FYDI

FOR YOUR DRUG INFORMATION

March 28, 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.

ULM
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.

Lack of Sterility Forces Voluntary Recall
All sterile products originating from clinical specialties compounding have been recalled after sterility issues arise – second recall in one week.
View Alert

Recall on Avastin Unit Dose Syringes
Clinical Specialties' products have been linked to potentially serious eye infections.
View Alert

Potential Mold Contamination Causes Med Prep Consulting Inc. Product Recall
All compounded products originating from Med Prep Consulting Inc. have been recalled after contamination discovered.
View Alert

Several Type 2 Diabetes Medications Linked to Pancreatitis and Pancreatic Cancer
Reports have indicated that incretin mimetic drugs (ie. Byetta, Januvia, Victoza, etc.) may increase the risk of pancreatitis and pancreatic cancer.
View Alert

Night Bullet, Dietary Supplement, Recalled
Sildenafil analogues, undeclared ingredients, have been found in Green Planet, Inc.'s male enhancement supplement.
View Alert

Fatal Heart Rhythms Linked to Azithromycin
FDA warns that the popular antibiotic azithromycin (Zithromax) may be linked to potentially irregular heart rhythms.
View Alert

Undeclared Ingredient Leads To Weight Loss Supplement Recall
Olaax Corp's MaxiLoss Weight Advanced softgels have been recalled due to containing the undeclared ingredient sibutramine.
View Alert

Omontys (Peginesatide) Recall
Serious hypersensitivity reactions, including death, have been associated with first dose.
View Alert

Gilead's Vistide Recall
The presence of particulates have been detected in Vistide (cidofovir injection).
View Alert

Rugby Natural Iron Supplement Recall
Ferrous sulfate 325 mg tablets, labeled as Rugby Natural Iron Supplement has been recalled; bottle may contain meclizine HCl 25 mg tablets.
View Alert

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News Items

Study Shows Ambien Improves Memory
A new study suggests that taking Ambien can move memories and information from short term to long term storage.
View Item

Study Reports Niacin Has Zero Benefits, May Harm
A new study has concluded that niacin provides no health benefit and may even harm those with vascular disease.
View Item
View Study

Child Cured of HIV
Two years later, a child shows no signs of HIV after administration of three anti-retrovirals post-birth.
View Item

CRE Infections on the Rise
A report showing strains of carbapenem-resistant *Enterobacteriaceae* (CRE) has prompted the CDC to sound the alarm.
View Item

FDA to Examine Calcitonin-Salmon Use and Cancer Risks
A review has found a small increase in the potential risk of cancer after long-term use of calcitonin-containing drugs.
View Item

Study Suggests Pregnant Women Should Avoid Vitamin D Supplements:
New research has shown that increased vitamin D intake during pregnancy causes an increase in food allergies for the child.
View Item

Drug Overdose Deaths on the Rise
Overdose fatalities have increased over the past eleven years, according to CDC letter in JAMA.
View Item
View Letter

FDA Rejects Novo's Long-Acting Insulin
Approval of the product in the future is likely, but only after more extensive testing related to heart risks have been completed.
View Item

Codeine Use in Children After Tonsillectomy May Be Fatal
The FDA issued the strongest possible warning to physicians to avoid prescribing codeine to children after surgery to remove tonsils, adenoids or both.
View Item

Nearly One-Third of Chemotherapy Drugs Are Used "Off-Label"
In 2010 4.5 billion dollars was spent on "off-label" use of chemotherapy drugs.
View Item

Combination of Two Drugs May Prevent Head and Neck Cancer
Studies show that taking the combination of erlotinib, an EGFR inhibitor, and celecoxib, a COX-2 inhibitor, showed promise in reducing the risk of head and neck cancer in high risk patients.
View Item

Star-Gazing Software Used to Fight Breast Cancer
Astronomers and cancer researchers have teamed up to view tumors using software developed to view the stars.
View Item

Priority Status Awarded to GSK for New HIV Drug
US regulators gave priority review status to an experimental drug (dolutegravir) for HIV/AIDS. This once daily drug has already performed strongly in clinical trials.
View Item

Folic Acid During Pregnancy May Decrease Risk of Autism
A study conducted in Norway shows women who took folic acid before and during pregnancy may have a reduced risk of having a baby with autism.
View Item

GSK Flu-Shot Linked to Narcolepsy
Children in Britain vaccinated with Pandemrix, H1N1 vaccine, were shown to have an increased risk for developing the sleep disorder narcolepsy.
View Item

CDC Suggests Pregnant Women Need Whooping Cough Vaccine—With Each Pregnancy
According to the CDC, pregnant women need to receive the Tdap vaccine booster during each pregnancy to protect their newborns from whooping cough.
View Item

New Dosage Recommendations for Zolpidem
Safety studies have shown that women need lower doses of *zolpidem*-containing products.
View Item

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Drug Approvals

Cancer Imaging Drug Approved
Approved drug, Lymphoseek is used to detect the spread of cancer to a patient's lymph nodes. The last time a lymph node locating drug was approved was over 30 years ago.
View Item

New Drug Approved For Postmenopausal Women Experiencing Pain During Sex
Osphena (ospemifene) has been granted FDA approval for the treatment of dyspareunia.
View Item

Drug Approved for Late-Stage Breast Cancer
Roche has brought a new breast cancer drug to the market—Kadcyla (ado-trastuzumab emtansine). This drug will benefit those who express large amounts of the HER2 protein.
View Item

FDA Approves Stivarga, A New GI Cancer Drug
Stivarga (regorafenib) is an oral tablet that was recently approved for unresectable or metastatic gastrointestinal stroma tumor.
View Item

FDA Approves Polamyst
Polyamyst, an agent for advanced multiple myeloma, has recently been approved.
View Item

FDA Approves Generic Doxil
Doxorubicin HCl, the generic version of cancer medication Doxil, will be available in 20mg and 50mg vials.
View Item

Ravicti (glycerol phenylbutyrate) Gains FDA Approval
An agent for urea cycle disorders, Ravicti offers management in patients 2 years of age and older.
View Item

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New Guidelines

Hyperphosphataemia in CKD Patient – New Guidelines Published
National Institute for Health and Clinical Excellence (NICE) has released new guidelines on treating hyperphosphataemia in chronic kidney disease (CKD).
View Guideline

New Guidelines Issued for Treating Children's Ear Infections
These guidelines use more stringent criteria for making a diagnosis and base treatment options on a child's age and severity of symptoms.
View Guideline

Infertility Guidelines Published
NICE has recently issued new guidance on treating infertility.
View Guideline

Updated GERD Guidelines Released
The American Journal of Gastroenterology has published new clinical guidelines regarding the diagnosis and management of gastroesophageal reflux disease (GERD).
View Guideline

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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's 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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University of Louisiana at Monroe College of Pharmacy
Drug Information Center
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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.

FYDI

FOR YOUR DRUG INFORMATION

May 6, 2013

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In this issue…

FDA MedWatch and Other Safety Alerts

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Valproate Products Contraindication for Pregnant Women
The FDA is advising of a contraindication based on evidence of decreased IQ scores in children of mothers who have taken anti-seizure medications valproate sodium and related products, valproic acid and divalproex sodium for prevention of migraine headaches.
View Alert

Kadcyla (ado-trastuzumab emtansine): Name Confusion Could Lead to Errors
The FDA has issued a Drug Safety Communication to notify that the incorrect nonproprietary name for Kadcyla (ado-trastuzumab emtansine) may appear in some electronic systems, which could potentially lead to medication errors.
View Alert

Labeling Issue Leads to Urgent Product Recall by Fenwal
Fenwal has issued a voluntary urgent recall on one lot of anticoagulant citrate phosphate dextrose solution, USP BLOOD-PACK unit with incorrect labeling.
View Alert

Piperacillin/Tazobactam for Injection Recalled
Fifteen lots of Piperacillin/Tazobactam for Inj., USP 40.5 grams, were recalled due to precipitation/ crystallization in IV bag or IV line after reconstitution.
View Alert

Samsca (tolvaptan): FDA Limits Use Due to Possible Liver Injury
The FDA has limited the duration and usage of the drug due to evidence suggesting possible severe adverse effects possibly leading to liver transplant or death.
View Alert

FDA Warns of Adverse Effects Linked to Anti-Seizure Medication
Potiga (Ezogabine) has been linked to pigment changes of the retina and blue skin discoloration.
View Alert

Multivitamin Supplement Recalled Due to Contamination
Saratoga Therapeutics LLC recalled 900 bottles of ebA Multivitamin Supplement due to undeclared milk components, though the label lists the product as free of milk components.
View Alert

Recall of One Touch Verio IQ Blood Glucose Meter
The Veria IQ meter has been discovered to turn off, rather than display high glucose warning when readings are greater than or equal to 1024 mg/dL.
View Alert

Sterility Assurance Concerns Leads to Recall of Nora Apothecary Products
Nora Apothecary & Alternative Therapies issued a recall on all compounded sterile compounded drug products due to concerns with quality control processes.
View Alert

Recall of Balanced Solutions Sterile Compounded Products
Concerns with quality control have resulted in recall on all lots of sterile products compounded by the pharmacy.
View Alert

Sterility Assurance Concerns Results in Recall of NuVision Pharmacy Products
NuVision Pharmacy is recalling all compounded lyophilized products containing HcG and Sermorelin/GHRH6.
View Alert

Sterility Assurance Concerns Results in Recall of ApotheCure Products
All sterile products compounded by ApotheCure, Inc. have been recalled due to sterility concerns.
View Alert

Quality Control Concerns Results in Recall of Green Valley Drugs Products
All Green Valley Drugs sterile products have been recalled due to concerns of quality control.
View Alert

Recall of Affirm XL, Dietary Supplement
The dietary supplement marketed for sexual enhancement contained an undeclared ingredient, a sildenafil analogue.
View Alert

Undeclared Ingredient Leads to Male Enhancement Product Recall
A product recall has been issued due to the presence of hydroxythiohomosildenafil, a sildenafil analogue, in ROCK-It MAN Male Enhancement Capsules marketed by Consumer Concepts, Inc.
View Alert

Recall of Insulin Infusion Pump
A false alarm or warning sound may prompt consumer to "rewind, load, and prime," which could potentially result in dose-related hypoglycemia.
View Alert

Recall of Intravenous Immune Globulin
Visible particles have been observed in BIVIGAM (immune globulin injection).
View Alert

Recall of Hospira's Sodium Chloride Injection, Flexible Container
Brass particulates have been identified in the primary container.
View Alert

Recall of Pallimed Solutions, Inc. Sterile Compound Products
All Pallimed Pharmacy sterile compound products dispensed since Jan. 1, 2013 are being recalled due to visible particulates.
View Alert

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News Items

FDA Lowers Age for Plan B Access to 15 Years
The FDA approves Plan B One-Step without prescription for women 15 years of age and older.
View Item

Proposal for Greater FDA Regulation Over Compounding Practices
The proposal would clarify FDA authority over "high-risk compounding" in order to improve protections for patients using these products.
View Item

FDA Rejects New Drug for Migraine
Levadex (dihydroergotamine) was denied FDA approval due to manufacturing concerns.
View Item

SSRI Therapy Around Time of Surgery Tied to Increased Complications
Selective Serotonin Reuptake Inhibitor (SSRI) use may increase surgery-associated risks, according to a recent study.
View Item

Effective Treatment for Distal Subungual Onychomycosis
Two separate trials show effectiveness of topical efinaconazole treatment for toenail fungal infection and slightly more than one-half of the subjects achieved mycological cure.
View Item

National Shortage of Tuberculin Skin Test
The CDC has issued recommendations for addressing the tuberculin skin test antigen shortage.
View Item

HIV Vaccine Study Halted by Investigators
An HIV vaccine trial was halted due of lack of efficacy and an increased risk of HIV infections among those who received the vaccine.
View Item

Valproate Therapy During Pregnancy Linked to Autism
A 10 year study in Denmark showed increased risk of childhood autism in babies born to mothers on valproate therapy.
View Item

Dutasteride Associated With Slower Progression of BPH
A post hoc analysis of the REDUCE study evaluated the possible benefit of treating asymptomatic or mildly symptomatic men with benign prostatic hypertrophy (BPH).
View Item

OxyContin Label Updated
The new labeling contains a warning that the product has physical and chemical properties that are intended to make abuse via injection difficult and decrease abuse via the intranasal route (snorting).
View Item

Multiple Sclerosis Drug Possibly Beneficial in Stroke Patients
A study found that the multiple sclerosis drug, Acorda, might also help stroke patients with impaired motor function.
View Item

Staphylococcus Aureus Vaccine Trial Terminated Due to Poor Clinical Outcomes
Subjects that received the vaccine had more infections and higher mortality than those that did not receive the vaccine.
View Item
View Article Abstract

ACE Inhibitor and Beta-Blocker for Cardiotoxicity Prevention in Chemotherapy
In the OVERCOME trial, enalapril and carvedilol may prevent left ventricular systolic dysfunction related to treatment with intensive chemotherapy.
View Item

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Drug Approvals

Procysbi (Cysteamine Bitartrate) Approved for Nephropathic Cystinosis
Procysbi has been granted orphan drug status for the treatment of cystinosis, a rare genetic disease that affects approximately 500 individuals in the United States and 3,000 persons worldwide.
View Item

Kcentra Approved for Urgent Reversal of Vitamin K Antagonist Anticoagulation
The prothrombin complex is the first drug approved for urgent reversal of the effects of vitamin K antagonist anticoagulation.
View Item

Amitiza (Lubiprostone) for Opioid-Induced Constipation
Sucampo and Takeda Pharmaceuticals introduce Amitiza for patients who suffer from opioid-induced constipation.
View Item

Simbrinza (Brinzolamide and Brimonidine) Approved for Glaucoma
Simbrinza is the first fixed-dose combination therapy available for glaucoma in the United States that does not include a beta-blocker.
View Item

New Higher Strength, Delayed-Release Dosage Form for Doryx (Doxycycline) Approved
Warner Chilcott has gained approval to add a 200 mg delayed-release formulation to the 75-mg, 100-mg and 150-mg strengths already available.
View Item

FDA Approves Quartette – Oral Contraceptive
Quartette (levonorgestrel/ethinyl estradiol and ethinyl estradiol) is approved as an ascending-dose, extended regimen oral contraceptive.
View Item

FDA Approves Sitavig
Sitavig (acyclovir) buccal tablet is indicated for the treatment of recurrent herpes labialis in immunocompetent adults.
View Item

FDA Approves Diclegis
Diclegis (doxylamine succinate and pyridoxine hydrochloride) has been approved for nausea and vomiting in pregnant women.
View Item

FDA Approves Invokana for Type-2 Diabetes
A first-in-class sodium-glucose co-transporter-2 inhibitor, Invokana (canagliflozin), has been approved for the treatment of Type 2 Diabetes.
View Item

Tecfidera (dimethyl fumarate) Approved for Relapsing Forms of Multiple Sclerosis
Tecfidera capsules reduce the number of relapses for patients with multiple sclerosis.
View Item

FDA Approves First Heptavalent Botulism Antitoxin
The antitoxin neutralizes all seven known botulinum nerve toxin serotypes and will be stored in the Strategic National Stockpile for emergency preparedness.
View Item

TOBI Podhaler for Cystic Fibrosis Therapy Approved
TOBI (tobramycin inhalation powder) Podhaler broadens the available delivery mechanism options for cystic fibrosis patients needing treatment for *Pseudomonas aeruginosa*.
View Item

Dotarem (Gadoterate Meglumine) MRI Agent Approved
A new magnetic resonance imaging agent, Dotarem has been approved to help radiologists identify CNS abnormalities.
View Item

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New Guidelines

Updated Recommendation for HIV Screening
U.S. Preventive Services Task Force (USPSTF) recommends screening adolescents and adults aged 15 to 65 years for HIV.
View Guideline

New Diabetes Algorithm: American Association Of Clinical Endocrinologists
The new guidelines address prediabetes, glycemic control, diabetes medication management, weight management therapies, and cardiovascular risk reduction.
View Guideline

Prostate Cancer Screening Guidelines Reviewed
The guidance statement from the American College of Physicians advises of limited potential benefits and substantial harms in prostate cancer screening.
View Guideline

Guidelines Released for Parenchymal Neurocysticercosis
The American Academy of Neurology guideline includes the recommended use of albendazole and a steroid for the treatment of neurocysticercosis.
View Guideline

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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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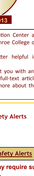

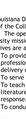

FYDI

FOR YOUR DRUG INFORMATION

November 19, 2013

Greetings from the Drug Information Center at the University of Louisiana at Monroe College of Pharmacy!
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ULM COLLEGE OF PHARMACY Drug Information Center

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In this issue…

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

FDA MedWatch and Other Safety Alerts

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Nature's Pharmacy and Compounding Center Products: Recalled
Nature's Pharmacy and Compounding Center of Asheville, NC is voluntarily recalling all lots of sterile products compounded by the pharmacy that are not expired.
View Alert

Over-the-Counter Topical Antiseptics: Drug Safety Communication
FDA is requesting changes made to labeling and packaging to increase safe use of certain over-the-counter topical antiseptic products.
View Alert

Vega Shakes and Protein Products Recalled
Certain Vega products containing trace amounts of Chloramphenicol are being recalled due to the possibility of causing severe hypersensitivity reactions in people with allergies to chloramphenicol.
View Alert

OxyElite Pro Recalled
The recalled products contained aegeline, a new dietary ingredient that lacks a history of use or evidence of safety.
View Alert

Low Molecular Weight Heparins: Drug Safety Communication
The FDA gives new recommendations for patients on anticoagulants for dosing, timing of spinal catheter placement and removal in order to decrease risk of spinal column bleeding and paralysis.
View Alert

Perrigo Acetaminophen Infant Suspension Recalled
Some recalled packaging may include oral syringe without dose markings, which can result in inaccurate dosing.
View Alert

MedStream Programmable Infusion Pump and Refill Kits: Class 1 Recall
Codman and Shurtieff, Inc. notifies health professionals of Class 1 recall on MedStream Programmable Pump and Refill Kits.
View Alert

Hospira's Lidocaine and Marcaine Recalled
Hospira voluntarily recalls user-level lot of 0.25% Marcaine injection due to discoloration and particulate matter found inside vials.
View Alert

Compounding Pharmacy Recalls Human and Veterinary Products
Specialty Medicine Compounding Pharmacy recalls all lots of unexpired medications due to particulates found in vials of compounded dextrose injections.
View Alert

Albuterol Inhalation Solution 0.083% Recalled
Nephron Pharmaceuticals recalls ten lots of the product as a precaution to aseptic process monitoring.
View Alert

Cefepime for Injection USP and Dextrose Injection USP Recalled
B. Bruan Medical Inc. voluntarily recalls 1g Cefepime for Injection USP and Dextrose Injection USP due to organic particulate in a reserve sample unit.
View Alert

FDA Issues Drug Safety Concern: Iclusig (Ponatinib)
FDA issues a warning regarding drug safety for Inclusig (Ponatinib) due to reports of serious adverse effects after administration of medication.
View Alert

FDA Notification: Perfect Body Solution and Burn 7
FDA advises consumers not to purchase Perfect Body Solutions and Burn 7 due to the product containing a controlled substance, Sibutramine.
View Alert

FDA Notification: Dr. Mao Slimming Capsules
FDA advises consumers not to purchase Dr. Mao Slimming Capsules due to the product containing a controlled substance, Sibutramine.
View Alert

FDA Notification: Be Inspired
FDA advises consumers not to purchase or use the product Be Inspired due to the presence of the controlled substance, Sibutramine.
View Alert

FDA Notification: Bella Vi Insane Amp'd And Bella Vi Amp'd Up
FDA advises consumers not to purchase or use Bella Vi Insane and Bella Vi Amp'd Up due to the products containing the controlled substance, Sibutramine.
View Alert

Dietary Supplements: Slim Fortune, Lidiy, and Slim Expert Recalled
B@B Trade, Inc. is voluntarily recalling all lots of Slim Fortune, Lidiy, and Slim Expert because the products contain the controlled substance, Sibutramine.
View Alert

Metoclopramide and Ondansetron Injection Recalled Due
Hospira, Inc. voluntarily recalls lot of Metoclopramide and Ondansetron injections due to glass particulate contamination.
View Alert

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News Items

FDA Grants Special Status to GW Pharmaceuticals' Drug for Rare Epileptic Disorder
FDA gave Epidiolex the orphan drug designation for Dravet syndrome.
View Item

FDA Approves Medical Device to Treat Epilepsy
The RNS Stimulator consists of a small neurostimulator implanted in the skull under the scalp to help reduce the frequency of seizures in epilepsy patients who have not responded well to medications.
View Item

New Guidelines Could Increase Statin Use
Recommendations from new guidelines could result in as many as 70 million people on statin therapy.
View Item

Novel Drug May Work in Hyperkalemia
An inorganic cation exchanger agent selectively traps potassium ions, making the novel drug a candidate for treating hyperkalemia in patients with chronic kidney disease.
View Item

U.S. Preventive Services Task Force Finds Evidence Lacking for Supplement Use
According to the USPSTF, there is not enough evidence regarding the use of vitamin and mineral supplementation in primary prevention of cardiovascular disease or cancer.
View Item

Novel Drug to Reduce LDL Cholesterol
A new approach using RNA interference to inhibit the synthesis of PCSK9 in the liver may contribute to lowering LDL cholesterol levels.
View Item

Medical Qigong: Alternative for Pain
Medical Qigong, a branch of traditional Chinese medicine, is an alternative when traditional medical pain treatments have failed.
View Item

Tamsulosin for BPH Associated with Severe Hypotension Risk
Tamsulosin may carry a doubled risk for severe hypotension when used for BPH symptoms, according to a U.S. insurance claims database.
View Item

Head-to-head HIV Study Showing HeDolutegravir Regimen is Superior to Efavirenz Regimen
A study showed that dolutegravir plus abacavir-lamivudine had a better safety profile and more effective through 48 weeks than efavirenz-tenofovir Df-emtricitabine.
View Item

Epilepsy Drug Potential in Alcohol Dependence Treatment
The results of a clinical trial suggest that gabapentin is beneficial in treating alcohol dependence when compared to placebo.
View Item

FDA Moves to Reduce Trans Fats in Processed Foods
The FDA announces preliminary determination that partially hydrogenated oils are not “generally recognized as safe” for use in food.
View Item

Three-Drug Combo Effectively Treats HCV Infection
Efficacy in treating HCV has been demonstrated with an investigational three-drug oral combination that avoids the use of both interferon and ribavirin.
View Item

OTCs Now Eligible FSA Expenses
New legislation repeals the portion of Obamacare that prohibits participants from using their flexible spending account funds to buy OTC medications.
View Item

Janssen Pharm to Plead Guilty For Misleading Marketing
The U.S. Department of Justice entered a guilty plea agreement with Janssen Pharmaceuticals, Inc to pay over $1.6 billion over misleading marketing messages for its schizophrenia drug Risperdal.
View Item

Qsymia for Weight Loss
In a 28 week study funded by VIVUS, overweight people who took the diet drug Qsymia (phentermine/topiramate) were shown to lose more weight than those on a placebo or either drug alone.
View Item

Stem-Cell Recipients on Statin Reduces GVHD
A small study showed that stem-cell transplant recipients had low rates of acute graft-versus-host disease when taking prophylactic atorvastatin.
View Item

New Inhaled Phosphodiesterase Inhibitor Looks Promising For Asthma and COPD
A series of preliminary studies shows that an inhaled dual phosphodiesterase inhibitor, inhibiting phosphodiesterases 3 and 4, is promising against asthma and chronic obstructive pulmonary disease.
View Item

FDA to Tighten Schedule of Hydrocodone Rx
The FDA will send its formal recommendation to the Department of Health and Human Services to tighten the restrictions on hydrocodone combination drugs such as Vicodin by early December.
View Item

Contaminated Steroid Injections Causes a Spectrum of Ailments
Patients made sick by contaminated steroid shots were found to have illnesses varying in severity from strokes to abscesses.
View Item

Pancreatic Cancer Life Extension with Chemo Combo
Results of a phase III trial showed that a combination of Abraxane and Gemzar significantly improved survival in patients with metastatic pancreatic cancer.
View Item

Nasacort Cleared for OTC Sale
Sanofi announced that triamcinolone acetonide (Nasacort AQ) should be expected to be available OTC by spring 2014.
View Item

HIV Vaccine Candidate Fails to Protect
A placebo-controlled clinical trial of the latest vaccine ended early due to temporary results showing that the drug would probably not work.
View Item

New Treatment Option for Parkinson's Psychosis
Pimavanserin is shown to be beneficial in alleviating symptoms of psychosis in patients with Parkinson's disease.
View Item

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Drug Approvals

FDA Approves Luliconazole
A one-week antifungal drug, Luzu (luliconazole) 1% cream, was FDA approved for the treatment of athlete's foot, jock itch, and ringworm in adults.
View Letter
View Label

FDA Approves Imbruvica
Imbruvica (ibrutinib) approved for use to treat patients with mantle cell lymphoma, a rare and aggressive type of blood cancer.
View Approval

FDA Approves Aptiom
Aptiom (eslicarbazepine acetate) was approved as an add-on medication to treat seizures associated with epilepsy.
View Approval

FDA Approves Gazyva
The FDA approved obinutuzumab for use together with chlorambucil to treat patients with previously untreated chronic lymphocytic leukemia (CLL).
View Approval

FDA Approves Opsumit
The FDA has approved macitentan (Opsumit, Actelion) for the treatment of pulmonary arterial hypertension in adults.
View Approval

Novoeight FDA Approved
Turoctocog alpha (Novoeight) is a recombinant coagulation factor VIII recently FDA approved for patients with hemophilia A.
View Approval

Adempas FDA Approved
Adempas (Riociguat) was FDA approved to treat adults with pulmonary hypertension.
View Approval

Duavee FDA Approved
Duavee (Conjugated Estrogens/Bazedoxifene) has been FDA approved for women who suffer from moderate-to-severe hot flashes associated with menopauce and to prevent osteoporosis after menopause.
View Approval

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New Guidelines

Primary Care Guidelines for the Management of Persons Infected with HIV: 2013 Update from the HIV Medicine Association IDSA
Guidelines focusing on the preventative care for common health problems as patients with HIV live longer.
View Guideline

2013 AHA/ACC Guidelines on the Treatment of Blood Cholesterol to Reduce Atherosclerotic Cardiovascular Risk in Adults
Changes in appropriate use of statins in patients at risk cause movement away from hard treatment targets of ATPIII Guidelines.
View Guideline

2013 AHA/ACC Guidelines on Lifestyle Management to Reduce Cardiovascular Risk
The new guidelines focus on healthy dietary habits for lifestyle management.
View Guideline

2013 AHA/ACC Guideline for the Management of Overweight and Obesity in Adults
This update addresses five critical questions on managing overweight and obesity in adults.
View Guideline

2013 AHA/ACC Guideline on the Assessment of Cardiovascular Risk
The guidelines called for a change in approach to assessing cardiovascular risk with a new equation for cardiovascular risk estimation.
View Guideline

BSR Guidelines on Psoriatic Arthritis
The British Society of Rheumatology published Psoriatic Guidelines for Treatment with Biologics.
View Guideline

Pediatric HIV Guidelines Updated
The new guidelines include the Prevention and Treatment of Opportunistic Infections Among HIV-Exposed and HIV-Infected Children from the Department of Health and Human Services.
View Guideline

CDC: Provisional Guidelines for Multidrug-Resistant TB
FDA-approved bedaquiline is included in the new guidelines as part of a combination therapy for adults with pulmonary multi-drug-resistant TB.
View Guideline

2013 ACCF/AHA Guideline for the Management of Heart Failure
The update to the guidelines refreshed concepts for recommendations in managing heart failure.
View Guideline

EAU Guidelines on Primary Urethral Carcinoma
The European Association of Urology has released guidelines on the diagnosis and treatment of patients with primary urethral carcinoma.
View Guideline

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- 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:

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Drug Interactions
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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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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.

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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An Nguyen and Chuong Nguyen, PharmD Candidates
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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.
View Item

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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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- 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
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