FYDI

FOR YOUR DRUG INFORMATION QUESTIONS

December 12, 2013

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.

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COLLEGE OF PHARMACY
Drug Information Center

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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.

Safety Communication: Philips Healthcare's HeartStart Automated External Defibrillators (AED)
HeartStart AEDs may be unable to deliver needed defibrillator shock in cardiac emergency situation.
View Alert

Drug Safety Communication: Onfi
FDA warns that the anti-seizure drug Onfi (clobazam) can cause a rare but serious skin reaction that can lead to permanent harm and death.
View Alert

Hydravax Recalled
IQ Formulations has initiated a recall of one lot of Hydravax, which possibly contained an undeclared ingredient - a diuretic.
View Alert

FreeStyle and FreeStyle Lite Blood Glucose Test Strips Recalled
Abbot is initiating a voluntary recall of 22 lots of FreeStyle and FreeStyle Lite Blood Glucose Test Strips in the U.S. due to possible erroneous low blood glucose test readings.
View Alert

Baxter's Nitroglycerin in 5% Dextrose Injection Recalled
Baxter International Inc. has recalled one lot of Nitroglycerin 5% Dextrose Injection due to particulate matter found in one vial.
View Alert

Hospira GemStar Infusion System: Class I Recall
The potential and distal pressure sensor calibration can drift, which may result in the pump failing the Occlusion Operational Test and other issues with error reporting.
View Alert

Spacelabs Anesthesia Workstations and Service Kits: Class I Recall
A potential defect in the CAS III Absorber products has been discovered regarding the Bag-to-Vent switch that may fail.
View Alert

Rosiglitazone: Drug Safety Communication
The FDA is requiring the removal of the 2010 prescribing and dispensing restrictions for rosiglitazone medications after recent data demonstrated that rosiglitazone did not show an increased risk of heart attack.
View Alert

Adipotrim XT Recalled
Dexeo Rebapi Inc., is voluntarily recalling lot #052012 of Adipotrim XT, due to an undeclared drug ingredient.
View Alert

Lexiscan and Adenoscan: Drug Safety Communication
The FDA is announcing a ban because risk of heart attacks and death with the use of the cardiac nuclear stress test agents Lexiscan and Adenoscan.
View Alert

P-Boost and NatuRECT Recalled
Tendex has voluntarily recalled specific lots of P-Boost and NatuRECT due the products containing the undeclared drug, tadalafil.
View Alert

ReadRX Recalled Due to Undeclared Drug
The FDA determined that one lot of ReizRX contained the undeclared hydroxythiohomosildenafil, while another lot also contained aminotadalafil.
View Alert

Rhino 5 Plus, Maxtremezon, and Extenzone Recalled
An analysis has determined that these products contain undeclared desmethylcarbodenafil and dapoxetine.
View Alert

VitaliKOR Fast Acting Recalled
The FDA has discovered that these products contain undeclared vardenafil and tadalafil.
View Alert

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News Items

Measles Still a Threat According to CDC
Though the number of cases currently reported is relatively small compared to those prior to the 1963 introduction of the vaccine, CDC Director, Tom Frieden stated more work needs to be done regarding global commitment to vaccinate.
View Item

Novel Insulin Effective When Used Three Times a Week
Novo Nordisk's investigational ultra-long-acting insulin has shown to improve glycemic control with "less than one daily injection.
View Item

FDA Issues Compounding Guidance
With the implementation of the new Drug Quality and Safety Act, the FDA will be aggressive in regulating compounding in industry and traditional pharmacies.
View Item

Meta-analysis Comparing Warfarin to New Oral Anticoagulants for AF
The meta-analysis suggests that new oral anticoagulants improve outcomes in patients with non-valvular atrial fibrillation (AF) when compared to warfarin, at the expense of increased gastrointestinal bleeding.
View Item

Obesity Shows Shorter NAC Regimen More Tolerable
A shorter n-acetylcysteine (NAC) treatment regimen for acetaminophen poisoning has demonstrated a decreased risk for early vomiting compared with standard therapy.
View Item

LABA-Only Asthma Rx Higher Risk of More Hospital Stays
Hospitalization risk was higher among asthmatics that refilled only their long-acting beta agonist (LABA) prescriptions.
View Item

Expired Auto-injectors Approved for Use
Auto-injectors including atropine (Atropen), atropine/pralidoxime chloride (DuoDote), morphine sulfate, pralidoxime chloride, and diazepam from Meridian Medical Technologies have been approved by the FDA for use beyond expiration date as a last resort.
View Item

Study Shows Improved Outcomes Restarting Warfarin After Major Bleed
A retrospective study showed that patients with atrial fibrillation who stopped taking warfarin due to major gastrointestinal bleed and then subsequently restarted anticoagulation therapy had improved outcomes.
View Item

Possible Link Between High Sodium "Fizzy" Medicines and Higher Heart Risks
Millions of patients worldwide taking fizzy, dissolvable, dispersible, and soluble medicines have an increased risk of heart attacks and strokes due to the high salt content in these products.
View Item

Modafinil Reduces Severity of Depression When Taken with Antidepressants
A new study found that modafinil used in combination with antidepressants reduces the severity of depression more than antidepressants alone.
View Item

New Aggressive HIV Strain Leads to Faster AIDS Onset
A recently discovered HIV strain leads to significantly faster development of AIDS than existing prevalent forms.
View Item

Morning-after Pill Possibly Less Effective for Overweight Women
An emergency contraceptive manufactured in Europe will come with a new label in 2014, warning that the pill may not be effective for women over 176 pounds.
View Item

Study Finds Combo Antibiotic for UTI Matches Standard Drug
In a Phase III non-inferiority trial, an experimental antibiotic combination ceftolozane/tazobactam worked comparably to standard therapy for complicated tract infections.
View Item

Andexanet Granted Breakthrough Therapy Designation
Portola Pharmaceuticals receives breakthrough therapy designation from FDA for their investigational factor Xa inhibitor andexine.
View Item

Baby's Bones Not Weakened by RA Treatment
Dutch researchers found that neither the use of prednisone nor the presence of active rheumatoid arthritis (RA) disease in pregnant women resulted in lowered bone mineral density in their children later in life.
View Item

Tesquinimod May Improve Survival for Advanced Prostate Cancer
A randomized trial showed an extra 3 months of life using an investigational immunomodulator for advanced prostate cancer, and a 7-month survival improvement in patients with bone metastases.
View Item

Mixed Results for Warfarin Dosing by Genotype
Three clinical trials have reported results data regarding benefit and cost using genotype-guided dosing of warfarin and similar drugs.
View Item

ENGAGE AF-TIMI 48: Edoxaban Noninferior to Warfarin for Stroke Prevention
Once daily edoxaban caused significantly less major bleeding and was found to be noninferior to warfarin for preventing stroke or systemic embolism in a randomized trial of patients with atrial fibrillation.
View Item
View Trial

ACA/AACC Defends Risk Calculator
The American Heart Association and the American College of Cardiology was prompted to defend the new risk calculator and statin recommendations, which have drawn negative feedback.
View Item

Oral Combo Achieves Near-Perfect HCV Cure Rates
A four-drug oral regimen for hepatitis C in initial results from the phase III SAPPHIRE-1 study after 12 weeks at the end of therapy show undetectable virus in 96% of treated patients.
View Item

Long-term Oral Contraceptive Use May Double Glaucoma Risk
According to new research, women who used birth control for three or more years have twice the risk of developing glaucoma later in life.
View Item

TOPCAT Results - Spironolactone Reduces Repeated Hospitalizations, but Not Mortality
The clinical Trial, Treatment of Preserved Cardiac Function Heart Failure with an Aldosterone Antagonist (TOPCAT) determined that spironolactone did not reduce the primary outcome of cardiovascular death, heart failure hospitalization, nor surviving a cardiac arrest in patients with heart failure and preserved ejection fraction.
View Item

Study Suggests Statin Use Not Linked to Cognitive Function Decline
A new study concluded that available evidence does not support an association between statins and memory loss or dementia.
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Drug Approvals

Sovaldi Approved for Chronic Hepatitis C
The FDA has approved Sovaldi (sofosbuvir), the second drug in two weeks approved for chronic hepatitis C virus.
View Item

Micropen Approved as New Topical Scar Treatment
Ocuiva Innovative Sciences has received FDA approval for a new scar-management hydrogel, Micropen.
View Item

FDA Approves First Drug for Peyronie's Disease
Xiaflex, a collagenase clostridium histolyticum (CCH) has been approved by the FDA as the first nonsurgical method for treating Peyronie's disease.
View Item

Velphoro Receives FDA Approved
The FDA has approved hyperphosphatemia drug, Velphoro (sucroferric oxyhydroxide) for chronic kidney disease patients.
View Item

Varithena Has Won U.S. Approval
U.S regulators have approved Varithena, a varicose vein treatment, as an alternative to surgical removal.
View Item

FDA Approves New Therapy for Chronic Hepatitis C Virus
The FDA has approved Olysio (simeprevir), a protease inhibitor, to treat chronic hepatitis C virus infection.
View Item

FDA Expands the Approved Use of Nexavar
The FDA has expanded the approved uses of Nexavar (sorafenib) to treat late-stage differentiated thyroid cancer.
View Item

FDA Approves H5N1 Adjuvant Vaccine
The FDA has approved the first adjuvant vaccine for the prevention of H5N1 influenza, also known as avian or bird flu.
View Approval

FDA Approves Noxafil Delayed-Release Tablets
The FDA has approved Merck's Noxafil (posaconazole) for fungal infections in immunosuppressed patients.
View Approval

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New Guidelines

Guidelines for Collaborative Practice Agreements Between Pharmacists and Physicians
The CDC in partnership with the American Pharmacists Association has published recommendations on collaborative practice agreements between pharmacists and physicians.
View Guideline

JaPNa Summary for Vaccine Storage
The NovoDex issue of the Journal of the American Pharmacists Association provides a summary of the important changes on proper storage and handling of refrigerated vaccines.
View Item

New Guidelines for Immunocompromised Patients Regarding Vaccinations
The Infectious Diseases Society of America (IDSA) has issued a new guideline for immunocompromised patient vaccinations.
View Item

AHA/ACC/CDC Science Advisory – An Effective Approach to High Blood Pressure Control
This collaborative advisory is intended to complement and support clinical guidelines to improve treatment and control of high blood pressure.
View Item
View Advisory

Guidance for Anemia in Heart Disease
The American College of Physicians has provided a clinical practice guideline for the treatment of anemia in patients with heart disease.
View Guideline

Guideline Update: Hypertension in Pregnancy
The American Congress of Obstetricians and Gynecologists Task Force on hypertension has updated recommendations on diagnostics and therapeutic.
View Guideline

NICE Clinical Guidelines for Neuropathic Pain – Pharmacological Management
The National Institute for Health and Care Excellence presents an updated guideline on the management of neuropathic pain in adults in non-specialist settings.
View Guideline

NICE Clinical Guidelines for Secondary Prevention of Myocardial Infarction
National Institute for Health and Care Excellence (NICE) has updated guidelines on secondary prevention in primary and secondary care for patients following a myocardial infarction.
View Guidelines

Multidisciplinary Guidelines for Quality Care in Dementia
The Dementia Measures Work Group provided a measurement set to improve outcomes for dementia patients.
View Guidelines

New Antibiotic Guidance for Common Infections in Children
Antibiotic overuse is the focus of a new report by the American Academy of Pediatrics in collaboration with the Centers for Disease Control and Prevention.
View Item

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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

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