FYDI

FOR YOUR DRUG INFORMATION

January 25, 2012

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 articles referenced in this issue, find out more about the services the DIC has to offer.

In this issue...
FDA MedWatch Alerts
News Items
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ULM COLLEGE OF PHARMACY Drug Information Center

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FDA MedWatch Alerts

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

Topical Hair Regrowth Products Recalled
Items from the Perfect Image Solutions Topical Hair Regrowth product line were recalled for being deemed as "unapproved new drugs" according to FDA regulations.
View Alert

New Risk Factor Identified for PML Associated with Tysabri
The FDA is notifying healthcare professionals that a positive test for anti-JC virus (JCV) antibodies is a risk factor for progressive multifocal leukoencephalopathy (PML), a serious brain infection which is associated with Tysabri use.
View Alert

New Boxed Warning and Contraindication for Cancer Drug, Adcetris
Used to treat Hodgkin lymphoma and another rare lymphoma, Adcetris has a new Boxed Warning stating the risk of progressive multifocal leukoencephalopathy due to two additional cases recently found when using the drug.
View Alert

Certain Bedford Lab Products Recalled for Presence of Glass Particles
Bedford Laboratories has issued a nationwide recall of certain lots of Phytonadione 1 mg/0.5 ml Injection and Vancomycin Bromide for injection due to the discovery of visible glass particles in a limited number of vials.
View Alert

Public Health Advisory: Incorrect Labeling and Packaging of Opiate Products
FDA issued an alert to patients and healthcare providers to double check Endo Pharmaceuticals opiate products to ensure that all tablets appear the same.
View Alert
View Instructions

Recall on Damaged OTC Products
Frequent reports of broken pills and mislabeled bottles caused Novartis Consumer Health Inc. to recall Excedrin, Bufferin, Gas-X Prevention, and NoDoz.
View Alert

Potential Health Risk Causes Recall on Dietary Supplements
Eclectic Institute is recalling freeze-dried capsules containing Gotu Kola and Bladderwrack due to possible salmonella contamination.
View Alert

Potential Injury for Sound-Alike Drugs Durezol and Duranol
Serious injury was reported when Durezol, a salicylic acid-containing wart remover, was given instead of the prescribed eye drops, Durezol.
View Alert

Third Concentration of Acetaminophen Now Available for Infants
A new concentration (160 mg/5 mL) of liquid acetaminophen for infants is now being marketed, which may be packaged with an oral syringe instead of the customary dropper.
View Alert

Voluntary Recall of Certain Motrin Products
McNeil is voluntarily recalling certain lots of Motrin products due to a delay in experiencing relief when used; consumers do not need to dispose or return products.
View Alert

Gilenya under Safety Review following Reported Death after First Dose
The FDA is evaluating the case of a patient with multiple sclerosis who died 24 hours after the first dose of Gilenya (fingolimod).
View Alert

Multaq Increases the Risk of Serious Cardiovascular Events including Death
Based on two clinical trials, PALLAS and ATHENA, the FDA is providing new prescribing information and recommendations for the use of Multaq.
View Alert

Possible Association of SSRI Antidepressants and Persistent Pulmonary Hypertension of the Newborn
Though there are conflicting studies, the FDA cautions healthcare providers and patients of the risk association and advises providers not to alter current clinical practice of treating pregnant patients for depression.
View Alert

FDA is Investigating on Clinical Phase IV of Pradaxa
FDA is investigating Pradaxa (dabigatran etexilate mesylate) due to numerous post-marketing reports of serious bleeding adverse events.
View Alert

Trilipix may not Lower Risk for Heart Attack or Stroke
From the information provided by the ACCORD Lipid trial, there was no difference in the risk of experiencing a cardiovascular event between the fenofibrate plus simvastatin group compared to simvastatin alone.
View Alert

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News Items

FDA Attempting to Preserve Class of Antibiotics for the Treatment of Human Illnesses
Effective on April 5, 2012, the cephalosporin drug class will no longer be used for disease prevention or at unapproved dosages in animals as an attempt to prevent bacterial resistance during use in humans.
View Article

Clarinex Goes Generic Soon, OTC or Prescription?
Perrigo announced that it has received approval to launch the generic equivalent starting July 1 of this year, but it has not been determined whether the drug will be available by prescription or allowed to be purchased over-the-counter.
View Article

Subcutaneous Herceptin Injection Shows Positive Results
Results from the phase III Hannah trial showed that the new investigational subcutaneous injection of Herceptin is comparably effective as Herceptin given as an intravenous infusion.
View Article

Vandetanib Effective for Medullary Thyroid Cancer
A study featured in the *Journal of Clinical Oncology* proves that once-daily use of vandetanib, a kinase inhibitor, is effective in treating advanced medullary thyroid carcinoma.
View Article

Steroid Medications Linked to Vitamin D Deficiency
As reported in the *Journal of Endocrinology & Metabolism*, researchers found that patients taking oral steroids may be twice as likely as non-users to develop a severe vitamin D deficiency.
View Article

Patients on Pradaxa Should have Renal Function Checked
The European Medicines Agency recommends baseline and annual renal function checks for patients taking Pradaxa.
View Article

Copaxone Reduced Brain Volume Loss in Multiple Sclerosis Patients
Copaxone (glatiramer acetate) use significantly reduced loss of brain volume in multiple sclerosis patients compared with other current therapies according to a new study.
View Article

Net Clinical Benefit of Adding Clopidogrel to Aspirin in Patients with Atrial Fibrillation
The ACTIVE clinical trials were analyzed to determine if benefits outweigh risk for treatment with both clopidogrel and aspirin to prevent a cardiovascular event in patients with atrial fibrillation, for whom warfarin is unsuitable.
View Article
View Abstract

Similar Efficacy Found in a Comparative Study of Weekly Sustained-Release Versus Daily Dosing of Growth Hormone
In a randomized, controlled study design, 51 growth hormone-deficient children showed no significant difference in safety and efficacy between weekly sustained-release and daily dosing of growth hormone treatments.
View Article

Put Down the Toilet Lid Before Flushing
Researchers found contamination of the diarrhea-causing bacteria, *C. difficile*, in air samples after flushing an uncovered toilet.
View Article

Aspirin a Possible Culprit for Age-Related Macular Degeneration
A study showed elderly patients taking daily dose of aspirin have a higher risk for wet age-related degeneration, an eye disease that rapidly progresses to permanent blindness.
View Article

Study Reveals Long-term Effectiveness of Nicotine Replacement for Smokers is Questionable
A study released by the University of Massachusetts Boston's Center for Survey Research reported that follow-ups at two and four years showed nicotine-replacement products made no difference in relapse rate.
View Article

New Checkpoint Before Patients are Discharged from Hospitals
Preventable medication-related problems can be reduced significantly if a pharmacist review patient charts prior to discharge to ensure appropriate therapy.
View Article

Drug Shortages Due to Stringent Federal Regulations has a Detrimental Domino Effect
Drug shortages leads to drug substitutions, delayed therapy, and higher costs for already overwhelmed patients.
View Article

Recommending Routine Vaccination of HPV for Males
After results showed that the Quadrivalent HPV vaccine prevents anal cancer in certain males, vaccination starting as early as 9 years old is now recommended by the Advisory Committee on Immunization Practices.
View Article

DEA Declares Carisoprodol Schedule IV Drug
The administrator of the Drug Enforcement Administration (DEA) placed carisoprodol including all of its salts and isomers into the schedule IV drug class of the Controlled Substances Act.
View Article

Neti Pot Proves Deadly after Improper Use
After the second death was reported from the brain-eating amoeba due to incorrect use of the neti pot, the Louisiana Department of Health and Hospitals urges people to only use distilled water when irrigating sinuses.
View Article

ALLTIDE Study Terminated by Novartis
Alltide III trial, involving high-risk patients with diabetes and renal impairment receiving Rasilez/ Tekturna in addition to standard anti-hypertensives, was stopped upon the discovery that patients were unlikely to benefit from the combination treatment versus standard care.
View Article

Reminder: Patients Must Never Share Insulin Pens
Even though a new needle is used for each injection, there is a risk of backflow of blood into insulin increasing possibility of hepatitis and HIV infections.
View Article

Beware of the New and the Old Acetaminophen Products for Infants
A new concentration of liquid acetaminophen, 160 mg/5 ml, may bring dosing confusion; thus, it is important make customers aware of the differences.
View Article

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Drug Approvals

FDA Approves Exparel for Post-Surgical Pain
Consisting of bupivacaine encapsulated in the multivesicular liposome *DepoFoam*, this new product is designed to extend analgesia for up to 72 hours.
View Article

Eylea Approved by FDA to Treat Eye Disorder in Elderly
Eylea (aflibercept) is a new treatment option for wet age-related macular degeneration, which is a leading cause of vision loss in older Americans.
View Article
View Guideline

A Fixed-Dose Combination of Ibuprofen and Famotidine (Duexis) Approved
The FDA has approved a fixed-dose combination of ibuprofen and famotidine (Duexis) to decrease the risk of developing NSAID-associated ulcers in patients who need symptomatic relief of osteoarthritis and rheumatoid arthritis.
View Article

FDA Approved Prevnar 13 Vaccine for Older Patients
Under the FDA's accelerated approval pathway for serious and life-threatening diseases, Prevnar 13 has been approved as an additional option for patients who are 50 years and older.
View Article

Nuvigil Approved for Self-administration
FDA has given approval to expand the product label of CSL Behring's C1 esterase inhibitor, Berinert for the use of self-administration for attacks of hereditary angioedema.
View Article

Edarbyclor Approved by FDA to Treat Hypertension
This drug manufacturer, Takeda, created Edarbyclor (azilsartan medoxomil and chlorthalidone) as the only fixed-dose therapy that combines an angiotensin II receptor blocker with clorthalidone in a once-daily tablet.
View Article

FDA Approves New Fentanyl Sublingual Spray
INSYS Therapeutics introduced this novel pain medication in a novel delivery device which offers benefits to cancer patients with episodes of breakthrough pain.
View Article
View all FDA-approved drugs at CenterWatch.com

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New Guidelines

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

New Treatment Option for Latent Tuberculosis Gets Recommendation from CDC
From the results of three clinical trials, this new once-weekly (12-dose) regimen will significantly shorten and simplify the course of treatment from about 9 months to 12 weeks.
View Guideline

Updates for Secondary Prevention and Risk Reduction for Atherosclerotic Disease
The revised guidelines made changes focusing on specific patient behaviors (i.e., physical activity, smoking cessation, and weight management), but did not alter major recommendations concerning blood pressure control and lipid management.
View Guideline

New Guidelines Issued for Common Tremor Disorder
According to an updated treatment guideline from the *American Academy of Neurology*, the anti-seizure drug, primidone, and the blood pressure drug, propranolol, are the most effective in treating shaking in people with essential tremor.
View Guideline

Hepatitis B Vaccination Recommended for Patients with Diabetes Mellitus
The Advisory Committee on Immunization Practices recommends that all previously unvaccinated patients between the ages of 19 and 59 that have been diagnosed with diabetes mellitus (type 1 or 2) be vaccinated against hepatitis B.
View Recommendation

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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
Complementary 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 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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Drug Information Center
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FYDI
FOR YOUR DRUG INFORMATION
April 16, 2012

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

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Counterfeit Version of Avastin Found
A counterfeit version of Altuzan (bevacizumab), an injectable cancer medication not approved for use in the U.S., was found to contain no active ingredients according to FDA lab test.
View Alert

FDA Clarifies Warning of Potential Risk of Abnormal Heart Rhythms with Celexa
The FDA has issued a Drug Safety Communication to clarify recommendations of dosing, warnings and precautions with regard to this risk of QT prolongation associated with Celexa (citalopram hydrobromide) use.
View Alert

Warning: Exparel may be Confused with Propofol
An alert has been issued by the Institute for Safe Medication Practices warning that Exparel may be confused with propofol due to their similar milky, white appearance in unlabeled syringes. Exparel accidently administered intravenously may result in life-threatening cardiac effects.
View Alert

Recall of Argatroban Injection
A voluntary recall has been issued for four lots of Argatroban Injection 50mg/50ml as visual particulates have been discovered in a sample.
View Alert

Recall of Unapproved Drug: Brilliant Blue G
FDA recalled Brilliant Blue G, an eye drop used in ophthalmic surgeries has been linked to causing fungal endophthalmitis.
View Alert

FDA Warns Beauty Products Containing Mercury Found in Seven States
FDA is warning patients not to use any beauty products that are marketed as skin lighteners or anti-aging treatments that remove age spots, freckles, blemishes and wrinkles because they may contain mercury.
View Alert

Statin Drugs Label Change
FDA has removed routine monitoring of liver enzymes from the label on all statin drugs. Additionally, the label has been revised regarding decreased cognitive function and increased blood glucose.
View Alert

Interaction Between Statins and Protease Inhibitors
FDA has notified healthcare professionals that there is a potential interaction between protease inhibitors and statins that may increase muscle injury.
View Alert

Drug Interaction Found Between Boceprevir and Ritonavir-Boosted HIV Protease Inhibitors
When these two drugs are used together, the effectiveness of both drugs can be decreased.
View Alert

FDA Recalls Medroxyprogesterone Vials
After finding silicone particles in Teva's medroxyprogesterone acetate injectable suspension vials and syringes, certain lot numbers are being recalled.
View Alert

LoSoma® 28 and Generic Equivalent Recalled
Pfizer Inc. has recalled 14 lots of the brand and generic of norgestrel and ethinyl estradiol tablets due to an inexact count of active and inactive ingredients and sequencing problems concerning the order of the pills.
View Alert

***Clostridium difficile*-Associated Diarrhea Associated with PPI's and H2 Antagonists**
Patients taking a PPI and experiencing diarrhea may have *Clostridium difficile*- Associated Diarrhea or CDAD. The FDA is working to change drug labels to include information about the increased risk of CDAD in patients taking PPI's.
View Alert

Recall on H&P Povidone Iodine Prep Pads Due to Potential Contamination
Testing of the prep pads showed contamination with a gram negative rod, Elizabethkingia meningoseptica, which could lead to life-threating infection.
View Alert

Recall on Wholistic Herbs, Inc "Koff and Kold" and "Kold Sore" Spray
After a routine inspection, FDA declared that products, "Koff and Kold" and "Kold Sore", were not tested properly to assure safety.
View Alert

Undeclared Drug Ingredient in RegenArouse
RegenArouse lot #130100 has been recalled for the presence of tadalafil which could cause a potential threat to consumers on certain medications.
View Alert

Recall on Infant Tylenol
574,000 bottles of infant grape flavored Tylenol were recalled by Johnson & Johnson due to a dosing system error.
View Alert

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News Items

Retinal Detachment Risk Associated with Oral Fluoroquinolone Use
A nested case-control study concluded that oral fluoroquinolones may increase the risk of developing a retinal detachment, which could account for an estimated 1,400 cases annually.
View Abstract

FDA Changes Levemir Pregnancy Risk Category
The FDA has changed Levemir's pregnancy risk category from 'C' to a more reassuring 'B' on the basis of a trial of 310 pregnant women who did not experience an increased risk of fetal abnormalities.
View Article
View Updated Product Label

Study Suggests Metformin May Help Prevent Primary Liver Cancer
A pre-clinical study has demonstrated that metformin prevents primary liver cancer in animal models.
View Article

Study Finds Antipsychotics in Pregnancy Possibly Associated with Neuromotor Deficits
A prospective controlled study determined intrauterine exposure to antipsychotics was associated with lower scores on a standard neuromotor test at 6 months of age.
View Study Abstract

HPV Vaccine Found to Reduce Disease Recurrence
A retrospective analysis of two previous trials suggests that previous vaccination with quadrivalent HPV vaccine significantly reduced the incidence of subsequent HPV-related disease recurrence.
View Article

Research Group Asks FDA to Fight Superbugs as Rare Diseases
The Infectious Diseases Society of America (IDSA) is proposing a plan to review certain antibiotics as orphan drugs with regard to treating drug-resistant bacteria.
View Article

FDA Approves Test that Will Detect Rare Brain Infection in Patients Taking Tysabri
The Stratify JCV Antibody ELISA test will help detect the presence of progressive multifocal leukoencephalopathy in patients using Tysabri to treat Crohn's disease or multiple sclerosis.
View Article

Monotherapy for HER2+ Breast Cancer
A study showed using lapatinib and trastuzumab for HER2+ breast cancer has a better response than using either drug alone.
View Article

Increase Awareness to Dosing IV Acetaminophen for Pediatrics
Numerous reports of miscalculation of intravenous acetaminophen for infants in United Kingdom increase concern for dosing.
View Article

Trans-Fatty Acid Blood Levels Are Declining
National Health and Nutrition Examination Survey for 2000-2009 that evaluated trans-fatty acid blood levels before and after 2006 enforced product label changes found a 58% decline.
View Article

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Drug Approvals

"Dry" Nasal Aerosol Corticosteroid, *Qnasl* Approved
The FDA has approved the first "dry" nasal aerosol corticosteroid, *Qnasl* (beclomethasone dipropionate) indicated for seasonal and perennial allergic rhinits in adults and adolescents 12 years and older.
View Approval

Affymax's Erythropoiesis-Stimulating Agent (ESA), *Omontys* Approved
The FDA has approved Omontys (peginesatide), the first new ESA agent to treat anemia since 2001.
View News Release

Botox Approved for Overactive Bladder
The FDA has approved Botox injections for patients with neurologically-related incontinence.
View Article

Ultrosa & Viokace: Approved Pancreatic Enzymes
Two new pancreatic enzymes were approved that aid in digestion. Ultresa and Vokace which can be used in conditions such as cystic fibrosis, chronic pancreatitis, or post pancreatectomy.
View Article

Binosto, Once-Weekly Effervescent Tablet Approved
The FDA has approved Binosto (alendronate sodium) effervescent tablet for once-weekly treatment of osteoporosis in postmenopausal women and as a treatment to increase bone mass in osteoporotic men.
View Article

Surfaxin Approved for Infant Breathing Disorders
Surfaxin approved to prevent breathing disorders in infants, which aids in preventing RDS in premature infants.
View Article

Cystic Fibrosis Receives New Treatment Option
Kalydeco (ivacaftor) was approved by the FDA to treat a rare form of cystic fibrosis in patients 6 years and older, who also have a gene specific mutation.
View Article

Tafluprost Opthalmic Solution Approved to Treat Glaucoma
Tafluprost is approved by FDA as the first FDA-approved prostaglandin analogue with no preservatives to treat glaucoma.
View Article

Gleevac Receives Expanded Use for Rare Cancer
The FDA approved of the regular use, instead of adjuvant therapy, of Gleevac (imatinib) in adult patients after surgery involving gastrointestinal stromal tumors.
View Article

Korlym Approved
This new medication approved by the FDA helps to control hyperglycemia associated with Cushing's Syndrome.
View Article

Generic Lexapro Approved
FDA approved generic lexapro indicated to treat depression and generalized anxiety disorder by Teva.
View Article

Generic Boniva Approved
The FDA approved generic Boniva, or ibandronate, made by Apotex Inc., Orchid Healthcare, and Mylan Pharmaceuticals Inc.
View Article

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New Guidelines

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Updated Guidelines on HIV Treatment
The revised version of the October 2011 guidelines includes new sections and updates to existing sections highlighted throughout.
View Guideline

New Recommendations for Type 2 Diabetes in ACP Guidelines
American College of Physicians recommends metformin as first choice for oral treatment if lifestyle modifications are refractory in patients; and a second drug is added to metformin if metformin alone cannot control hyperglycemia.
View Guideline

New ACCP Guidelines - Antithrombotic Therapy and Prevention of Thrombosis – Evidence-based Clinical Practice Guideline
The 9th edition of the Antithrombotic Therapy and Prevention of Thrombosis is now available.
View Guideline

New Guidelines for Managing Acute Bacterial Rhinosinusitis
The Infectious Diseases Society of America has released a clinical practice guideline on the management of acute bacterial rhinosinusitis in children and adults.
View Guideline

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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

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September 21, 2012

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Drug Information Center

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FDA MedWatch and Other Safety Alerts

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Notification of Possible Increased Risk of Heart Failure with Mirapex
The FDA is working with the manufacturer to further clarify heart failure risk associated with pramipexole.
View Alert

El Salvador Drug, Instestinomicina Contains Ingredient Formally Withdrawn from U.S.
The FDA has advised consumers to discontinue use of Intestinomicina that contains chloramphenicol, which was formally withdrawn from the U.S. market in July 2012.
View Alert

Serious Burns from OTC Topical Pain Relievers
The FDA issued safety warnings to alert consumers and health professionals of serious burns from OTC topical pain reliever products.
View Alert

Recall on Qualitest Hydrocodone Bitartrate and Acetaminophen Tablets 10 mg/500 mg
Qualitest recalled one lot because tablets may contain a higher dosage of acetaminophen.
View Alert

Recall for Nimodipine
The manufacture of Nimodipine issued a recall for one lot of Nimodipine 30mg due to crystallization.
View Alert

FDA Issues Alert for Prescribing Revatio (Sildenafil) in Children
Revatio (sildenafil) should not be prescribed to children age 1-17 years old for pulmonary arterial hypertension.
View Alert

Hospira Hydromorphone Hydrochloride Injection Recalled
One lot of Hydromorphone injection was recalled due to a complaint that a single Carpuject contained more than 1mL labeled fill volume.
View Alert

Codeine Use May Cause Risk of Life-Threatening Events or Death in Certain Children
Cases are under review by the FDA involving children who developed serious adverse effects or died after taking codeine for pain management after tonsillectomy and/or adenoidectomy for obstructive sleep apnea syndrome.
View Alert

EphBurn 25 Dietary Supplement Recall
Ephedrine alkaloids were found in the dietary supplement which could cause serious adverse effects.
View Alert

Hospira Issues Recall for I-Flow ON-Q Pump with ONDEMAND Bolus Button
The pump may not lock when depressed causing a greater rate of continuous infusion.
View Alert

Midalozam Dosing Syringe Changes
Special Products Ltd has made the final changes to the syringe and is requesting that all patients should be informed to use the syringe graduations.
View Alert

Care Fusion Class 1 Recall
Due to malfunctioning of this product, serious injury and death may occur.
View Alert

Hospira Propofol Injectable Emulsion Recalled Due to Glass Vial Defect
Three lots of Propofol were recalled due to visible particles embedded in the glass.
View Alert

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News Items

Study Reports Increased Off-Label Antipsychotic Use in U.S. Children
A study that represented thirty-five percent of U.S. children reported the off-label use of antipsychotics has increased among children enrolled in Medicaid over the past ten years.
View Article

Psychotropic Drugs Cause Increased Risk for Car Accidents
Antidepressants, benzodiazepines, zolpidem, and zaleplon are associated with an increased risk for motor vehicle accidents.
View Article

Study Showed Dolutegravir Noninferior to Raltegravir for Treatment-Naïve HIV Patients
This is an article summarizing the results of a study between Dolutegravir and Raltegravir.
View Article
View Abstract

Tight Glycemic Control After Cardiac Surgery in Kids
Tight glycemic control in kids after cardiac surgery has no benefits in the rate of infection, mortality, and length of hospital stay.
View Article

Many Americans Hoard Prescriptions and Ignore Healthcare
Due to the poor economy, many people are cutting back on their health care and hoarding medications.
View Article

Depression and Suicidal Thoughts Linked to Patients Previously on Finasteride with Sexual Side Effects
A study showed that patients with sexual side effects from taking finasteride suffer with depression and suicidal thoughts as well.
View Article
View Abstract

Statins Associated with Lowering the Risk of Pancreatitis
A recent meta-analysis suggests that statins may lower the risk for pancreatitis.
View Article
View Abstract

Creatine Used with an SSRI May Benefit Depression
In an eight week randomized controlled trial, adding creatine to an SSRI seems to enhance the medication's antidepressant effects.
View Article
View Abstract

CDC Reports Worst West Nile Outbreak
The number of cases reported is at its highest ever, with 75% of the cases being in the southern states.
View Article

Statin Potency Linked to Muscle Side Effects
Muscle weakness adverse events linked to the potency of statin drugs.
View Article

Breast Cancer Drug Aids Survival
Trastuzumab emtansine, created by Roche, has been proven to significantly extend the lives of women with an aggressive type of breast cancer compared with those receiving the standard treatment.
View Article

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Drug Approvals

New Drug for Brittle Nails Approved
Nail (polyvinylacetate) nail solution has been approved for brittle nail syndrome, one of the most common forms of nail dystrophy.
View Article

FDA Approved Generic Actos
Mylan Pharmaceuticals received FDA approval for pioglitazone for treatment of type 2 diabetes.
View Article

FDA Approved License Extension for Tradjenta Tablets
The FDA has approved a supplemental new drug application for linagliptin (Tradjenta) tablets for use as add-on therapy to insulin.
View Article

FDA Approved New HIV Treatment
The FDA approved Stribild (elvitegravir, cobicistat, emtricitabine, tenofovir disoproxil fumarate), a once a day combination pill used to treat HIV patients that have never been treated for HIV.
View Article

FDA Approved Drug for Treating Late State Prostate Cancer
Xtandi (enzalutamide) was approved for treatment of castration-resistant prostate cancer that has spread or reoccurred.
View Article

FDA Approved Drug to Treat Irritable Bowel Syndrome
Linzess (linaclotide) was approved for chronic idiopathic constipation and constipation associated with irritable bowel syndrome.
View Article

FDA Approved New Treatment for Cancer Patients with Severe Neutropenia.
Ybo-filgrastim was approved for certain cancer patients experiencing neutropenia.
View Article

FDA Approved Generic Singulair
The first generic Singulair (montelukast sodium) was approved by the FDA for treatment of asthma and allergies.
View Article

Gevokizumab Granted Orphan Drug Status by FDA
Gevokizumab, a monoclonal antibody, is used for treating noninfectious intermediate uveitis, posterior uveitis, panuveitis, or chronic noninfectious anterior uveitis.
View Article

First Cushing's Disease Drug Released in the UK
Pasireotide (Signifor) is an injection that is available for adult patients with Cushing's Disease when surgery has failed or is not an option.
View Article

FDA Approved Generic Singulair
The first generic Singulair (montelukast sodium) was approved by the FDA for treatment of asthma and allergies.
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New Guidelines

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Child Influenza Vaccination Schedule Updated
The Advisory Committee on Immunization Practices (ACIP) has published its recommendations for the 2012-2013 Influenza Season.
View Guideline

Care Coordination Emphasized in New European STEMI Guideline
New STEMI guidelines released emphasize on-care coordination.
View Guideline

Revised Guideline for Pregnant HIV-infected Women
The revised guideline offers more treatment options for use of antiretroviral drugs in pregnant HIV-infected women.
View Guideline

Updated Adult Immunizations
The University of Michigan Health System updated guidelines on adult immunizations for preventative health care.
View Guideline

Exercise-Induced Bronchoconstriction Practice Parameter
The Joint Council of Allergy, Asthma, and Immunology released its recommended practice parameter on exercise -induced bronchoconstriction.
View Guideline

Practice Parameter Third Update on Allergen Immunotherapy
The Joint Council of Allergy, Asthma, and Immunology released its updated practice parameters on allergen immunotherapy.
View Guideline

Strep Throat Guidelines Updated
The 2002 Strep Throat guidelines have been updated.
View Guideline

American Academy of Pediatrics Flu Guidelines
The American Academy of Pediatrics has released its recommendations for this flu season.
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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 Usage 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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Drug Information Center
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FYDI
FOR YOUR DRUG INFORMATION

October 23, 2012

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

Ross Freeman, PharmD Candidate
James Zhang, PharmD Candidate
Gregory W. Smith, PharmD, Director
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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.

FDA Releases Fungal Meningitis Statement
View the latest CDC Healthcare Update, the FDA statement and the New England Compounding Center Customer List pertaining to the fungal meningitis outbreak among patients who received contaminated steroid injections.
View Update
View NECC Customer List
View CDC Update

Potentially Oversized Hydrocodone Combo Recalled
Qualitest recalled one lot because tablets may contain a higher dosage of acetaminophen.
View Alert

Hospira Lactated Ringer's & 5% Dextrose Injection 1000 ml Bag Recalled
One batch of Lactated Ringer's and 5% Dextrose Injection, 1000 ml flexible containers was found to have mold.
View Alert

ACTRA-Sx 600 Capsule Recalled
The FDA has issued a recall for Body Basics product Actra-Sx for not declaring that their product contained Sildenafil Citrate.
View Alert

H & P Surgical Supplies Recalled
The FDA recalled Povidone Iodine Swabsticks, Prep Solutions, Scrub Solutions, and Prep Gel due to inadequate microbial testing.
View Alert

Opana Misuse May Lead to Fatal Blood Disorders
FDA released a statement saying abuse of Opana ER by injection may lead to thrombotic thrombocytopenia purpura.
View Alert

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Medwatch Voluntary Reporting Form

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News Items

Cervical Cancer Vaccine Under Development
A Pennsylvania pharmaceutical company is in the early stages of clinical trials for a vaccine to help fight off cervical cancer.
View Item

Obesity in Teenage Boys Leads to Low Testosterone Levels
Researchers at a medical school have discovered that testosterone levels are indirectly proportional to BMI; therefore, overweight teenage boys are at risk for delayed sexual maturation.
View Item

Prenatal Mercury Exposure Possibly Linked to Development of ADHD in Kids
Children of mothers whose hair samples had mercury levels of at least 1 µg/g were at increased risk for hyperactivity and impulsivity.
View Item

CDC Has New Recommendations for Hepatitis C Testing
CDC recommends all 'baby boomers' born between 1945-1965 to be tested for Hepatitis C.
View Item

Nobel Prize for Medicine Awarded to UK & Japanese Scientists
Drs. John Gurdon and Shinya Yamanaka shared the Nobel Prize for their discovery of adult stem cells that can be transformed back into embryo-like stem cells to be used in damaged organs.
View Item

Aspirin May Have Beneficial Effects for Brain Function in Elderly Women
Studies show that women aged 70-92 years of age with heart diseases showed less decline in brain and cognitive function than those who were not on Aspirin.
View Item

Possible Risk of Glaucoma from Drinking Coffee
Study has shown that people that drink 3+ cups of coffee may have increased risk of glaucoma and eventual blindness.
View Item

NeuroVax Files for Orphan Designation for Multiple Sclerosis
Immune Response Biopharm, Inc. has filed for orphan designation in relation to its drug NeuroVax for the treatment of Multiple Sclerosis.
View Item

Study Suggests Apixaban Better than Warfarin for Atrial Fibrillation
Researchers have found that Apixaban is better than and safer than warfarin in the treatment of atrial fibrillation and also has benefits in stroke.
View Item

FDA Takes Aim at Illegal Internet Pharmacies
The FDA has teamed up with the international regulatory and law enforcement agencies to take action against more than 4,000 different internet pharmacies.
View Item

Are Expired Meds Being Thrown Away Too Soon?
Researchers have reason to believe that certain medications still meet the FDA's regulations for potency up to forty years after expiration.
View Item

Black Mamba Snake Venom Vs. Morphine for Pain
Researchers have discovered two proteins contained in black mamba venom that show analgesic properties similar to morphine, without some of the harmful adverse effects.
View Item

Vitamin C Possibly Helps Lower Risk of Gout
Researchers' finding suggest that increased intake of Vitamin C may decrease the incidence of gout in men.
View Item

New Onset Snoring During Pregnancy May Indicate Hypertension
Researchers have discovered that pregnant patients that have begun snoring due to pregnancy may be at an increased risk for hypertension and preeclampsia.
View Item

Benzodiazepines May Cause Dementia in the Elderly
Researchers have discovered that new use of benzodiazepines in the elderly may be associated with an increased risk of dementia.
View Item

Acute Pancreatitis Associated with DPP-4 Inhibitors
Researchers have added new information to the package insert after they found that DPP-4 inhibitors have a risk for causing acute pancreatitis.
View Item

New Updates from ACIP Regarding Pneumonia Vaccinations in High-risk Patients
New updates for 13-Valent Pneumococcal Conjugate Vaccine and 23-Valent Pneumococcal Polysaccharide Vaccine for immunocompromised adults.
View Item

The Future of Inhaled Vaccines
A new review article has been published in *Journal of Aerosol Medicine and Pulmonary Drug Delivery* describing the future of inhaled vaccines.
View Item

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Drug Approvals

Actemra Approved as Second Line Therapy in Rheumatoid Arthritis
The FDA has given Roche's Genentech product, Actemra, approval for use as second line therapy instead of third line therapy for Rheumatoid Arthritis.
View Item

Watson Gains FDA Approval on Two Generics
The FDA has granted Watson Pharmaceuticals approval on the generics for Avapro and Sanctura XR.
View Item

FDA Approve New Dermatological Drug
The FDA has approved Sandoz's generic form of Topicort, desoximetasone ointment, for symptoms of various skin diseases.
View Item

FDA Approves Liquid ADHD Medicine
The FDA has approved Quillivant XR (methylphenidate hydrochloride) for the treatment of ADHD.
View Item

New Colorectal Cancer Drug Released
FDA has approved a new treatment, Stivarga (regorafenib), for patients with colorectal cancer which has progressed after previous treatment and spread to other parts of the body.
View Item

New Asthma Drug Approved From Acton
Aerospan (flunisonide) HFA has been approved by the FDA as a maintenance inhaler for people aged 6 and older.
View Item

New Injection Drug Approved for Macular Edema
EYLEA (aflibercept) has been approved by the FDA for the treatment of macular edema following central retinal vein occlusion (CRVO).
View Item

FDA Approves Generic Diovan HCT
The FDA has approved the generic of Diovan HCT in various strengths.
View Item

New Drug Application for Selective Norepinephrine Reuptake Inhibitor (SNRI)
Forest Laboratories has submitted a new drug application for Levomilnacipran, an SNRI for treatment of Major Depressive Disorder.
View Item

Humira Approved for Treatment of Ulcerative Colitis
The FDA has expanded the approval of Humira to include Ulcerative Colitis.
View Item

Subcutaneous Heart Defibrillator
The FDA has approved the use of the first subcutaneous heart defibrillator.
View Item

FDA Approves Lotemax Gel
The FDA has approved Lotemax gel use for treatment of inflammation and pain after ocular surgery.
View Item

FDA Approves the Use of Imaging Agent in Detection of Prostate Cancer
The FDA has approved the use of Choline C 11 injections to help detect recurrent prostate cancer.
View Item

Oparxio Earns Orphan Drug Status from FDA
The FDA has granted Cell Therapeutics Inc. drug Opaxio orphan drug status to treat glibastoma multiforme.
View Item

New Label Updates to Exjade
FDA has revised Exjade's black box warning and other label information.
View Item

New FDA-Approved Drug Cystaran
Cystaran 0.44% ophthalmic solution from Sigma Tau Pharmaceuticals now approved for corneal cystine crystal accumulation from cystinosis.
View Item

FDA Withdraws Approval for Budeprion XL 300 mg
The FDA has announced that it is withdrawing approval of Budeprion XL 300 mg manufactured by Impax Laboratories due to lack of therapeutic equivalency to Wellbutrin.
View Item

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New Guidelines

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New Guidelines for Management of Bleeding with Pradaxa
A new guideline has been released for management of bleeding in the emergency department from direct thrombin inhibitor, Pradaxa.
View Guideline

Clinical Practice Guideline for Hypothyroidism
New guideline released for management of hypothyroidism in adults.
View Guideline

New Gout Guideline released
American College of Rheumatology released a new guideline regarding management of gout, including new first-line treatments for hyperuricemia.
View Guideline

NICE Releases Guidelines for Management of Crohn's Disease
The National Institute for Health and Clinical Excellence has released a guideline for the management of Crohn's Disease in adults, children, and young people.
View Guideline

New Guideline for Septic Arthritis from Injections
CDC has released an interim treatment guideline for septic arthritis from injection of potentially contaminated steroid products.
View Guideline

Guideline for Live Attenuated Influenza Vaccine
New guideline released for the use Live Attenuated Influenza Vaccine in healthcare personnel from Society for Healthcare Epidemiology of America (SHEA).
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