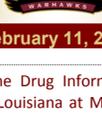


FYDI

FOR YOUR DRUG INFORMATION



February 11, 2011

ULM COLLEGE OF PHARMACY Drug Information Center



Ben Bordelon, PharmD Candidate
Chad Kimball, PharmD Candidate
Gregory W. Smith, PharmD, Director

Drug Information Services
318.342.5501
druginfo@ulm.edu

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 Alerts
News Items
Drug Approvals
New Guidelines

FDA MedWatch Alerts

Hydrocodone/Acetaminophen Recalled Due to Mislabeling

Qualitest Pharmaceuticals mislabeled a bottle of Hydrocodone and Acetaminophen Tablets, USP 10mg/500mg with a Phenobarbital Tablets, USP 32.4mg label.

[View Article](#)

Recall of American Regent Injectable Products

American Regent injectable products, Sodium Thiosulfate Injection USP 10% and Potassium Phosphates Injection, USP, were recalled because physical particles of glass were found in vials.

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Recall of Nite Rider Maximum Sexual Enhancer For Med and STUD Capsules

Nite Rider Maximum Sexual Enhancer and STUD capsules were recalled due to an undeclared drug ingredient. Sildenafil was found in both products making them an unapproved new drug.

[View Article](#)

Recall of Triad Alcohol Prep Pads, Alcohol Swabs, and Alcohol Swabsticks

The Triad Group initiated this recall due to potential microbial contamination. The recall includes STERILE and non-sterile Triad alcohol prep pads, swabs, and swabsticks.

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Avandia (rosiglitazone) Labeling Revised

The FDA has revised the labeling of rosiglitazone by adding information on the cardiovascular risks (including heart attack) to the physician labeling and patient Medication Guide.

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Withdrawal of Propoxyphene from US Market

FDA recommends propoxyphene-containing products be removed from the US market due to risks of cardiac toxicity.

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Recall of Albuterol Sulfate Inhalation Solution 0.083%

The Ritedose Corporation has mislabeled 0.5 mg/3 mL unit dose vials of Albuterol Sulfate Inhalation with the incorrect concentration.

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Acetadote Injectable Recalled

Cumberland Pharmaceuticals Inc. issued a recall of Acetadote (acetylcystine) Injectable vials due to particulate matter.

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Multaq Associated with Severe Liver Injury

Healthcare professionals are being notified by the FDA that Multaq can cause rare, but severe liver damage. In two cases that were reported, patients suffered liver failure and required liver transplantation.

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Prescription Products Containing Acetaminophen Restricted to 325mg per Dosage Unit

Manufacturers of acetaminophen prescription drug products were asked by the FDA to restrict the strength of acetaminophen to 325 mg per dosage unit. Prescription drug products that contain acetaminophen will have Boxed Warnings stressing the potential for allergic reactions and severe liver injury.

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Metronidazole Tablets Recalled Due To Underweight Tablets

Metronidazole 250 mg Tablets, product lot # 312566, were recalled due to the presence of underweight tablets which may contain inadequate doses of the active ingredient.

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Accidental Overdoses Reported with Morphine Sulfate Oral Solutions

Severe adverse events and deaths have occurred from accidental overdose of morphine sulfate oral solutions. Most of the errors have occurred as healthcare professionals wrongly interchanged milliliters (mL) for milligrams (mg) in orders.

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News Items

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

Diabetes is on the Rise

The CDC estimates that close to 26 million American have diabetes and 79 million have prediabetes. Diabetes is projected to affect 1 in 3 U.S. adults by 2050 if the existing trends continue.

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Increasing Access to MTM Could Help Decrease Healthcare Costs

Sen. Kay Hagan stated to the Senate Thursday the importance of increasing access of medication therapy management (MTM). Hagan proposed to increase MTM access to seniors with any chronic condition.

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New Research Shows Antidepressants are Prescribed Without Indicated Diagnosis

Over 25% of Americans taking antidepressants have not been diagnosed with an approved indication. Without a proper diagnosis, the risk of side effects may not be worth the health benefits of antidepressants.

[View Article](#)

Adults with ADHD may be at Increase Risk for Dementia

A recent study linked adults who suffered from attention-deficit and hyperactivity disorder with a form of dementia, known as DLB (dementia with Lewy bodies). It is believed that there is a common neurotransmitter dysfunction in both diseases.

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[View Abstract](#)

Factors that can Affect Self-Monitoring Glucose Results

A recent study investigated capillary blood glucose monitoring under different circumstances including unwashed hands, washed hands, after handling fruit, and after external pressure. The study concluded that unwashed hands, handling fruit, and external pressure can affect the first drop of blood. Washing hands, if possible, before self-monitoring blood glucose is the best option.

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Possible Link between Statin Therapy and C-Reactive Protein (CRP) Levels

Authors of a recent clinical trial hypothesized that levels of CRP would affect how well statin therapy would modify major vascular events. The trials results showed that statin therapy reduces the amount of major vascular events in patients, no matter the CRP concentrations.

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Use of Escitalopram in Healthy Menopausal Women may Reduce Hot Flashes

In a clinical trial, escitalopram (Lexapro®) was effective in reducing the amount of hot flashes experienced by healthy menopausal women.

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Tamiflu Oral Suspension on Backorder

Tamiflu for Oral Suspension is currently on backorder by the manufacturer, Genentech, due to an increase in demand. Tamiflu capsules and FDA-approved instructions are available for emergency compounding if needed.

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Testing for Alzheimer's in Living Patients

The FDA is considering the approval of PET scans as diagnostic tests for Alzheimer's disease. The only way to confirm Alzheimer's now is by performing an autopsy on the patient's brain.

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Treating Acute Otitis Media with Antibiotics

It is current practice that antibiotics are not administered for children with acute otitis media until after three days of diagnosis. Researchers are found that symptoms of acute otitis media are reduced when antibiotics are started at diagnosis.

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Fake Bath Salts Banned in Louisiana

Fake bath salts were placed on the Schedule I drug list January 6th by Gov. Bobby Jindal. Fake bath salts were sold at many convenient stations and are referred to as "the poor man's meth" by law enforcement agencies. The drug has similar effects to those of ecstasy and cocaine.

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Drug Approvals

FDA Grants Regorafenib Orphan Drug Status

FDA has approved regorafenib as an orphan drug in the treatment of gastrointestinal stromal tumors (GIST).

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Makena Injection Approved for Reduction of Risk of Preterm Delivery

FDA approves Makena (hydroxyprogesterone caproate) injection under the agency's accelerated approval regulation. This injection is to reduce the risk of preterm delivery before 37 weeks of pregnancy, in pregnant women with a history of at least one spontaneous preterm birth.

[View Article](#)

FDA Approves Natroba, a New Topical Suspension for Head Lice

Natroba (spinosad) Topical Suspension 0.9% has been approved by the FDA for the treatment of head lice in patients ages 4 years and older.

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Abstral Approved for the Treatment of Breakthrough Pain for Adults with Cancer

Abstral (fentanyl) transmucosal tablets have been approved by the FDA to help manage pain in cancer patients.

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Triple Drug Combination Approved by the FDA for Treatment of High Blood Pressure

Amturnide was approved by the FDA, December 23, 2010, for the treatment of high blood pressure. Amturnide combines aliskiren, amlodipine, and hydrochlorothiazide in a single tablet.

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Viibryd Approved for the Treatment of Major Depressive Disorder

Viibryd (Vilazodone HCl) is a dual-acting antidepressant approved to treat major depression in adults. The drug is a selective serotonin reuptake inhibitor and serotonin 1A receptor partial agonist.

[View Article](#)

FDA approves Allegra for OTC

Allegra (Fexofenadine HCl) has been approved as an over-the-counter allergy medication for adults and children two years of age and older.

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New Guidelines

New updated guidelines for Cerebral Venous Thrombosis

Updated guidelines on the diagnosis and management of cerebral venous thrombosis have been issued by the American Heart Association/American Stroke Association.

[View Guidelines](#)

New updated guidelines for the Management Extracranial Carotid and Vertebral Artery Disease

Updated guidelines on the management of patients with extracranial carotid and vertebral artery disease have been issued by the American Heart Association.

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New Childhood and Adolescent Immunization Schedule Guidelines

The committee on infectious diseases has issued new guidelines for childhood and adolescent immunization schedules.

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318-342-5501

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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, 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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- 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 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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View [previous issues](#) of the FYDI newsletter.

For comments and suggestions please email druginfo@ulm.edu.

Disclaimer: No information source can replace clinical judgment applied to a specific case. Some of the drug therapy we write about will be outside the labeled indications for specific products. References will be provided when possible. Consult these references, product labeling, and/or give us a call if we can help with specific cases. This newsletter is supported by the University of Louisiana at Monroe College of Pharmacy and is not intended for commercial promotion.

FYDI

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March 18, 2011

ULM COLLEGE OF PHARMACY Drug Information Center



Brigette Deville, PharmD Candidate
Ashley Slocum, PharmD Candidate
Gregory W. Smith, PharmD, Director

Drug Information Services
318.342.5501
druginfo@ulm.edu

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[News Items](#)
[Drug Approvals](#)
[New Guidelines](#)

FDA MedWatch Alerts

Antipsychotics Labeling Revised

The Pregnancy section of drug labels for the entire class of antipsychotic drugs has been updated by the FDA to include more information about the potential risk for extrapyramidal side effects and withdrawal symptoms in newborns whose mothers used these drugs during the third trimester of pregnancy.

[View Alert](#)

One Lot of Warfarin Recalled

Upsher-Smith Laboratories is recalling lot number 284081 of warfarin tablets (marketed as Jantoven) due to product mislabeling. Some bottles of the drug possibly contain the 10mg (white) tablets instead of the intended 3mg (tan) tablets.

[View Alert](#)

Terbutaline Should Not Be Used for Prolonged Preterm Labor

The FDA is issuing a boxed warning to injectible terbutaline (a bronchodilator) to caution against the off-label use for the prevention or prolonged treatment (48-72h) of preterm labor in pregnant women. Postmarketing reports of serious adverse reactions in women receiving terbutaline for obstetric uses have demonstrated that the risks of using terbutaline in pregnant women exceed the benefits.

[View Alert](#)

U.S. Marshals Seize Unapproved Auralgan Otic Solution

At the request of the FDA, U.S. Marshals seized Auralgan Otic Solution, a prescription medication used for the treatment of inflammation and pain associated with ear infection because the product has not received FDA approval.

[View Alert](#)

King Pharmaceuticals Recalls Embeda® (Morphine Sulfate/Naltrexone Hydrochloride) Extended Release Capsules

All dosages of Embeda® Extended Release Capsules have been voluntarily recalled from wholesalers and retailers in the US due to a stability defect found in the extended-release product during routine testing.

[View Article](#)

Recall of Extenze Tablets

Two lots of Extenze tablets were recalled due to undeclared drug ingredients. Tadalafil and sildenafil were found in one lot while tadalafil and sibutramine were found in the other.

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Removal of Unapproved Prescription Cough, Cold, and Allergy Drug Products from the U.S. Market

The FDA announced that unapproved prescription cough, cold, and allergy drug products that have not been evaluated by the FDA will be removed from the market in the U.S.

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PPIs Associated with Low Magnesium Levels

Healthcare professionals are being notified by the FDA that long term use of prescription proton pump inhibitor drugs may cause hypomagnesemia.

[View Alert](#)

Kaletra Labeling Revised

The FDA notified healthcare professionals of the revised labeling of Kaletra (lopinavir/ritonavir) oral solution due to the adverse events such as serious heart, kidney, and breathing problems in premature babies.

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Label Change for Topamax

Healthcare professionals and patients are being notified of an increased risk of development of cleft lip and cleft palate in infants born to women treated with Topamax (topiramate) during pregnancy. Topiramate is being placed in Pregnancy Category D.

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News Items

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

Zinc Reduces the Duration and Severity of the Common Cold in Healthy People

A recent meta-analysis found that zinc may be effective in shortening the duration and severity of the common cold when administered within 24 hours of the onset of symptoms.

[View Abstract](#)

Bisphosphonates Linked to Increased Risk for Unusual Fracture

A recent study linked bisphosphonate use in older women to an increased risk of subtrochanteric or femoral shaft fractures.

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Elderly Women on Bone Medications May Live Longer

Despite recent negative press, findings recently reported by Australian researchers may assuage some of the concerns patients may have about taking bisphosphonates. These preliminary findings demonstrate that elderly women taking bisphosphonates live longer than those who do not receive treatment.

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[View Abstract](#)

New Anticoagulant Added to Atrial Fibrillation Guidelines

The American Heart Association issued a "focused" update of the Afib guidelines in which the recently approved anticoagulant dabigatran (Pradaxa®) is recommended as an alternative to warfarin for the prevention of stroke in patients with Afib.

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Experts Seek to Clarify Confusing Medication Labels

A recent study found that nearly half of patients misunderstand the directions on their prescription bottle labels. Experts are currently seeking ways to clarify medication label directions and improve patient compliance.

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Parents Give Cough and Cold Meds to Young Children Despite Warnings

Following the 2008 FDA recommendation to avoid OTC cough and cold product use in children younger than 2 years of age, results of a recent poll demonstrate continued use of these products in this age group, as well as continued recommendation of these products by physicians.

[View Article](#)

Obama Budget Proposal Targets Brand Name Drugs

As part of his 2012 budget proposal, President Obama has released two proposals that could create greater competition between large pharmaceutical companies and generic manufacturers. These proposals include shortening market exclusivity for brand-name drugs and ending "pay-for-delay" deals made between these companies.

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Pharmacist-Directed Anticoagulation Service Improves Quality of Care

Researchers with a Henry Ford Hospital study report that "a pharmacist-directed anticoagulation service improves the way medication is managed for patients with heparin-induced thrombocytopenia (HIT)". When compared to patients treated by the primary medical team, patients treated by the anticoagulation service had a reported favorable response to alternative anticoagulant agents three times faster and were 32% more likely to receive proper drug dosing.

[View Article](#)

Combining Annual Flu Shot With Other Vaccines May Increase Child's Seizure Risk

Results from a CDC investigation suggest that "combining the annual flu shot with other vaccines- particularly the pneumococcal PCV13 vaccine- may increase a child's risk of seizure associated with high fever". While approximately 1 in 25 kids under age 5 experience a febrile seizure, the combination is reported to increase this risk by a reported one case per 1,600 double vaccinations in children between 12 and 23 months of age.

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Disulfiram to be Tested as Possible AIDS Treatment

Researchers from the University of California, San Francisco, and John's Hopkins University plan to investigate whether disulfiram "can deplete the pool of residual virus that regular AIDS drugs don't clear" by "flushing out latent reservoirs of HIV" an effect that would allow the successful cessation of HIV drugs without the subsequent rebound of the disease. The basis for this study is research demonstrating that methyltransferase blockers can reactivate HIV in vitro. Disulfiram has demonstrated methyl transferase blocking activity in cancer cells.

[View Article](#)

Olmesartan Delays Microalbuminuria in Diabetes, but with Risks

A recent trial published in the *New England Journal of Medicine* investigated whether treatment with an angiotensin-receptor blocker (ARB) would delay or prevent the occurrence of microalbuminuria in patients with type 2 diabetes and normoalbuminuria. Results of the study demonstrated that the use of olmesartan significantly delayed the onset of microalbuminuria compared to placebo. In addition, nearly 80% of patients receiving olmesartan achieved target blood pressure (<130/80 mmHg). However, a higher rate of fatal cardiovascular events associated with olmesartan treatment was reported in patients with preexisting coronary heart disease.

[View Abstract](#)

Use of Opioid Analgesics during Pregnancy may Increase the Risk of Birth Defects

The National Birth Defects Prevention Study showed an association between early pregnancy maternal opioid analgesic treatment and certain birth defects.

[View Abstract](#)

Authorities in Japan have been Distributing Potassium Iodide Tablets to People near Affected Nuclear Power Reactors

Potassium iodide blocks the uptake of radioactive iodine by the thyroid. Frequently-asked-questions have been published by the FDA and the U.S. Nuclear Regulatory Commission with regard to potassium iodide.

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FDA Advises Consumers of Unapproved Potassium Iodide

Despite experts advising U.S. consumers that there is no need to stockpile potassium iodide, demand has spiked due to the worsening situation in Japan. The FDA is advising consumers to "...be wary of products that falsely claim to protect against radiation."

[View Article](#)

Antihypertensive Drugs May Benefit Heart Patients with Normal Blood Pressure

Results of a new study indicate that the use of antihypertensive agents in normotensive patients reduces the risk of stroke, congestive heart failure, all-cause mortality, and a combination of cardiovascular disease outcomes in these patients.

[View Article](#)

Once-Weekly Exenatide Misses Endpoint in Key Study

Results from the DURATION-6 trial report that once-weekly exenatide (Bydureon®) failed to demonstrate noninferiority to daily liraglutide (Victoza®). Investigators stated that "Bydureon® failed to meet the prespecified primary endpoint of noninferiority to Victoza®."

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Drug Approvals

FDA Approves Edarbi, a New Angiotensin II Receptor Blocker

FDA approves Edarbi (azilsartan medoxomil) for the treatment of high blood pressure. The drug will be available in two doses, 40 and 80 mg.

[View Article](#)

FDA Approves Daliresp, a New Drug to Treat Chronic Obstructive Pulmonary Disease

Daliresp (roflumilast) has been approved by the FDA as a pill taken daily to decrease the frequency of exacerbations or worsening of symptoms from severe COPD. The drug is a phosphodiesterase type-4 inhibitor; a new drug class for the treatment of COPD.

[View Article](#)

FDA Approves Benlysta to Treat Lupus

Benlysta (belimumab) is the first new lupus drug approved in 56 years and is indicated for use in patients with active, autoantibody-positive lupus (systemic lupus erythematosus) who are receiving standard therapy. Benlysta is administered via intravenous infusion. It acts by inhibiting the B-lymphocyte stimulator (BLYS) protein, which may reduce the number of abnormal B cells thought to be a problem in lupus.

[View Article](#)

FDA Approves Corifact, the First Treatment for Congenital Factor XIII Deficiency

FDA approves Corifact (Factor XIII concentrate (Human)) to prevent bleeding in people with the rare genetic defect. It received orphan-drug designation by the FDA because it is intended for use in a rare condition.

[View Article](#)

[View all FDA-approved drugs at CenterWatch.com](#)

New Guidelines

New Updated Guidelines on Secondary Stroke Prevention

An update of the Prevention of Stroke in Patients with Stroke and Transient Ischemic Attack has been issued by the American Heart Association/American Stroke Association.

[View Guidelines](#)

New Updated Guidelines on the Management of Patients with Atrial Fibrillation

An update of the management of atrial fibrillation has been issued by the American College of Cardiology Foundation/American Heart Association Task Force.

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New Updated Guidelines for the Use of Antimicrobial Agents in Neutropenic Patients with Cancer

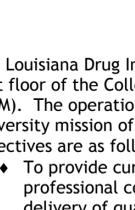
An update of clinical practice guidelines has been issued by the Infectious Diseases Society of America.

[View Guidelines](#)

New Updated Guidelines Issued for the Women's Cardiovascular Disease Prevention

Updated guidelines on the prevention of cardiovascular disease in women have been released by the American Heart Association.

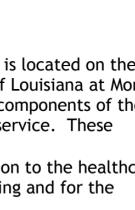
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- Laboratory Interpretation
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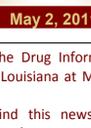
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May 2, 2011

ULM COLLEGE OF PHARMACY Drug Information Center



Tejash Desai, PharmD Candidate
Gregory W. Smith, PharmD, Director

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FDA MedWatch Alerts

Tysabri Prescribing Information Update

The FDA has updated the prescribing information for Tysabri regarding the risk of progressive multifocal leukoencephalopathy associated with using the drug for the treatment of multiple sclerosis and Crohn's disease.

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X-Hero and Male Enhancer Recalled for Undeclared Ingredients

Lab analysis detected active ingredients sulfosildenafil in the product X-Hero and taladafafil in Male Enhancer.

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Meds IV Pharmacy Products Recalled Due to Outbreak of Serratia Marcescens Bacteremia in Alabama Hospitals

The Alabama Department of Public Health (ADPH) is investigating an outbreak of Serratia marcescens bacteremia among patients receiving total parenteral nutrition in six Alabama hospitals. ADPH is aware of 19 cases related to this outbreak.

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Special Storage and Handling Requirements for Pradaxa

FDA is alerting the public of the potential for product breakdown from moisture and loss of potency of Pradaxa capsules. The drug should only be dispensed and stored in the original packaging.

[View Alert](#)

Greenstone's Citalopram And Finasteride Recalled Due to Possible Mislabeling

Due to the possibility that incorrect labels have been placed on packaging, Greenstone LLC is voluntarily recalling medicines with lot number F10510058-A including Citalopram 10mg Tablets (100-count bottle) and Finasteride 5mg Tablets (90-count bottle).

[View Alert](#)

Risk Evaluation and Mitigation Strategy (REMS) For Yervoy (ipilimumab) Against Severe Immune-Mediated Adverse Reactions

Healthcare professionals were informed about the risk evaluation and mitigation strategy (REMS), that is required to ensure that the benefits of Yervoy outweigh the risks of severe and fatal immune-mediated adverse reactions.

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Risk of Methemoglobinemia Associated With Benzocaine Topical Products

The FDA continues to receive reports of methemoglobinemia, a serious and potentially fatal adverse effect, associated with benzocaine products.

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Increased Risk of Developing New Malignancies Linked With Revlimid (lenalidomide)

FDA is notifying the public of clinical trials conducted inside and outside the United States that found that patients treated with Revlimid (lenalidomide) may be at an increased risk of developing new types of cancer.

[View Alert](#)

Axent FlexiShield Mini Recalled Due To Particles of Tungsten

Xoft Axent Flexishield Mini product, has been recalled due to the possibility of particles of tungsten being shed.

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Class 1 Recall On Penumbra Coil 400 by Penumbra Inc

Premature detachment of the coil implanted in patient may cause the coil to unintentionally migrate leading to serious injury including blood clots and stroke.

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Updated Reports of Hepatosplenic T-Cell Lymphoma Associated With Tumor Necrosis Factor (TNF) blockers

FDA continues to receive reports of a rare cancer of white blood cells, primarily in adolescents and young adults being treated for Crohn's disease and ulcerative colitis with medicines known as tumor necrosis factors (TNF) blockers, as well as with azathioprine, and/or mercaptopurine.

[View Alert](#)

Topamax Recalled Due to Musty Odor

Ortho-McNeil-Janssen Pharmaceuticals, Inc., has recalled two lots of Topamax (topiramate) 100mg Tablets due to consumer reports of an uncharacteristic odor thought to be caused by trace amounts of TBA (2,4,6-tribromoanisole).

[View Alert](#)

Clogged, Blocked Oral Syringes and Feeding Tubes Caused by Lansoprazole Orally Disintegrating Tablets

Teva's lansoprazole delayed-release orally disintegrating tablet when administered as a suspension, has been reported to have clogged and blocked oral syringes and feeding tubes, including both gastric and jejunostomy types.

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News Items

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

Calcium Associated with Increased Risk of Cardiovascular Events

Though the initial analysis of data from one of the Women's Health Initiative trials did not show significant association, subsequent analysis of participant taking non-protocol supplementary calcium found an association between calcium supplementation and an increase in risk of myocardial infarction.

[View Item](#)

[View Abstract](#)

FDA's Risk Management Strategy for Long-Acting Opioids

The Office of National Drug Control Policy reports that the FDA is taking action requiring drug manufacturers to develop an education program for prescribers regarding the safe use of opioids.

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[View FDA News Item](#)

Study Shows Pioglitazone Lowers Risk of Progression to Diabetes

The investigators determined that 18 people needed to be treated for one year to prevent one case of diabetes.

[View Abstract](#)

Musty Odor Reason for another Tylenol Recall

McNeil Consumer Healthcare announces it was conducting a voluntary consumer recall of one product lot of eight-hour extended-release caplets because of a "musty or moldy odor."

[View Article](#)

Asthma Risk of Unborn Child in Pregnant Women

Use of acetaminophen in pregnant women may be linked with increased risk of asthma in their unborn children

[View Article](#)

Soladek Vitamin Solution Out of Proportion

The FDA has warned consumers to stop using Soladek, a vitamin-solution product, because the product may contain dangerously high levels of vitamins A and D.

[View Article](#)

FDA Make Recall Web Search Easier to Deal With

On April 4, 2011, the FDA launched a new consumer-friendly Web resource allowing consumers to search for recalls easier and quicker on the FDA's website.

[View Article](#)

[View FDA Search Resources](#)

Study Suggests Statins May Lower Death Rates from Pneumonia

The London School of Hygiene and Tropical Medicine have concluded from a study to show the benefits of taking statins against dying from pneumonia.

[View Article](#)

'Pain Contracts' May Be Necessary to Get Prescriptions

Doctors may ask patients to sign "pain contracts" or "opioid treatment agreements" that spell out the rules patients must follow to monitor drug use.

[View Article](#)

Stopping Estrogen Reduces Stroke Risks

The long-term follow-up of a landmark study has suggested that strokes and other health issue linked with estrogen pills appear to decrease when women quit taking them after menopause.

[View Article](#)

Omega-3 Fatty Acids May Prevent Atrial Fibrillation

A meta-analysis of RCTs was conducted to examine the role of Omega-3 fatty acids in the prevention of atrial fibrillation.

[View Article](#)

Effect of Phentermine plus Topiramate in Overweight and Obese Adults

The CONQUER study assessed efficacy and safety of phentermine plus topiramate combination as an adjunct to diet and lifestyle for weight reduction in adults who were overweight or obese, and had weight related co-morbidities.

[View article](#)

Oral Birth Defects Caused by Steroid Medications?

Corticosteroid drugs used in pregnant women for asthma or other chronic ills may not have a greater risk of birth defects.

[View Article](#)

Statins May Help Eliminate Kidney Complications Post Elective Surgery

Taking a statin prior to a major elective surgery reduces potentially serious kidney complications, according to a study appearing in the *Journal of the American Society Nephrology* (JASN).

[View Article](#)

Use of Angiotensin Receptor Blockers Linked With The Risk of Cancer?

A recent meta-analysis of 9 studies associated use of ARBs with a modest increase in risk of incident cancer, particularly lung cancer. However, according to an analysis of registry data, this possibility of this association has been denied.

[View Article](#)

Antenatal Corticosteroids at 34-36 Weeks' Gestation Has No Effect on Respiratory Disorders in Late Preterm Infants

Results from a randomized controlled trial published early online in the BMJ, concluded the use antenatal corticosteroids does not reduce the incidence of respiratory disorders in newborn infants.

[View Article](#)

[View Abstract](#)

Shortage of ADHD Drugs Concern Parents

Nationwide shortages of popular drugs used to treat ADD and ADHD are sending parents checking multiple pharmacies in search for Adderall and Ritalin to keep their kids calm.

[View Article](#)

Heartburn Drugs Offer Little Asthma Relief

Doctor prescribing heartburn drugs in asthmatic patients for wheezing may not necessarily be a good option.

[View Article](#)

Drug-Resistant Bacteria Found in Nearly Half of U.S Meat

Study finds that much of meat and poultry sold in supermarkets is contaminated with drug-resistant staph bacteria.

[View Article](#)

FDA Requests Manufacturers of Long-Acting Beta-Agonists to Conduct Further Safety Trials

The FDA is requiring manufacturers to further evaluate the safety of long-acting beta-agonists (LABAs) when used in combination with inhaled corticosteroids for the treatment of asthma.

[View Article](#)

Patients with Inflammatory Bowel Disease Infected With C.Difficile May Be at Higher Risk of Death

Patients becoming infected with *Clostridium difficile*, may face a six fold greater risk of death when admitted to hospital with inflammatory bowel disease.

[View Article](#)

Drug Approvals

Tentative approval of emtricitabine capsules, 200 mg

On March 29, 2011, the FDA granted tentative approval for emtricitabine capsules, 200 mg, an antiretroviral agent for the treatment of HIV-1 infection. Under the President's Emergency Plan for AIDS Relief, "Tentative approval" means that the drug has met all FDA quality, safety and efficacy standard requirements, but is not eligible for U.S. marketing due to patent protections.

[View Emergency Plan for AIDS Relief](#)

FDA Approves Zyclara® (Imiquimod) Cream for External Genital Warts

The FDA has approved Graceway® Pharmaceuticals' Zyclara® Cream for treating external genital and perianal warts in patients 12 years of age and older.

[View Article](#)

Zostavax Now Indicated for Patients 50 years and Older

Merck's Zostavax shingles vaccine, which is already indicated for those ages 60 years and older has been approved in patients 50 to 59 years of age.

[View Article](#)

Horizant Approved for Restless Legs Syndrome

The FDA has approved Horizant Extended Release Tablets (gabapentin enacarbil), a once-daily treatment for the treatment of moderate-to-severe restless legs syndrome.

[View Article](#)

Zactima: A New Treatment for a Rare Form of Thyroid Cancer

The FDA has approved Zactima (vandetanib) for treating adult patients with late-stage (metastatic) medullary thyroid cancer who are surgery-ineligible and who have symptomatic or growing disease.

[View Article](#)

New Drug Application Accepted for Oxybutynin (Anturo®) Gel

A New Drug Application for oxybutynin (Anturo®) gel in patients with overactive bladder has been accepted by the FDA. The application submission is supported by data from a 12-week phase III trial in 600 patients.

[View Article](#)

INVEGA® Approved For Schizophrenia In Adolescents

The FDA has approved INVEGA® (paliperidone) extended-release tablets for the indication of schizophrenia in adolescents 12 to 17 years of age.

[View Article](#)

Actemra Approved for Systemic Juvenile Idiopathic Arthritis

Actemra (tocilizumab) has been approved by the FDA for monotherapy or in combination with methotrexate, for active systemic juvenile idiopathic arthritis (SJIA) in children 2 years of age and older.

[View Article](#)

FDA approves Rituxan to treat two rare disorders

The FDA has approved Rituxan (rituximab), in combination with glucocorticoids, for the treatment of two rare disorders that cause vasculitis, Wegener's granulomatosis and microscopic polyangiitis.

[View Article](#)

FDA Approves Viramune XR

Approval of Viramune XR now allows patients to have the benefit of a new HIV treatment option for use in with other HIV medications

[View Article](#)

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New Guidelines

Evidence-based Guideline for the Treatment of Painful Diabetic Neuropathy (PDN)

This guideline issued by the American Academy of Neurology addresses the question, "What is the efficacy of a given treatment... to reduce pain and improve physical function and quality of life (QOL) in patients with PDN?"

[View Guideline](#)

An Update of the 2007 Guideline - 2011 ACCF/AHA Focused Update of the Guideline for the Management of Patients With Unstable Angina/Non-ST-Elevation Myocardial Infarction

These updated recommendations reflect a consensus of expert opinion resulting from thorough review of recent clinical trials and other new data deemed to have patient care impact.

[View Guideline](#)

Guidelines for Immune Thrombocytopenic Purpura (ITP) Management

The numerous advances in the management of ITP has mandated an update to these 1996 guidelines, from the American Society of Hematology

[View Guideline](#)

CDC Guideline for Recommended Immunization Schedules for Ages 0 through 18 Years of Age

The annually published immunization schedules from the CDC's Advisory Committee on Immunization Practices summarize recommendations for currently licensed vaccines for this age group.

[View Guideline](#)

AAACE's Guidelines for Clinical Practice for Developing a Diabetes Mellitus Individual Care Plan

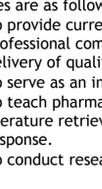
The guidelines, developed by the American Association of Clinical Endocrinologists (AAACE), provide guidance for comprehensive care that incorporates microvascular and macrovascular risk considerations rather than an isolated focus of glycemic control.

[View Guideline](#)

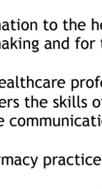
Management of Atopic Eczema in Primary Care

This guideline from the Scottish Intercollegiate Guideline Network (SIGN) provides recommendations for the management of atopic eczema, based on current evidence for best practice.

[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:

- Adverse Drug Events
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- Clinical Kinetics
- Drug Dosage and Scheduling
- Drug Identification
- Drug Interactions
- Drug Regulations/Laws
- Drug Use Evaluation/Support
- Institutional Review Board Support
- Investigational/Foreign Drugs
- IV Compatibility
- Laboratory Interpretation
- Pharmacoeconomics
- Pharmacy and Therapeutics Committee Support
- Pregnancy and Lactation
- Product Compounding
- Therapeutic Drug Monitoring
- Therapeutic Uses/Drugs of Choice
- Toxicology
- Travel/Health Information

The DIC has a new phone number and provides information services exclusively to the healthcare professionals of the State of Louisiana. Additionally, this service is available to Medicaid providers through support from the Louisiana Medicaid Pharmacy Benefits Management Program.

Please contact us and let us assist you with any drug information needs at our new number for Healthcare Professionals Drug Information Service: **318-342-5501**

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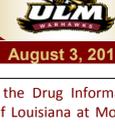
View [previous issues](#) of the FYDI newsletter.

For comments and suggestions please email druginfo@ulm.edu.

Disclaimer: No information source can replace clinical judgment applied to a specific case. Some of the drug therapy we write about will be outside the labeled indications for specific products. References will be provided. 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



August 3, 2011

ULM COLLEGE OF PHARMACY Drug Information Center



Kelly Marks, PharmD Candidate
Kerry McNeal, PharmD Candidate
Beverly Walker, RPH, PharmD Candidate
Gregory W. Smith, PharmD, Director
Drug Information Services
318.342.5501
druginfo@ulm.edu

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 Alerts
News Items
Drug Approvals
New Guidelines

FDA MedWatch Alerts & News Items

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Possible Serious CNS Reactions When Taking Zyvox (Linezolid) With Psychiatric Medications
FDA has received reports of serious CNS reactions when Zyvox (linezolid) is given to patients who are taking psychiatric medications that work through the serotonin system of the brain.

[View Alert](#)

Methylene Blue Interaction with Serotonergic Psychiatric Medications

Serious central nervous system reactions are possible when methylene blue is administered to patients taking serotonergic medications

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Chantix (Varenicline) Linked to Increased CV Risks

Labeling for varenicline now indicates that some patients may be at an increased risk for adverse cardiovascular events.

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Potential Risk of Esophageal Cancer Associated with Bisphosphonates

There is ongoing review of data from published studies to evaluate whether the use of oral osteoporosis drugs (bisphosphonates) is associated with an increased risk of cancer of the esophagus.

[View Alert](#)

Multaq (Dronedaron) Trial Halted Due to Other Cardiovascular Problems

Sanofi-Aventis stopped a trial of Multaq, the PALLAS study, in patients with permanent atrial fibrillation due to increased risk of cardiovascular adverse effects and death.

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Tamiflu for Oral Suspension Label Change

Product labeling has been revised to reflect a new concentration (6 mg/ml) of Tamiflu (oseltamivir phosphate) oral suspension.

[View Alert](#)

New Risk Evaluation and Mitigation Strategy (REMS) for Nulojix

Bristol-Myers Squibb has informed healthcare professionals of a new REMS for Nulojix (belatacept) required to ensure benefits outweigh risks of post-transplant lymphoproliferative disorder (PLTD) and progressive multifocal leukoencephalopathy (PML).

[View Alert](#)

Impaired Cognitive Development Associated with Valproate Use in Pregnancy

Children born to mothers who take valproate sodium or related products (valproic acid and divalproex sodium) during pregnancy may have a greater risk in achieving lower cognitive test scores.

[View Alert](#)

Uncharacteristic Odor Results in Tylenol Extra Strength Caplets Recall

Moldy odor linked to the presence of trace amounts of a chemical known as 2,4,6-tribromoanisole (TBA) results in the recall of one product lot of 225 count bottles of Tylenol Extra Strength Caplets.

[View Alert](#)

Recall on Nature Relief Instant Wart and Mole Remover Due to Risk of Severe Skin Burns

FDA has advised that the active ingredient, calcium oxide, can cause severe burns of the skin which could require medical attention.

[View Alert](#)

Recall on Mislabeled Strengths of Endocet

Bottles of Endocet (oxycodone/acetaminophen) 10 mg/325 mg have been recalled due to the potential of some bottles containing more than the labeled amount of acetaminophen.

[View Alert](#)

Bottles of Butalbital, Acetaminophen, and Caffeine Tablets; and Hydrocodone Bitartrate and Acetaminophen Tablets Recalled

Recall issued due to the possibility of bottles containing incorrect tablets and the potential for the administration of butalbital and caffeine instead of hydrocodone.

[View Alert](#)

Modified Dosing Recommendations for ESAs

New recommendations for Erythropoiesis-Stimulating Agents (ESAs) suggest more conservative dosing to increase safety in patients with chronic kidney disease (CKD). ESA labels now warn that CKD patients are at greater risk when administered ESAs to target hemoglobin (Hgb) > 11 g/dL. The new label also recommends to consider starting ESA treatment when Hgb level is < 10 g/dL. Target ranges have been removed, and it is now suggested to individualize dosing and to use the lowest possible dose of ESA needed to reduce the need for RBC transfusions.

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Voluntary Recall of Risperidone and Risperidal Tablets

One product lot each of Risperidone Tablets and Risperidal Tablets have been recalled due to an uncharacteristic odor associated with the chemical 2,4,6-tribromoanisole (TBA)

[View Alert](#)

Particulate Matter in Indomethacin for Injection Results in Recall of One Lot

A nationwide voluntary recall of indomethacin for injection, USP, 1 mg Single Dose Vial (NDC # 55390-299-01, Lot 1948138, Exp. Date September 2011) has been issued as it may contain particulate matter which has been identified as active drug substance and not foreign material or contamination.

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Thyroid Cancer and Pancreatitis Linked with Victoza Use

The FDA has issued a warning regarding the use of the diabetes drug liraglutide (Victoza) and the risks of developing thyroid cancer and pancreatitis.

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Medication Errors Linked to Name Confusion Between Risperdal and Ropinirole

The FDA has notified healthcare professionals and the public of medication errors in which patients were given risperidone (Risperdal) instead of ropinirole (Requip) and vice versa, resulting in some patients needing to be hospitalized.

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Serious Form of Prostate Cancer Risk Associated with 5-ARI's

Labeling for 5-alpha reductase inhibitors (ARI) now indicates a potential for increased risk in developing high-grade prostate cancer when taking this medication for extended periods of time.

[View Article](#)

Zocor Label Change

New restrictions, contraindications, and dose limitations have been established for the cholesterol lowering drug Zocor (simvastatin).

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Drug Safety Review Completed for ARBs

The FDA's meta-analysis of 31 randomized controlled trials suggests no evidence for an increased risk of new cancer in patients receiving angiotensin receptor blockers (ARBs).

[View Alert](#)

Potential Contamination with Beta Lactam Products Leads to Recall

Multiple repackaged products from Aidapak Services were recalled due to potential cross contamination of non-penicillin drug products with beta lactam containing products.

[View Alert](#)

Drospirenone May Increase Risk of Blood Clots

Two newly published studies suggest an increased risk of venous thromboembolism in women who take birth control pills containing drospirenone.

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New Warning for Actos: Potential Increased Risk of Bladder Cancer

Information regarding the use of Actos (pioglitazone) for more than one year and its association with an increased risk of bladder cancer has been added to the drug's *Warnings and Precautions* section of the label.

[View Alert](#)

Two Case Reports of Serious Adverse Effects of Pradaxa (Dabigatran) Elderly

An article in the Archives of Internal Medicine reports dabigatran, used for the prevention of stroke in patients with atrial fibrillation, had a strong correlation to severe bleeding in the elderly.

[View Article](#)

Teflon Component May Increase Risk of Arthritis

Individuals with high blood levels of the man-made chemical used in non-stick coatings are at a greater risk for developing arthritis.

[View Article](#)

Prophylactic Medicine Reduces Risk of HIV Infection

A studies regarding patients who took prophylactic doses of antiviral drugs showed a significant decrease in HIV infections.

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Smoking During Pregnancy Increases Birth Defects

A review of past studies suggests that smoking during pregnancy could lead to serious birth defects that could potentially be life-threatening.

[View Article](#)

Potential Link Between Bone Density and MS

An increased number of individuals in the early stages of multiple sclerosis (MS) often also suffer from osteoporosis, suggesting a potential link between the two disease states.

[View Article](#)

Scientists Discover Highly Resistant Strain of Gonorrhea

The new strain, called H041, was found to be extremely resistant to all cephalosporin antibiotics.

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Drug Approvals

Brilinta Approved by FDA to Treat Acute Coronary Syndromes

The blood-thinning drug Brilinta (ticagrelor), in combination with aspirin maintenance doses of 75 to 100 mg once daily" was found to be more effective than Plavix for the prevention of heart attacks and death.

[View Article](#)

New Flu Vaccine

A new influenza virus vaccine has been developed for the 2011 – 2012 season.

[View Article](#)

FDA Approves laViv® (azficel-T) for the Treatment of Nasolabial Fold Wrinkles

laViv® (azficel-T) is the first and only autologous cellular product approved by the FDA indicated for the improvement of the appearance of moderate to severe nasolabial fold wrinkles in adults.

[View Article](#)

Afinitor for Rare Pancreatic Cancer Approved by the FDA

The FDA has approved Afinitor (everolimus) for the treatment of progressive neuroendocrine tumors (PNET) of pancreatic origin in patients with unresectable, locally advanced or metastatic disease.

[View Article](#)

FDA Approves Sutent for Rare Type of Pancreatic Cancer

Sutent (sunitinib malate) is the second drug approved by the FDA for the treatment of progressive neuroendocrine tumors (PNET) located in the pancreas that cannot be surgically removed or has spread to other parts of the body.

[View Article](#)

FDA Approves Tradjenta to Treat Diabetes Type 2

Tradjenta (linagliptin) has been approved by the FDA for the management of blood sugar in patients with Type 2 Diabetes. Tradjenta, a dipeptidyl peptidase-4 inhibitor, can be used alone or in combination with metformin, sulfonyleurea or pioglitazone.

[View Article](#)

Incivek for Patients with Hepatitis C Approved by the FDA

The FDA approved Incivek (telaprevir) for the management of genotype 1 chronic hepatitis C in treatment naive adults and individuals who did not respond well to drug therapy.

[View Article](#)

FDA Approves Victrelis for Chronic Hepatitis C Treatment

Victrelis (boceprevir) has been approved by the FDA for the management of chronic hepatitis C in treatment naive adults or individuals who did not respond well to drug therapy. The drug is indicated as an adjunctive treatment with peginterferon alpha and ribavirin.

[View Article](#)

FDA Approves DIFICID™ for the Treatment of Patients with Clostridium Difficile-Associated Diarrhea (CDAD)

DIFICID (fidaxomicin) tablets indicated for the treatment of Clostridium difficile-associated diarrhea (CDAD) have been approved by the FDA in adults 18 years of age and older.

[View Article](#)

FDA Approves EDURANT™ for Use in Treatment-Naïve Adults with HIV-1

Eduvant (rilpivirine) is a non-nucleoside reverse transcriptase inhibitor (NNRTI) that has been approved by the FDA, in combination with other antiretroviral agents (ARVs), for the treatment of human immunodeficiency virus type 1 (HIV-1) in adults who have never taken HIV therapy.

[View Article](#)

Nulojix Approved to Prevent Acute Kidney Transplant Rejection

Nulojix (belatacept) is a selective T-cell costimulatory blocker approved by the FDA for the prevention of organ rejection following a kidney transplant. Nulojix is administered via 30-minute intravenous infusions and has been approved as an adjunctive treatment with corticosteroids, basiliximab, and mycophenolate mofetil.

[View Article](#)

Pfizer and Acura Announce FDA Approval of Oxecta™

Oxecta is the first immediate-release oxycodone HCl formulation utilized by Acura Pharmaceuticals AVERSION® Technology, designed to restrict opioid abuse and misuse via intravenous injection of dissolved tablets or nasal inhalation of crushed tablets.

[View Article](#)

Potiga™ Approved for Partial-Onset Seizures in Adults

The FDA has approved Potiga (ezogabine) tablets, as combination therapy, in the treatment of partial-onset seizures in adults aged 18 and older.

[View Article](#)

FDA Approves Arcapta Neohaler for the Treatment of COPD

The FDA has approved a once-daily bronchodilator, Arcapta Neohaler (indacaterol maleate), which could provide better patient adherence for patients with chronic obstructive pulmonary disease (COPD).

[View Article](#)

Oral Anticoagulant Xarelto Approved for DVT Prevention

Xarelto (rivaroxaban), a once-daily oral anticoagulant, has been approved by the FDA for the prevention of deep venous thrombosis during surgery.

[View Article](#)

[View all FDA-approved drugs at CenterWatch.com](#)

New Guidelines

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Update of the 2007 ACP Guidelines for Management of Stable COPD

The American College of Physicians (ACP), American College of Chest Physicians, American Thoracic Society (ATS) and European Respiratory Society have issued and update of the 2007 guidelines on diagnosis and management of stable chronic obstructive pulmonary disease. (COPD).

[View Guideline](#)

FDA Proposes Health 'App' Guidelines

With an increase in the number of health-related apps available to owners of smartphones, the FDA is now proposing guidelines that would outline a small number of apps the agency will oversee, attempting to reduce risks of medical apps that do not work as intended.

[View Article](#)

AACE's Guidelines for Hyperthyroidism and Other Causes of Thyrotoxicosis

Management Guidelines of the American Thyroid Association and American Association of Clinical Endocrinologists

[View Guideline](#)

An Update to 2010 Guideline – 2011 CDC's U.S. Medical Eligibility Criteria for Contraceptive Use

Revised recommendations for the use of contraceptives during the postpartum period

[View Guideline](#)

An Update of the 2005 Guideline -2011 ACCF/AHA Performance Measures for Adults with Coronary Artery Disease and Hypertension

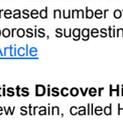
This updated measure set focuses on outpatient care exclusive of the emergency department.

[View Guideline](#)

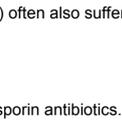
Booster Dose of Inactivated Vero Cell Culture-Derived Japanese Encephalitis Vaccine Recommendations for Travelers

New data on the persistence of neutralizing antibodies following primary vaccination with JE-VC and the safety and immunogenicity of a booster dose of JE-VC provides better coverage for travelers to Asia.

[View Guideline](#)



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FYDI
FOR YOUR DRUG
INFORMATION



September 16, 2011

ULM
COLLEGE OF PHARMACY
Drug Information Center



Daniel Benoit, PharmD Candidate
Danielle Meche, PharmD Candidate
Gregory W. Smith, PharmD, Director
Drug Information Services
318.342.5501
druginfo@ulm.edu

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New Guidelines

FDA MedWatch Alerts

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Zofran Labels Revised: Avoid Use with Congenital Long QT Syndrome

Revised Zofran labels will include a recommendation to avoid use in patients with congenital long QT syndrome due to the risk of Torsade.

[View Alert](#)

Class I Recall of SynchoMed II Implantable Drug Pump

The infusion pump indicated for therapy requiring morphine sulfate, methotrexate, baclofen and other drugs is being recalled due to reduced battery performance in certain devices.

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Risk of Legionella and Listeria Infections with TNF α Blocker Use

The Boxed Warning for the entire class of Tumor Necrosis Factor- α (TNF α) blockers has been updated to reflect the risk of infection from Legionella and Listeria bacterial pathogens.

[View Alert](#)

Modified Dosing Recommendations for ESAs

New recommendations for Erythropoiesis-Stimulating Agents (ESAs) suggest more conservative dosing to increase safety in patients with chronic kidney disease (CKD).

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Saphris Use Linked to Serious Allergic Reactions

Saphris (asenapine maleate), a drug used to treat the symptoms of schizophrenia and bipolar disorder, has been implicated in type I hypersensitivity reactions.

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New Contraindication and Updated Warnings with Reclast (zoledronic acid)

Reports of patients that took the drug and had to be put on dialysis or having fatal outcomes prompted the FDA to update drug warnings.

[View Alert](#)

Recall of H & P Industries Products Containing Povidone Iodine

The FDA has requested the recall of all lots due to H & P Industries manufacturing povidone iodine products without a proper system for testing microbial content.

[View Alert](#)

High Doses of Celexa (citalopram hydrobromide) Associated with Heart Arrhythmias

The FDA is notifying healthcare professionals and the public that citalopram hydrobromide should not be taken at doses greater than 40 mg/day due to the risk of serious abnormalities in heart activity.

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Possible Increased Risk of Death Associated with Somatropin

Evidence regarding recombinant human growth hormone (somatropin) and increased risk of death is inconclusive, according to the FDA; prescribing and use of the medication should continue according to labeled recommendations while this safety issue is under review.

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Recall of Multiple Dose Vials of Vasopressin Injection, USP

There has been a nationwide voluntary recall of multiple lots of Vasopressin Injection, USP to the retail and hospital level due to vials that may not maintain potency throughout product shelf-life.

[View Alert](#)

FDA Says Chronic, High-Dose Diflucan Use Might Carry Risk for Birth Defects

Based on cases of rare and distinct birth defects in infants whose mothers were treated with high-doses (400-800 mg/day) of Diflucan (fluconazole), the pregnancy category for fluconazole indications other than vaginal candidiasis has been changed from category C to category D.

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Class I Recall of GEM Premier 4000 PAK Cartridges Due to Inaccurate Results

Inaccurately low potassium test results exceeding the allowable error may result if these cartridges are used on the GEM Premier 4000 critical care system.

[View Alert](#)

Recall of Sibutramine-Containing Dietary Supplements

Slim Forte Slimming Capsules, Slim Forte Slimming Coffee, and Botanical Slimming Soft Gel products marketed for weight loss have been recalled due to the presence of the controlled substance, sibutramine, which was removed from the U.S. market for safety reasons in 2010.

[View Alert](#)

Potential Increased Risk of Bladder Cancer Associated with Actos

The FDA is informing the public of a drug label update for medications containing pioglitazone, which includes safety information regarding pioglitazone use for more than one year and an association of an increased risk of bladder cancer.

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News Items

New Factor Xa Inhibitor Shown Superior to Warfarin in Atrial Fibrillation Patients

A study has shown that Eliquis (apixaban), a novel oral direct factor Xa inhibitor used for atrial fibrillation patients, was superior to warfarin in preventing stroke and systemic embolism, caused less bleeding and resulted in decreased mortality.

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Report from the Institute of Medicine (IOM) Finds Vaccines to be Safe

A new report from the Institute of Medicine shows that commonly suggested immunizations cause relatively few adverse events.

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First Treatment Specifically for Scorpion Stings Approved by the FDA

Anascorp, Centruroides Immune F(ab) \prime 2 (Equine) Injection, was approved as an orphan drug for scorpion stings, mostly prevalent in Arizona, and received priority review.

[View Article](#)

Researchers Discover New Gene for Ovarian Cancer

Carriers of a faulty copy of the RAD51D gene have an almost one in eleven chance of developing ovarian cancer.

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U. S. HHS Approves Birth Control Without Copay

The U.S. Department of Health and Human Services (HHS) has approved guidelines to mandate all insurance plans cover birth control and other women's preventative care.

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Botox Approved to Treat Urinary Incontinence Associated with Neurologic Conditions

The FDA has approved Botox (onabotulinumtoxinA) injection to treat urinary incontinence in patients with bladder overactivity associated with neurologic conditions such as spinal cord injuries and multiple sclerosis.

[View Article](#)

Pfizer Hopes to Get OTC Status Approval for Lipitor

According to *The Wall Street Journal*, Pfizer hopes to get FDA approval of an OTC version of Lipitor (atorvastatin calcium), whose patent will expire November 30th.

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Rotigotine Patch for Restless Leg Syndrome Efficacious Up to 5 Years

A new study evaluated the benefit of Neupro (rotigotine transdermal system) in patients with restless leg syndrome and results indicated safety, efficacy, and tolerability for over 5 years of treatment.

[View Article](#)

Broad Spectrum Antiviral Drug Shows Potential in Trials

Researchers at Massachusetts Institute of Technology (MIT) have developed a potentially cutting-edge drug that may safely treat a broad spectrum of viral infections in humans such as the common cold and influenza.

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FDA Warns of Fake Emergency Contraceptive, Evital

The FDA issued a warning not to use Evital, a counterfeit version of the morning-after pill, to all U.S. consumers.

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Antidepressant Prescriptions without Psychiatric Diagnoses on the Rise

An increasing number of clinicians are prescribing antidepressants to patients without psychiatric diagnoses, ranging from 59.5% to 72.7% between 1996 and 2007.

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Study Suggests Risperidone Not Effective in Posttraumatic Stress Disorder

According to a new study, Risperidol (risperidone) is not effective in the treatment of posttraumatic stress disorder (PTSD) experienced by military personnel.

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[View Abstract](#)

High Dose Zinc May Help with Colds

Results of a meta-analysis reported in *The Open Respiratory Medicine Journal* suggest that high, not low, dose zinc lozenges may shorten the duration of the common cold.

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FDA Approves Updated Prescribing Information for Gilenya

The oral multiple sclerosis drug Gilenya (fingolimod) has updated prescribing information that includes data on T1 gadolinium-enhancing magnetic resonance imaging (MRI).

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HPV Vaccine Useful for Preventing Anal Infections

Researchers have reported a new study showing that the vaccine against human papillomavirus (HPV) may protect women against two viral strains that can cause infections leading to anal cancer.

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FDA Releases "Strategic Plan for Regulatory Science"

This strategic plan will result in the modernization of the science used to develop and evaluate products critical to the nation's health, economy, and security.

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Kids Might Be Able to Go Without Fasting Before Lipid Screening

A new study published in *Journal Pediatrics* suggests that some children can safely skip fasting before cholesterol tests.

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Cancer Deaths Not Affected by Breast Cancer Screenings

Researchers analyzed data from three pairs of European countries and found little variation in breast cancer mortality rates between women screened and unscreened by mammography, suggesting that the reduction of breast cancer death rates may be attributed to better treatment and health systems and is not directly affected by screening.

[View Article](#)

Drug Approvals

Zelboraf Approved to Treat Late-Stage Melanoma

Zelboraf (vemurafenib) is a BRAF inhibitor that improves overall survival and is indicated for the treatment of patients with tumors expressing a genetic protein mutation called BRAF V600E.

[View Article](#)

FDA Approves Complera, a Once-Daily Combination Tablet for HIV-1

This once-daily fixed dose combination tablet containing emtricitabine/rilpivirine/tenofovir DF (FTC/RPV/TDF) is indicated for the treatment of human immunodeficiency virus type 1 (HIV-1) infections in treatment naive patients.

[View Article](#)

FDA Approves Adcetris for Two Lymphoma Types

Adcetris (brentuximab vedotin) has been approved for the treatment of both Hodgkin lymphoma (HL) and systemic anaplastic large cell lymphoma (ALCL).

[View Article](#)

Firazyr Approved to Treat Acute Hereditary Angioedema Attacks

Firazyr (icatibant) injection has been approved for the treatment of acute attacks of hereditary angioedema (HAE) in patients ages 18 years and older.

[View Article](#)

FDA Approves Xalkori for Certain Types of Non-Small Cell Lung Cancers

Xalkori (crizotinib) has been approved to treat certain patients with late-stage non-small cell lung cancers (NSCLC) in patients expressing the abnormal anaplastic lymphoma kinase (ALK) gene.

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[View all FDA-approved drugs at CenterWatch.com](#)

New Guidelines

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

2011 Update of the Effectiveness-based Guidelines for the Prevention of Cardiovascular Disease in Women

The previously published guideline summary from the American Heart Association (AHA) for the prevention of cardiovascular disease in women has been updated.

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Evidence-based Guidelines for *Helicobacter pylori* Infection in Children

New guidelines by a joint committee have been accepted on how, who, and when to treat children with suspected *H. pylori* infections.

[View Guideline](#)

Prevention and Control of Influenza with Vaccines: 2011 Recommendations of the Advisory Committee on Immunization Practices (ACIP)

Updated guidance by the Centers for Disease Control and Prevention on the utilization of influenza vaccines in the United States for the 2011-12 flu season.

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Updated Recommendations for Bladder Cancer Screening from the U.S. Preventive Services Task Force

Update of the 2004 U.S. Preventive Services Task Force recommendation on screening for bladder cancer in asymptomatic adults.

[View Guideline](#)

Guidelines for the Use of Antiretroviral Agents in Pediatric HIV Infection

The Panel on Antiretroviral Therapy and Medical Management of HIV-Infected Children has issued its current recommendations concerning when to start treatment, what medications to safely use, and how to monitor young HIV-infected children.

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Updated Guidance on the Use of Meningococcal Vaccine

The Advisory Committee on Immunization Practices has updated booster dose guidance for a newly licensed meningococcal conjugate vaccine that can be used for younger children and other persons at an increased risk for meningococcal disease.

[View Guideline](#)

Disorders of Lipid Metabolism, an Evidence-Based Nutrition Practice Guideline.

An updated guideline from the American Dietetic Association concerning hyperlipidemia medical nutrition therapy protocols.

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The Clinical Management of Primary Hypertension in Adults

Updated guidelines commissioned by the National Institute for Health and Clinical Excellence (NICE) on treatment protocols for adult primary hypertension patients.

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Guidance for Non-HIV-Specialized Providers Caring for HIV-Infected Residents Displaced from Disaster Areas

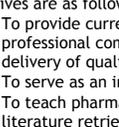
New protocols compiled by various panels on how to properly assess and treat HIV-infected patients that have been displaced by natural disasters and have not yet secured HIV care.

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Clinical Practice Guidelines for the Management of Community-Acquired Pneumonia in Infants and Children Older Than 3 Months of Age

The Pediatric Infectious Diseases Society and the Infectious Diseases Society of America has provided guidelines for clinicians to responsibly manage and treat otherwise healthy infants and children diagnosed with community-acquired pneumonia.

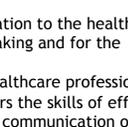
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- ◆ To serve as an information resource center for faculty, students, and healthcare professionals.
- ◆ To teach pharmacy students, pharmacists, and other healthcare providers the skills of efficient literature retrieval, critical evaluation of the information, and accurate communication of a response.
- ◆ To conduct research for the advancement of drug information and pharmacy practice.

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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 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.



October 20, 2011

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Chinedu Akunne, PharmD Candidate
Melissa Botello, PharmD Candidate
Gregory W. Smith, PharmD, Director
Drug Information Services
318.342.5501
druginfo@ulm.edu

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 Alerts
- News Items
- Drug Approvals
- New Guidelines

FDA MedWatch Alerts

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

Chemo Drug, Sprycel Linked to Pulmonary Arterial Hypertension

The FDA alerted that Sprycel (dasatinib), which is used to treat chronic myeloid leukemia or acute lymphoblastic leukemia, might increase the risk of Pulmonary Arterial Hypertension.

[View Alert](#)

Birth Control Pills Containing Drospirenone May Increase Risk for Blood Clot

Preliminary results from the FDA-funded study suggest a 1.5-fold increase in the risk of developing a blood clot in women who take drospirenone-containing contraceptives compared to those taking other hormonal contraceptives.

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Povidone Iodine Prep Pads Recall

H&P Industries recalled all lots of Povidone Prep Pads after analytical testing showed the presence of a contaminant, which could lead to life-threatening infections.

[View Alert](#)

FDA Issues Recall of Uprizing 2.0, a "Testosterone Booster"

FDA banned Uprizing 2.0, labeling it an unapproved new drug for containing an undisclosed ingredient, superdrol, a synthetic steroid.

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Qualitest Pharmaceuticals Issues Recall of Oral Contraceptives

Qualitest Pharmaceuticals issued a nationwide recall due to packaging errors that could lead to inadequate contraception. Products include: Cyclofem 7/7/7, Cyclofem 1/35, Emoquette, Gildress FE 1.5/30, Gildress FE 1/20, Orsythia, Previfem, Tri-Previfem.

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News Items

Angiomax Lowers Bleeding Risk in Comparison to Heparin

An analysis of the Evaluation of Drug-Eluting Stents and Ischemic Events (EVENT) Registry concluded that bivalirudin (Angiomax) use during percutaneous coronary intervention (PCI) resulted in a decreased risk of bleeding compared with unfractionated heparin alone or heparin with glycoprotein IIb/IIIa inhibitors.

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Prehypertensive Patients are at a High Risk for Stroke

New research suggests that middle-aged prehypertensive patients are 68% more likely to have a stroke than normotensive patients.

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New Restriction Recommendations on Multaq

Due to increased risk of liver, lung and cardiovascular adverse events, the European Medicines Agency's Committee (EMA) has recommended restrictions for the use of Multaq (dronedrone), and that agencies currently taking the drug should "have their treatment evaluated by their doctor at their next scheduled appointment".

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Darexaban Development Discontinued

Astellas Pharma had been developing darexaban for prevention of venous thromboembolism post hip or knee replacement surgery and stroke prevention in patients with atrial fibrillation, however development was discontinued after considering the crowded market for blood thinners.

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Aspirin Associated with Vision Loss

A new European study reports that elderly with daily aspirin regimens are twice as likely to have late stage macular degeneration than seniors who do not take aspirin.

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Antiplatelet Therapy Combined with SSRI Increases the Risk of Bleeds

Researchers found that taking an antiplatelet drug combined with a SSRI increases the risk of bleeding up to 42% compared to taking aspirin alone.

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New Procedure Detects First Events in Cancer Development

Researchers have found a new procedure that can detect tumor growth in its earliest stages, which could lead to further discovery of ways to treat and possibly stop tumor growth.

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'Off-Label' Use of Antipsychotics Show Mixed Results

Off-label use of atypical antipsychotics has been shown to help certain patients, while it may be harmful for others.

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Experts Urge Drug Companies to Report All Clinical Trial Results

A few international experts insist that drug companies report the results of clinical trials regardless, of the outcomes, even if it does not become a marketable final product.

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Oral Steroids Use Linked to Severe Vitamin D Deficiency

A U.S nationwide study has concluded that oral steroid users are two times more likely to have severe vitamin D deficiency, suggesting that vitamin D levels should be monitored more closely during oral steroid use.

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Possible Cholesterol-Related Cardiovascular Risk Found with NSAID Use

Results of an animal study showed that subjects with high cholesterol that received naproxen had lower "myocardial perfusion" compared to those with normal cholesterol, implying that cholesterol control in patients taking NSAIDs may be especially important.

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Cheap Drug Increases Chances to Quit Smoking

A relatively inexpensive drug, Cytisine, which was initially marketed in Bulgaria in 1964, has been shown to give smokers a cheaper way to overcome their addiction.

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Cortisone Injection to Prevent Post Traumatic Stress Disorder (PTSD)

In a study designed to mimic the natural release of cortisone after a traumatic event, trauma patients given an extra shot of cortisone were 60% less likely to develop PTSD.

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IVIG Not Beneficial for Treatment of Sepsis in Newborns

A large study showed that newborns with sepsis that were treated with intravenous immune globulin (IVIG) in addition to antibiotics had similar outcomes as those treated with only antibiotics.

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[View Abstract](#)

New Vaccine May Reduce HIV to a 'Minor Infection'

Researchers in Spain, claim that a potent vaccine, MVA-B, may make HIV no more alarming than the herpes virus. The majority of the patients tested with the new vaccine developed HIV-protective antibodies.

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Controlling Alzheimer's with Intranasal Insulin

A pilot study suggests that inhaled insulin may slow the progression, and/or preserve the cognition of patients with Alzheimer's disease.

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[View Abstract](#)

Bayer Claims that Xarelto has Acute Coronary Syndrome (ACS) Benefit

Bayer announced the study results that Xarelto (Rivaroxaban) plus the standard ACS therapy showed good outcomes in strokes, myocardial infarctions, and mortality.

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Computers Used to Predict New Uses for Existing Medicines

Using computational methods to recreate the mechanisms of existing drugs was originally used for established indications. Recently these methods have branched out to identifying newer indications.

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VFEND/ERAXIS Combination No Better Than VFEND Monotherapy

Pfizer Inc. reported the results of a Phase III trial that showed that combination of VFEND (voriconazole) and ERAXIS (anidulafungin) did not achieve statistical superiority when compared to VFEND monotherapy for invasive aspergillosis.

[View Article](#)

Insomnia Treatment, Silenor Considered for Rx-to-OTC switch

Somaxon Pharmaceuticals and Procter & Gamble have met with the FDA to discuss the potential for OTC Silenor, a lower dose formulation of doxepin as an insomnia treatment.

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Bevacizumab Possibly Increases Risk for Infertility

The product label for bevacizumab has been revised to include a warning about ovarian failure and other possible adverse reactions.

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Additional Risks Found for Women Exposed to DES In Utero

Researchers found that the risk for 12 adverse health outcomes were significantly elevated in the women exposed to diethylstilbestrol (DES) in utero, suggesting the importance of lifelong monitoring for these women (including mammography and cervical cytology).

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Psoriasis Proven to Increase Risk of Cardiovascular Disease

Results of two recently published cohort studies have concluded that the presence of psoriasis, whether mild or severe, is associated with increased risks for atrial fibrillation and ischemic stroke.

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Parenteral Nutrition Product Shortage Recommendations

The American Society for Parenteral and Enteral Nutrition (A.S.P.E.N.) has developed conservation recommendations and alternate therapy measures in order to cope with the shortages in electrolyte and mineral injections for parenteral nutrition therapy.

[View Article](#)

SPS3 Stroke Trial Halted Clopidogrel-Aspirin Arm

The Neurological Disorders and Stroke (NINDS) has stopped the double-antiplatelet intervention arm of the Secondary Prevention of Small Subcortical Strokes (SPS3) trial, due to a nearly two-fold rate of bleeding compared to the aspirin monotherapy arm.

[View Article](#)

Omega-3 Supplements May Hurt ICU Patients

Omega-3 fatty acids do not help critically ill patients with acute lung injury. A trial showed that patients with sepsis, and pneumonia did worse when their feedings contained the antioxidant.

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[View Trial](#)

Study Nulls Antibacterial Soaps and Antibiotic Resistance Link

A new study confirms that there is no link between the use of antibacterial cleansing products at home and antibiotic resistance.

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Vitamin E May Increase Risk of Prostate Cancer

The Selenium and Vitamin E Cancer Prevention Trial (SELECT) concluded that vitamin E supplementation increases the risk of developing prostate cancer.

[View Article](#)

Chest Pain Complaints in Children Rarely Cause for Alarm

A study by the Children's Hospital Boston showed that only 1 percent of children and young adults ages 7 to 22 that presented with evaluated for chest pain were of a cardiac cause.

[View Article](#)

Medications Greatly Improve Life Expectancy of HIV-1 Patients

A U.K. study showed people treated for HIV infection lived 15 years longer, but still lived 13 years less than the general population.

[View Study](#)

Drug Approvals

Ferriprox Approval

The FDA approved Ferriprox (deferiprone) to treat certain patients with iron overload due to frequent blood transfusions who have an inadequate response to chelation therapy.

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FDA approves Combivent® Respimat®

Combivent Respimat is a propellant-free inhaler that uses a slow-moving mist to deliver the same active ingredients of Combivent.

[View Article](#)

FDA Approves Diabetes and Cholesterol-Lowering Combination

On October 7, 2011, the FDA approved the combination medication, Juvivync (sitagliptin and simvastatin) for the treatment of type 2 diabetes and high cholesterol.

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FDA Approves Gel to Stop Blood Flow

On October 4, 2011, the FDA approved the device LeGoo, a gel that temporarily stops blood flow during blood vessel surgery to allow surgeons to reconnect the vessels.

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Remicade Approved to Treat Ulcerative Colitis in Children

On September 27, 2011, the FDA approved Remicade (infliximab) to treat moderate to severe ulcerative colitis cases in children 6 years and older.

[View Article](#)

Solaris Approved to Treat Hemolytic Uremic Syndrome

On September 23, 2011, the FDA approved Solaris (eculizumab), the first drug that treats Hemolytic Uremic Syndrome (aHUS), a rare blood disease that mostly affects children.

[View Article](#)

Prolia Receives Two New FDA Indications

Prolia has been approved to increase bone mass in women at high risk for fracture receiving adjuvant aromatase inhibitor therapy for breast cancer and for men who have received androgen deprivation therapy for nonmetastatic prostate cancer.

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Strides Acolab Gets FDA Approval for Three Injectable Drugs

Strides Acolab Ltd. subsidiary, Onco Therapies Ltd. gained FDA approval for Paclitaxel Injection USP, a drug on the shortage list, and Clindamycin Injection, USP. Strides also gained tentative approval for Oxaliplatin Injection. All products will be launched in 2012.

[View Article](#) – Paclitaxel & Oxaliplatin

[View Article](#) – Clindamycin

Cialis Approved to Treat BPH

The FDA approved Cialis (tadalafil) to treat the signs and symptoms of benign prostatic hyperplasia (BPH), and for the simultaneous occurrence of BPH and erectile dysfunction.

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[View all FDA-approved drugs at CenterWatch.com](#)

New Guidelines

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ADHD Management Guidelines Updated

Updates include: screening of children who exhibit ADHD symptoms should include children between ages 4 through 18 years; first-line treatment should be behavioral therapy for children aged 4 to 5 years with ADHD; and, a combination of medication and behavioral therapy is preferred for older children.

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Peripheral Arterial Disease Guidelines Updates

The 2005 guidelines from the American College of Cardiology and the American Heart Association have been updated.

[View Guideline](#)

New Guidelines for CAP in Children

The Infectious Diseases Society of America and the Pediatric Infectious Diseases Society have published a comprehensive evidence-based guideline for community-acquired pneumonia in children older than 3 months.

[View Guideline](#)

Vaccine Updates

The American Academy of Pediatrics (AAP) has updated guidelines involving the tetanus toxoid, reduced-content diphtheria toxoid, acellular pertussis vaccine (Tdap), poliovirus vaccine, and hepatitis A vaccine.

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New Guidelines on Thromboembolism in Pregnancy

The American College of Obstetricians and Gynecologists published guidelines that suggest the use of pneumatic compression devices in patients before undergoing a cesarean delivery.

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