Management of Valvular Heart Disease
The American Heart Association and the American College of Cardiology have issued new practice guidelines for the management of patients with valvular heart disease.
View Guideline

Guideline Update: Prevention of Stroke in Nonvalvular Atrial Fibrillation
The American Academy of Neurology has issued an updated guideline on stroke prevention in patients with nonvalvular atrial fibrillation.
View Guideline

Access to full-text articles may require subscription. Contact the Drug Information Center for literature retrieval assistance.

Back to Top

ULM COLLEGE OF PHARMACY Drug Information Center

318-342-5501
Online Requests

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

The DIC has a new phone number and provides information services exclusively to the healthcare professionals of the State of Louisiana. 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**
Online Requests

Back to Top

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.

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.