

# FYDI

FOR YOUR DRUG INFORMATION



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## ULM COLLEGE OF PHARMACY Drug Information Center



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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.

### In this issue...

**FDA MedWatch and Other Safety Alerts**  
**News Items**  
**Drug Approvals**  
**New Guidelines**

#### 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.

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**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.

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

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**FreeStyle and FreeStyle Lite Blood Glucose Test Strips Recalled**  
Abbot is initiating a voluntary recall of 20 lots of FreeStyle and FreeStyle Lite Blood Glucose Test Strips in the U.S. due to possible erroneous low blood glucose readings.

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**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.

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

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

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**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.

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**Adipotrim XT Recalled**  
Deseo Rebajar Inc., is voluntarily recalling lot #052012 of Adipotrim XT, due to an undeclared drug ingredient.

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**Lexiscan and Adenoscan: Drug Safety Communication**  
The FDA is announcing a rare but serious risk of heart attack and death with the use of the cardiac nuclear stress test agents Lexiscan and Adenoscan.

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

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**RezzRX Recalled Due to Undeclared Drug**  
The FDA determined that one lot of RezzRX contained the undeclared hydroxyflthiohosildenafil, while another lot also contained aminotadalafil.

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**Rhino 5 Plus, Maxtrezezen, and Extenzezone Recalled**  
An analysis has determined that these products contain undeclared desmethylcarbendenaflil and dapoxetine.

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

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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.

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**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."

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**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.

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**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.

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**Study 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.

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**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.

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**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.

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**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.

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**Possible Link Between High Sodium "Fizzy" Medicines and Higher Heart Risks**

Millions of patients worldwide taking effervescent, dispersible, and soluble medicines have an increased risk of heart attacks and strokes due to the high salt content in these products.

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**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.

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**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.

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**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.

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**Study Finds Combo Antibiotic for UTI Matches Standard Drug**

In a Phase III non-inferiority trial, an investigational antibiotic combination ceftolozane/tazobactam worked comparably to standard therapy for complicated tract infections.

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**Andexanet Granted Breakthrough Therapy Designation**

Portola Pharmaceuticals receives breakthrough therapy designation from FDA for their investigational factor Xa inhibitor antidote.

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**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.

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**Tasquinimod 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.

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**Mixed Results for Warfarin Dosing by Genotype**

Three clinical trials have reported variable data regarding benefit and cost using genotype-guided dosing of warfarin and similar drugs.

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**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.

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**AHA/ACC 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.

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**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.

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**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.

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**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.

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**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.

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**Microcyn Approved as New Topical Scar Treatment**

Oculus Innovative Sciences has received FDA approval for a new scar-management hydrogel, Microcyn.

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**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.

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**Velphoro Receives FDA Approved**

The FDA has approved hyperphosphatemia drug, Velphoro (sacroferric oxyhydroxide) for chronic kidney disease patients.

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**Varithena Has Won U.S. Approval**

U.S. regulators have approved Varithena, a varicose vein treatment, as an alternative to surgical removal.

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**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.

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**FDA Expands the Approved Use of Nexavar**

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

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**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.

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**FDA Approves Noxafil Delayed-Release Tablets**

The FDA has approved Merck's Noxafil (posaconazole) for fungal infections in immunosuppressed patients.

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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.

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**JaPhA Summary for Vaccine Storage**

The Nov/Dec issue of the Journal of the American Pharmacists Association provides a summary of the important changes on proper storage and handling of refrigerated vaccines.

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**New Guidelines for Immunocompromised Patients Regarding Vaccinations**

The Infectious Diseases Society of America (IDSA) has issued a new guideline for immunocompromised patient vaccinations.

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**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.

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**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.

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**Guideline Update: Hypertension in Pregnancy**

The American Congress of Obstetricians and Gynecologists Task Force on hypertension has updated recommendations on diagnostics and therapeutic.

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**NICE National 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.

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**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.

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**Multidisciplinary Guidelines for Quality Care in Dementia**

The Dementia Measures Work Group provided a measurement set to improve outcomes for dementia patients.

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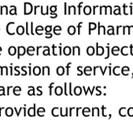
**New Antibiotic Guidance for Common Infections in Children**

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.

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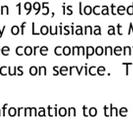
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The Louisiana Drug Information Pharmacy (DIC), which became operational in 1995, is located on the first floor of the College of Pharmacy (COP) Bienville Building of the University of Louisiana at Monroe (ULM). The operation objectives of the DIC are 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 providers.
- ◆ 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 the use of 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**

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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.