ULM COLLEGE OF PHARMACY
DRUG INFORMATION CENTER

JANUARY 15, 2009

FYDI
FOR YOUR DRUG INFORMATION

MATT DOWELL, PHARMD CANDIDATE 2009
GREGORY W. SMITH, PHARMD

In this issue…

FDA Medwatch Alerts

Singulair and Behavior/Mood Changes
The FDA is still reviewing clinical trial data to assess other neuropsychiatric events related to montelukast, zafirlukast, zileuton. The FDA has not come to a conclusion regarding the clinical trial data associated with these three drugs. View Alert

Vytorin vs. Zetia vs. Zocor: Update of Safety Review
In early 2008, the FDA issued an Early Communication because of concerns that some patients who achieved greater decreases in their LDL cholesterol levels by taking Vytorin did not show lesser amounts of plaque build up in their carotid arteries. After two years of study, carotid artery thickness increased by 0.011 mm in the Vytorin group while the Simvastatin alone group increased by 0.006 mm. The FDA concluded that there was no significant difference between the two groups in terms of plaque levels. FDA researchers noted a statistical decrease in the levels of LDL cholesterol for patients taking Vytorin. View Alert

Innohep May Increase Risk of Death in Elderly Patients with Renal Insufficiency
Celgene has issued a Dear Healthcare Professional letter describing a controlled clinical study that Innohep (tinzaparin sodium injection) may increase the risk of death in elderly patients with renal insufficiency. View Alert

Cranial Implant Kit Recall
Stryker Leibinger USA and FDA announced a Class 1 recall on their cranial implant kits distributed between November 5, 2007 and October 23, 2008. The products are being recalled because sterility could not be assured. View Alert

Hydromorphone Recall
ETHEX and FDA announced a nationwide recall of a single lot of Hydromorphone HCL 2 mg Tablets due to the possibility of oversized tablets. View Alert

Weight Loss Pills Declared Unsafe
The FDA has expanded its nationwide alert on certain diet pills. The FDA has identified 41 more tainted weight loss products that may be a risk to consumers' health. View Alert

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News Items:

Tamiflu Resistance
On December 19, 2008, CDC issued an interim guidance for health care professionals on the use of influenza medications this upcoming flu season. A high proportion of the influenza A viruses are becoming resistant to Tamiflu. The CDC is monitoring this situation very closely and has issued guidance for health care professionals. View Article Here

Antipsychotic Therapy Over Long Term in Alzheimer's Patients May Increase Mortality
A long term study has shown that patients with Alzheimer's disease that were treated over time with antipsychotic medications have an increased risk of mortality. After following up every year over a three year period, more patients treated with antipsychotic drugs died than those who had discontinued their medication. View Article Here

Vicks VapoRub May Cause Respiratory Distress in Infants, Animal Study Suggests
The *Chest* study suggests that Vicks VapoRub may act as an airway irritant in young children. Studies were done in healthy ferrets, which have airways similar to humans. The studies showed that when the ointment was applied mucus secretion increased while ciliary activity decreased. View Article Here

Lack of Sleep Linked to More Colds
People who sleep fewer than seven hours a night are nearly three times more likely to develop a cold than people who sleep at least eight hours or more. View Article Here

U.S. Lets Drugmakers Advise Doctors on Unapproved Uses
Pharmaceutical companies can now tell doctors about their medication's unapproved uses. The FDA guidelines allow manufacturers to distribute medical journal articles that describe unapproved uses of their drugs. View Article Here

Nationwide Recall of Peanut Butter
Peanut Corporation of America announced a voluntary recall of peanut butter that was produced in its Blakely Georgia processing facility due to the fact it may be contaminated with salmonella. The peanut butter that is being recalled is sold by PCA in bulk for institutional and food service industry use. None of the peanut butter being recalled is sold to the public through retail stores. Salmonella poisoning can result in abdominal cramping, diarrhea, and fever. Most symptoms develop within 12 to 72 hours after the infection. Most people recover in 4 to 7 days without treatment. View Article Here

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Guidelines Update:

Childhood and Adolescent Immunization Schedules Revised

The 2009 immunization schedules for children and adolescents have been approved by the American Academy of Pediatrics, the Advisory Committee on Immunization Practices of the Centers for Disease Control and Prevention, and the American Academy of Family Physicians. View Article Here

Adult Immunization Schedule Revised
The CDC released an updated schedule of recommended immunizations for adults. There are no new vaccines, but the updated schedule does feature a few clarifications and more streamlined format. For example, the new schedule now states that the pneumococcal polysaccharide vaccine should be administered to asthma patients. Article available via Pubmed.gov

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Drug Approvals

FDA Approves Drug For Patients with Advanced Prostate Cancer
The FDA has recently approved the injectable drug Degarelix for the treatment of prostate cancer. Degarelix belongs to a class of drugs called gonadotropin releasing hormone receptor inhibitors. Degarelix works by slowing the growth of prostate cancer by suppressing testosterone.
View Article Here

FDA Approves New Acne Gel Epiduo
Epiduo is a new prescription acne gel that has been approved by the FDA for use in patients 12 years of age and older. Epiduo contains a combination of benzoyl peroxide 2.5% and adapalene 0.1%. View Article Here

Mint Flavored Nicorette Approved by the FDA
The FDA approved Watson Pharmaceuticals Inc.'s generic version of Nicorette. Watson plans to start selling the new mint flavored gum in early January. The FDA approved the new mint flavored polacrilex gum in 2 mg and 4 mg strengths. View Article Here

FDA Approves New Nasal Inhaled Steroid for the Treatment of Allergic Rhinitis
Collegium Pharmaceutical announced on January 8 that the FDA has approved AllerNaze Nasal Spray, an aqueous based intranasal steroid indicated for the once daily treatment of nasal symptoms associated with both seasonal and perennial allergic rhinitis in adults and children that are 12 years of age or older. View Article Here

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Resource Update

NLM Gateway
The NLM Gateway is a Web-based system that allows you to search many systems at the U.S. National Library of Medicine at one time; it allows "one stop searching". This new system is targeting Internet users that are new to the NLM's online resources. It allows users to find out what information is available. There are three categories including bibliographic resources, consumer health resources, and other resources. Under each category is a table that contains collections such as Pub-Med, Medline Plus, NLM catalogue, etc that users can access. This resource is very helpful for new or experienced researchers and would be an excellent site to start looking for Forum information. View Resource

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ULM COLLEGE OF PHARMACY
DRUG INFORMATION CENTER

FEBRUARY 6, 2009

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FOR YOUR DRUG INFORMATION

MATT DOWELL, PHARMD CANDIDATE 2009
GREGORY W. SMITH, PHARMD

In this issue…

FDA Medwatch Alerts

Life Threatening Side Effects with the Use of Skin Products
The FDA has issued an advisory to alert consumers about the potential hazard of using skin numbing products. These topical anesthetics contain drugs such as lidocaine, tetracaine, benzocaine, and prilocaine. Applying more than recommended can result in high levels reaching the blood causing irregular heartbeats, seizures, and death. View Alert

Ongoing Safety Review of clopidogrel bisulfate
Some reports claim Plavix is less effective in some patients than it is in others. The FDA and the makers of Plavix plan to conduct studies that will allow them to better understand and characterize the effects of genetic factors and other drugs on the effectiveness of Plavix.
View Alert

FDA Warns Consumers against Dietary Supplement
The FDA is warning consumers not to take Venom HYPERDRIVE 3.0. This dietary supplement contains sibutramine which is a controlled substance with risks for abuse or addiction.
View Alert

ETHEX Issues Nationwide Voluntary Recall
ETHEX Corporation is issuing a nationwide voluntary recall on a list of products because they may have been manufactured under conditions that did not comply with current Good Manufacturing Practices. View Alert

ETHEX Adds Prescription Prenatal and Iron Supplements to Nationwide Recall
ETHEX Corporation has added a list of prenatal and iron supplements to their nationwide recall.
View Alert

Xigris Ongoing Safety Review
The FDA is aware of a study which reported that patients with sepsis taking Xigris had an increased risk of bleeding and death. The FDA is working with the manufacturer to evaluate the incidence of serious bleeding events and mortality. View Alert

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News Items:

Salmonella Peanut Butter Source Found in Georgia
The latest outbreak of illnesses caused by Salmonella Typhimurium are from peanut butter and paste products produced by the Peanut Corporation of America at its Blakely processing plant in Georgia. View Article

Study Suggests Steroids Do Not Help Wheezing Kids
According to new research, steroids, a common treatment for young children prone to wheezing and colds, do not help and may even be harmful. Preschoolers in Britain were hospitalized with a wheezing attack and who were treated with prednisolone stayed admitted just as long as the other children treated with placebos. View Article

Newer Antipsychotics Increase Risk for Sudden Cardiac Death
According to a study in the Jan. 15 issue of the *New England Journal of Medicine*, people who use newer antipsychotic drugs are twice as likely as to have sudden cardiac death. A study done at the Vanderbuilt University School of Medicine and Geriatric Research, Education, and Clinic Center concluded that the newer antipsychotic drugs did not appear to be any safer than the older drugs when it came to sudden cardiac death. View Article

Data Suggests ADHD Drugs Can Cause Hallucinations in Some Kids
FDA researchers' analyzed data from 49 clinical studies conducted by the makers of the ADHD drugs and found that they can cause psychosis and mania in some patients. Children have hallucinated that worms, bugs or snakes were crawling on them. View Article

FDA to Improve the Safety of Drugs Produced Outside the United States
The FDA will launch a voluntary pilot program that will help promote the safety of drugs and active ingredients produced outside the United States. View Article

FDA Panel Urges That Darvon be Banned
FDA advisors have recommended that Darvon be banned. Darvon has been prescribed for the past 52 years. Consumer groups are argued that the drug and its derivatives do not offer strong enough pain relief and poses risks for overdose. View Article

Doctors Turning to Electronic Prescribing
The economic stimulus legislation making its way through Congress includes $20 billion to push for the adoption of health information technology including electronic prescribing. President Barack Obama has made electronic prescribing part of his plan to improve the U. S. healthcare system. View Article

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Guidelines Update:

New Guidelines for Opioid-Linked Respiratory Depression
Updated guidelines have been published in the February issue of *Anesthesiology* regarding the prevention, detection, and treatment of respiratory depression associated with neuraxial opioids. The new guidelines recommend that a history and physical exam be performed to identify patients with an increased risk of respiratory depression prior to administering neuraxial opioids.
View Article

Drug Approvals

FDA Approves Fibromyalgia Drug
The FDA approved Savella for the management of fibromyalgia. Fibromyalgia is a chronic condition characterized by widespread pain and decreased physical function. The safety and efficacy of Savella was proven in two U.S. phase III Clinical Trials. Savella should be available in pharmacies by March 2009. View Article

FDA Approves New Drug for Treatment of Bleeding in Patients with Rare Disorder
The FDA approved RiaSTAP which is used for treatment of bleeding in patients with congenital fibrinogen deficiency. RiaSTAP is an IV fibrinogen concentrate made from the plasma of healthy blood donors. RiaSTAP is indicated for people with little or no levels of fibrinogen.
View Article

FDA Approves GELNIQUE for the Treatment of Overactive Bladder
Watson Pharmaceuticals has announced that the FDA has approved GELNIQUE Gel 10%. GELNIQUE is the first and only topical gel for the treatment of overactive bladder. Since the gel is applied transdermally, it is not metabolized by the liver. This results in lower amounts of side effects such as dry mouth and constipation. View Article

FDA Approves KAPIDEX for the Treatment of GERD
Takeda Pharmaceuticals has announced that the FDA has approved KAPIDEX delayed release capsules for once daily treatment of heartburn associated with symptomatic non-erosive GERD. KAPIDEX is the first proton pump inhibitor designed to provide two separate releases of medication. View Article

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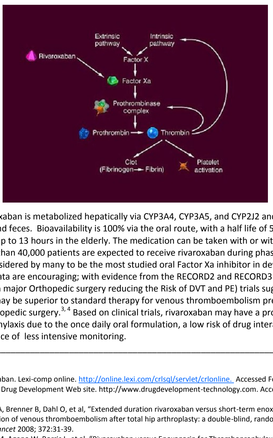
Pipeline Drug Spotlight

Rivaroxaban is a new orally administered anticoagulant, jointly manufactured by Bayer and Johnson & Johnson, which may soon be on pharmacy shelves. The new agent is sold under the brand name Xarelto in Europe, but has not yet been approved in the US. The manufacturer filed a New Drug Application with the FDA in July of 2008, which is still pending. Rivaroxaban works by inhibiting platelet activation and clot formation via direct, selective and reversible inhibition of factor Xa. Upon FDA approval, clinical trial data suggests that rivaroxaban would offer the convenience of oral administration without the need for intensive coagulation monitoring, which could potentially be a major improvement in anticoagulation therapy. It is indicated for the primary prevention and treatment of venous thromboembolism (VTE) following orthopedic surgery. Rivaroxaban is indicated after knee or hip replacement at a dose of 10 mg once daily starting 6 to 10 hours after surgery. The manufacturer recommends that rivaroxaban should be continued for 14 days after a knee replacement and 35 days after a hip replacement. Rivaroxaban should not be used in significant hepatic impairment or if creatinine clearance is less than 30 mL/min and is contraindicated in pregnancy and nursing mothers[1].

The most common complication of rivaroxaban is bleeding, while other common adverse events include nausea and increased transaminases. The medication should not be used with other anticoagulants, antiplatelet agents, CYP3A4 inducers or inhibitors, thrombolytic agents, NSAIDS, or salicylates. Grapefruit juice may also increase the levels and effects of rivaroxaban. While on this medication, prothrombin time, CBC, renal function, and hepatic function should be monitored[1].



Rivaroxaban is metabolized hepatically via CYP3A4, CYP3A5, and CYP2J2 and is eliminated in the urine and feces. Bioavailability is 100% via the oral route, with a half life of 5 to 9 hours in children and up to 13 hours in the elderly. The medication can be taken with or without food[1].

More than 40,000 patients are expected to receive rivaroxaban during phase III clinical trials. It is considered by many to be the most studied oral Factor Xa inhibitor in development[2]. Clinical trial data are encouraging; with evidence from the RECORD2 and RECORD3 (REgulation of Coagulation in major Orthopedic surgery reducing the Risk of DVT and PE) trials suggesting that rivaroxaban may be superior to standard therapy for venous thromboembolism prevention following orthopedic surgery.[3, 4] Based on clinical trials, rivaroxaban may have a promising role in thromboprophylaxis due to the once daily oral formulation, a low risk of drug interactions, and the convenience of less intensive monitoring.

References

1. Rivaroxaban. Lexi-comp online, http://online.lexi.com/crlsql/servlet/crlonline. Accessed February 4, 2009.
2. Xarelto. Drug Development Web site. http://www.drugdevelopment-technology.com. Accessed February 4, 2009.
3. Kakkar A, Brenner B, Dahl O, et al, "Extended duration rivaroxaban versus short-term enoxaparin for the prevention of venous thromboembolism after total hip arthroplasty: a double-blind, randomized controlled trial," *Lancet* 2008; 372:31-39.
4. Lassen M, Ageno W, Borris L, et al, "Rivaroxaban versus Enoxaparin for Thromboprophylaxis after Total Knee Arthroplasty," *N Engl J Med* 2008; 358: 2776-86.

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APRIL 9, 2009

FYDI
FOR YOUR DRUG INFORMATION

DANIEL ABERCROMBIE, PHARMD CANDIDATE 2009
GREGORY W. SMITH, PHARMD

In this issue…

FDA Medwatch Alerts

Consumer level recall for digoxin

The FDA has issued a consumer level recall for Digoxin 0.125 mg and 0.25 mg manufactured by Caraco pharmaceuticals due to inappropriate size of tablets. This deviation could indicate increased amounts of active ingredient in each tablet.

View Alert

Consumer level recall of Class 1c antiarrhythmic medication

The FDA and Watson pharmaceuticals have issued a recall for Propafenone HCL 225 mg to health care professionals and patients. Some tablets may contain higher levels of active component than specified.

View Alert

Black box warning to be added to metoclopramide-containing products

The FDA has mandated that products containing metoclopramide be issued a black box warning for the development of tardive dyskinesia associated with high-doses or long term use.

View Alert

Unapproved prescription narcotics drugs halted

The FDA has sent nine companies warning letters to halt the production of narcotic drugs that have not been proven safe and effective.

View Alert

News Items:

***Salmonella* contamination in pistachio products**

Multiple strands of *Salmonella* have been found in contaminated pistachio products from Setton

Pistachio of Terra Bella Inc. This has prompted the company to recall over one million pounds of pistachios.
View Article

"Diabetes Ten City Challenge" looking successful
The APhA program developed to improve patient health outcomes and decrease healthcare costs appears to be successful. This pharmacist-led program has shown a 23% increase in patients achieving goal blood glucose levels while simultaneously reducing annual cost by seven percent.
View Article

Sick smokers find triple therapy the most effective
A new study showed that smokers with some other illness, such as heart disease, cancer, or diabetes, find it more effective to stop smoking on triple therapy. This study determined that taking bupropion, wearing a nicotine patch, and using a nicotine inhaler was more successful than the nicotine patch alone.
View Article

Broccoli sprouts may prevent stomach cancer
According to a report in Cancer Prevention Research broccoli sprouts, which contain the phytochemical sulforaphane, suppressed *Helicobacter pylori* infection. This bacterium is known to be a major cause of stomach cancer.
View Article

Healthy older adults not being screened for colon cancer
A Veterans Administration study showed that many adults age 70+ without comorbidities were not screened regularly for colon cancer.
View Article

Clopidogrel and ASA reduce stroke risk
A new study in *The New England Journal of Medicine* showed that clopidogrel combined with aspirin reduced the risk of stroke in atrial fibrillation patients that could not receive warfarin, however the risk of major hemorrhage increases.
View Article

Genetics testing used to predict optimal dosing for warfarin
New evidence has shown that genetic variations in CYP2C9 and VKORC1 genes influence the effectiveness of warfarin. This has sparked the National Institute of Health to launch a clinical trial to test whether a gene-based strategy for prescribing the initial warfarin dose will improve patient outcomes.
View Article

Drug Approvals

FDA approves new kidney cancer medication
The FDA has approved Everolimus for advanced kidney cancer patients. This medication prevented the growth of cancer for five months, but overall benefits are limited. There was no increase in quality of life and patients did not live longer than patients on alternate medications.
View Article

FDA approves new vaccine to prevent Japanese Encephalitis
The FDA has approved Ixiaro, a vaccine to prevent Japanese Encephalitis in adults and military

The FDA has approved Ixiaro, a vaccine to prevent Japanese Encephalitis in adults and military traveling to Asia.
View Article

Generic Topamax approved
The FDA has approved several manufactures for the production of topiramate tablets to prevent seizures.
View Article

FDA approves new drug for the management of hyperuricemia
Takeda Pharmaceuticals has announced that the FDA has approved Uloric (febuxostat) for the chronic management of hyperuricemia in patients with gout. Febuxostat is a xanthine oxidase inhibitor, which lowers serum uric acid in patients.
View Article

Guidelines Update:

AHA releases new guidance for preventing Rheumatic Fever
New guidelines suggest that the primary prevention of rheumatic fever is the correct diagnosis and treatment of group A streptococcal pharyngitis. The AHA guideline, which endorsed by the American Academy of Pediatrics, provides dosing regimens to help prevent the development of RF.
View Guideline

The ACCF/AHA new guidelines on heart failure
The ACCF/AHA has recently updated guidelines for the treatment and diagnosis of heart failure. The 2009 updates focus on natriuretic peptides in stratifying risk, race-specific treatments, treatments with comorbidities, and treatment while hospitalized.
View Guideline

CDC issues new guidance for treating opportunistic infections in HIV patients
The CDC's updated guidelines focus on the importance of antiretroviral therapy for the prevention and treatment of opportunistic infections. Each OI in the guideline covers epidemiology, clinical manifestation, diagnosis, prevention of exposure, and treatment of disease.
View Guideline

Guidelines on Opioids in Noncancer Pain
The American Pain Society and The American Academy of Pain Medicine issued guidelines for opioid use in noncancer pain. The guideline recommends that a complete history, physical examination, and appropriate testing (including substance abuse risk) be conducted before prescribing opioid therapy.
View Guideline

Resource Update

Facts & Comparisons® 4.0

Have you checked out Facts & Comparisons® 4.0 lately?

Our subscription to Facts & Comparison has been enhanced through Wolters Kluwer's new

Academic Partnership Program.

The New Academic Partnership Program includes:

- Value-Added Modules & New Tools:
  - Trissel's IV-Chek
  - ToxFacts
  - Formulary Monograph Service
  - 5-Minute Clinical Consult
  - Cancer Chemotherapy Manual
  - MedCalc 3000
- Quarterly New Product Features: New content & enhancements for students, including the enhanced Drug Identifier, drug-drug comparison tables, and more.
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- Impact on Product and Program Enhancements: This is your opportunities to provide feedback regarding both the product and the new Academic Partnership Program.
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With Facts and Comparison® 4.0 we have access to complete drug information references including:

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- Drug Interaction Facts™
- Drug Identifier
- Herbal Interaction Facts
- MedFacts Patient Information
- (English and Spanish)
- Review of Natural Products
- A to Z Drug Facts
- Nonprescription Drug Therapy™
- Off-Label Drug Facts®
- Interactive Comparative Drug Tables
- Drug Interaction & Disease Profile Screening Tool
- Medical Calculators
- Black Box Warnings
- Pregnancy and Lactation Warnings
- Bioequivalency Codes
- Investigational Drugs
- Manufacturer Index
- Patient Assistance Program Information
- Orphan Drugs
- Medication Guides
- FDA Medwatch Links
- Drug & Industry News

Facts & Comparison® 4.0, as well as our other subscribed references may be accessed through the Reference Resources section on the ULM College of Pharmacy webpage.

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MAY 1, 2009

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DANIEL ABERCROMBIE, PHARMD CANDIDATE 2009
GREGORY W. SMITH, PHARMD

In this issue…

Special Alerts

Swine Flu update and useful resources
Influenza A (H1N1), a.k.a. swine flu, has recently been elevated to pandemic alert level 5 by the World Health Organization, reflecting confirmed person to person transmission. The CDC has now compiled resources for the public and healthcare providers to remain knowledgeable about the disease and treatment options for a variety of population groups. Use the following link to retrieve this information.
View Item

Swine Flue medication susceptibility
The CDC has tested Influenza A (H1N1) to determine the most effective treatment. This viral strand is resistant to adamantane and rimantadine, but susceptible to oseltamivir, zanamivir, and two investigational drugs peramivir and A-315675.
View Item

FDA authorizes emergency use of antiviral medications and tests
The FDA has now issued Emergency Use Authorizations in response to requests by the CDC to help combat the swine flu outbreak. These provisions include the medications oseltamivir and zanamivir, as well as the diagnostic test rRT-PCR Swine Flu Panel.
View Item

ASHP Foundation Pandemic Influenza Resources
These resources were compiled by the ASHP Foundation to support pandemic influenza institutional planning efforts and to foster pharmacist involvement in the pandemic preparedness process.
View Item

FDA MedWatch Alerts

Manufacturers of botulinum toxin products strengthen product label warnings
The FDA is requiring product label revisions, including a boxed warning addressing the risk of adverse events associated with the spread of the toxin beyond the injection site.
View Alert

Nature and Health Co. issues voluntary recall
The FDA lab analysis of Libimax found that it contained tadalafil, the active ingredient of Cialis. These findings have prompted Nature and Health Co. to withdraw its unapproved drug from the market.
View Alert

Non-acetone nail polish remover recalled
Personal Nail Products has issued a voluntary recall of 6 fl oz non-acetone nail polish remover due to the potential of causing chemical burns.
View Alert

FDA issues voluntary recall of dietary supplements
Universal ABC Beauty Supply International has issued a voluntary recall for many of it's dietary supplements. This was prompted when the FDA found amounts of sibutramine, the active component of the FDA-approved drug Meridia.
View Alert

View or Report FDA MedWatch Alerts

News Items:

Botox useful for more than just wrinkles
The usefulness for botulinum toxin has been proven to be effective in four FDA approved disease states: muscle disorders, neck disorders, excessive sweating, and eyebrow furrows. The off-label uses have included, but not limited too, speech impediments, migraines, oily skin, and drooling. With the every increasing need for new solutions to old problems Botox may just be the answer.
View Article

Statins may reduce risk of prostate cancer
New research shows that men taking statins may be two to three times less likely to develop prostate cancer. This research brings promising outcomes for the second deadliest cancer in the United States.
View Article

FDA changes stance on concomitant use of ceftriaxone and intravenous calcium containing products
FDA now recommends that concomitant use of ceftriaxone and intravenous calcium products not be used in neonates < 28 days. The previous recommendation included all age groups not to receive ceftriaxone and intravenous calcium products within 48 hours of each other.
View Article

Anti-platelet therapy may be source of cerebral microbleeds
New study to be published in the June issue of *Archives of Neurology* indicates that aspirin and other anti-platelet therapies may lead to microbleeds in the brain.
View Article

Pharmacist receiving increased pay for MTM
Do to the rise in healthcare cost associated with medication mismanagement, some insurers are paying pharmacist more for MTM services. With the ever evolving field of pharmacy, MTM is providing an advancement in pharmacist-patient relationships and increase positive health outcomes.
View Article

Ryan Haight Online Pharmacy Consumer Protection Act now implemented
The Ryan Haight Online Pharmacy Consumer Protection Act has increased the requirements for online pharmacy operations. The DEA enforces the new regulations of the bill and advocates that it will decrease the cybercrime associated with illegal sells of online controlled substances.
View Article

FDA requires new labeling on OTC pain medications
New label requirements on acetaminophen and NSAIDS are now required by the FDA. They now have to indicate potential safety concerns such as internal bleeding and liver damage.
View Article

Strong Physician-Patient-Pharmacist relationships decrease medication errors
New study shows that when pharmacists are involved with medication reconciliation at hospitals, medication errors decrease.
View Article

Drug Approvals

FDA approves new anti-malarial medication
Coartem (artemether and lumefantrine) tablets have been approved by the FDA for the treatment of acute, uncomplicated malaria infections for patients greater than 5 kilograms.
View Article

FDA approves another treatment for Pediculosis capitis
Benzyl alcohol 5% lotion has now been approved by the FDA to treat head lice in patients 6 months of age and older.
View Article

FDA approves new injectable arthritis medication
Centocor Ortho Biotech Inc. has received approval by the FDA for Simponi (golimumab). It is a monthly treatment for moderate-to-severe rheumatoid arthritis, active psoriatic arthritis, and active ankylosing spondylitis.
View Article

FDA approves Plan B for younger girls
Due to a ruling found in federal court, the FDA was mandated that Plan B be approved without a prescription for girls age 17 and older.
View Article

Resource Update

The **National Institute of Drug Abuse (NIDA)** at http://www.nida.nih.gov is a resource provided by the National Institute of Health (NIH) and a component of the U.S. Department of Health and Human Service.

NIDA's mission is "to lead the Nation in bringing power of science to bear on drug abuse and addiction."

The information available at NIDA includes:

- In depth information on drugs and substances of abuse
- Treatment referral resources
- Educational resources and material on drugs of abuse targeted for students of all ages
- Drug information facts and classroom tools for parents and teachers
- NIDAMED—screening tools and practice resources for medical and health professionals
- Grants and funding opportunities, as well as research dissemination
- News and events
- Directory of web resources for specific areas of substance abuse such as club drugs, steroid abuse or inhalants

For more information, visit NIDA at http://www.nida.nih.gov

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JULY 9, 2009

FYDI
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In this issue…

FDA Medwatch Alerts

Hi-Tech Pharmaceuticals, Inc. issues nationwide recall of dietary supplement
The discovery of benzamidenafil, a PDE5 inhibitor, in a sample of Stamina-Rx prompted a nationwide recall of all Stamina-Rx products. Benzamidenafil is not an FDA-approved product.
View Alert

FDA issues update on cefepime safety
After collecting and reviewing additional data concerning the safety of cefepime, the FDA declares cefepime is still an appropriate treatment option.
View Alert

FDA advises public to discontinue use of Zicam nasal products
The FDA has advised consumers to stop using Zicam nasal sprays as a result of more than 130 reports of consumers losing their sense of smell after using Zicam nasal spray products.
View Alert

Smoking cessation medications now required by FDA to contain Boxed Warnings
Manufacturers are now required to include a Boxed Warning Chantix and Zyban prescribing information. Problems such as changes in behavior, depression, hostility, and suicidal thoughts have been reported by patients.
View Alert

Risk of fatal overdose prompts FDA actions on propoxyphene products
FDA makes new requirements for manufacturers concerning the labeling and dispensing of propoxyphene-containing products.
View Alert

Possible link between insulin and cancer
FDA is aware of recent studies showing a link between Lantus and cancer, but advises patients to continue taking their insulin unless directed otherwise by their physician.
View Alert

News Items

CDC updates recommendations for Hib vaccine
Starting July 2009, the Hib vaccine booster dose will be reinstated after its suspension on December 13, 2007. The CDC recommends a booster dose to be given at ages 12-15 months after receiving the Hib vaccine series at ages 2, 4, and 6 months.
View Article

Doctors discourage hosting and attending "Swine flu parties"
Officials discourage the public from hosting "swine flu parties". Some people feel it is better to expose their children to swine flu rather than avoid it; however, many doctors feel it is safer to avoid the potentially fatal virus.
View Article

Obama signs new law concerning tobacco products
President Obama has given the FDA power to control tobacco products under the Family Smoking Prevention and Tobacco Control Act. So far, this is the nation's toughest law against smoking.
View Article

Advisory panel wants Vicoden and Percocet removed from market
FDA advisory panel votes 20-17 to recommend the prescribing of Percocet and Vicoden be outlawed. Much concern has been raised due to the ability of acetaminophen containing products to cause serious liver damage.

View Article

OTC and Rx acetaminophen products
Information on the safe use of acetaminophen-containing products and FDA rulings concerning the medication can be found at the link below.
View Item

New depression medication class shows positive results in phase III studies
Vilazodone represents the first medication in a new class of depression medications. The new drug application is expected to be submitted to the FDA by the end of the year.
View Article

Trial shows positive results for two medications in prevention of eye problems, not kidney problems
Enalapril and losartan, two medications prescribed to diabetic patients in order to prevent kidney complications, have shown to slow the development of diabetic retinopathy.
View Article

Caffeine may be an answer to Alzheimer's prevention
Researchers from the US and Japan have discovered that 500 mg of caffeine given to adult mice daily prevented Alzheimer's signs. Clinical trials in humans are anticipated to produce promising results.
View Article

Possible treatment of prostate cancer accomplished by sound waves
A UK trial studied the effectiveness of sound waves in the treatment of prostate cancer. Although this treatment method has less side effects than surgery, long term effectiveness is unknown.
View Article

Benefit of H2-Receptor Antagonist Shown in FAMOUS Trial
Patients on low-dose aspirin therapy may be protected from developing stomach and upper-intestinal ulcers by taking famotidine.
View Article

New strain of flu virus found in Canada
Two workers on a pig farm have been diagnosed with a new strain of the flu virus that contains genes from the seasonal flu and a flu virus often found in herds of pigs. Authorities confirm it is not a new strain of the current pandemic swine flu.
View Article

Poison Control Centers in danger of closing
Even though Poison Control Centers serve as a very important resource to the public health, some officials believe these centers should be part of budget cuts. The following article provides information concerning the services Poison Control Centers provide and the need for such resources.
View Article 1 of 2
View Article 2 of 2

Guidelines Update

New guideline update from American Geriatrics Society
The American Geriatrics Society has released an update of the guidelines for management of persistent pain in the elderly.
View Guidelines

Drug Approvals

FDA approves new anemia medication
Feraheme (ferumoxytol) injection has been approved by the FDA for the treatment of iron deficiency anemia in adults.
View Article

FDA approves new treatment for abnormal heart rhythms
Multaq (dronedarone) tablets have been approved to treat heart rhythm disorders in patients with a history of atrial fibrillation or atrial flutter.
View Article

FDA approves another use for Alimta
Alimta (pemetrexed) has been recently approved as the first maintenance medication for advanced lung cancer. Alimta is also indicated as treatment for mesothelioma, non-small cell lung cancer, and advanced non-small cell lung cancer
View Article

FDA approves generic Plan B
The first generic version of Plan B has been approved by the FDA and is currently available by prescription only for females 17 years of age and younger.
View Article

Resource Update

Introducing the Johns Hopkins ABX Guide at http://www.hopkins-abxguide.org/

The Johns Hopkins ABX Guide is an on evidence-based reference tool that provides timely and authoritative antibiotic information.

Key Features of the Johns Hopkins ABX Guide include:

- More than 560 modules of information
- Organized by Diagnosis, Drugs, Pathogens, Management and Vaccines
- Alphabetically listed topics with information in bullet form for quick and easy navigation and use
- Diagnostic criteria
- Treatment regimens and algorithms
- Therapeutic indications
- Drug manufacturer formulations
- Common and renal dosing guides
- Drug interactions
- Sections on biodefense, anthrax and travel
- Interactive Q & A forums with clinical experts
- Author opinions
- Literature Reviews

The ABX Guide is also available in handheld formats: Palm, PocketPC, Blackberry and iPhone.

See the Johns Hopkins ABX Guide at http://www.hopkins-abxguide.org/

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ULM COLLEGE OF PHARMACY
DRUG INFORMATION CENTER

JULY 30, 2009

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In this issue…

FDA Medwatch Alerts

FDA enlightens physicians and patients about dangers of body building supplements
FDA states body building products containing steroids or steroid-like substances are new unapproved products, not dietary substances as advertised. Adverse events such as serious liver injury, stroke, kidney failure and pulmonary embolism have been reported.
View Alert

Luv N' Care issues nationwide recall of teethers
Nuby Gel Filled, Cottontails, and Playschool Teethers have been recalled due to the discovery of potentially harmful bacteria found in the gel of two lots.
View Alert

Teva Pharmaceuticals issues recall of two lots of Propofol Injectable Emulsion
After 41 adverse events occurred following the administration of Propofol Injectable Emulsion 10 mg/mL 100 mL vials with lot numbers 31305429B and 31305430B have been recalled which contained elevated endotoxin levels.
View Alert

Covidien and FDA issue recall Mallinckrodt Sodium Chromate Cr-51 Injection lot
Upon discovering one lot of the radiopharmaceutical agent to be subpotent, a recall has been issued. Using the subpotent product can produce an incorrect test result.
View Alert

FDA issues recall of Stabilet Infant Warmer models
The listed models of the infant warmer are recalled due to a fire hazard warning and possible injury to patients and caregivers. Also in the article is a list of actions to be taken immediately concerning the removal of the models.
View Alert

News Items:

Michigan students design new CPR mattress
A group of Michigan Technological University students have designed a mattress that enables CPR to be administered more effectively.
View Article

Sunbeds now assigned to Group 1 risk category
Tanning beds and UV radiation exposure have been moved from the Group 2 risk category to the Group 1 risk category of cancer causing agents. Individuals using a tanning device before 30 years of age are at a 75% increased risk of developing melanoma.
View Article

Alternative to chemotherapy seems hopeful in treatment of leukemia
JAK2 mutations have been shown in children with Down syndrome and now also in children with leukemia. JAK2 inhibitors are a new class of medications being studied to cure childhood leukemia.
View Article

Recent study highlights four risks factors for patients undergoing bariatric-surgery
Four risk factors have been identified that place patients at an increased risk of complications during or after bariatric-surgery. Despite the risks, health officials feel the surgery is beneficial and provide advice for before and after prevention of complications.
View Article

Glucose meter for children now available on gaming systems
DIDGET, a blood glucose meter manufactured by Bayer, is available for Nintendo DS and Nintendo DS Lite gaming systems. It is designed to reward children for meeting personalized target ranges and maintaining consistent blood glucose testing habits.
View Article

HAART should be standard treatment for HIV positive pregnant women in poorer countries
A new study has compared treatment with HAART versus zidovudine plus nevirapine therapy. Zidovudine plus nevirapine is the standard treatment for HIV positive mothers in poorer countries. The study suggest healthcare officials focus more on effectiveness than financial concerns.
View Article

New study shows evidence of protein linking African Americans and high risk of hypertension and kidney disease
Results from a new study have shown increased levels of TGF-B1 in hypertensive and non-hypertensive African Americans compared to Caucasians. More research needs to be conducted to discover the exact mechanism of TFG-B1 and possibly develop a new class of anti-hypertensive medications.
View Article

Tractor trailer containing Sanofi-Aventis products stolen
A tractor trailer transporting Lovenox, Xyzal, Nasacort AQ, and Benzacilin gel was stolen July 9, 2009. Refer to the article for specific lot numbers and where to report information concerning the stolen products.
View Article

Drug Approvals

FDA approves Plan B One-Step
Plan B One-Step is a single dose emergency contraceptive. It is available to females 17 years of age and older without a prescription and by prescription only to females under the age of 17.
View Article

FDA approves another new platelet inhibitor
Effient (prasugrel) is a $P2Y_{12}$ approved for the prevention of thrombotic events in patients with ACS scheduled for a PCI. Studies have shown prasugrel to be more effective than clopidogrel; however, it was associated with a higher risk of adverse bleeding effects.
View Article

FDA approves new therapy for break through pain in adult cancer patients
Onsolis (fentanyl) has been approved for patients already tolerant to opiod therapy, 18 years of age and older, and need treatment for break through pain associated with cancer. It is dosed in a buccal soluble film and is not bioequivalent to other fentanyl products.
View Article

Guideline Updates

Seasonal Flu vaccination guidelines updated
It is now recommended that all children 6 months to 18 years of age receive the seasonal flu vaccination. Also updated are the vaccines with specific viral strains that are to be administered.
View Update

H1N1 vaccination made priority for five targeted groups
The ACIP has targeted five population groups to be the primary recipients of the H1N1 vaccine and help prevent the spread of the virus. The groups are focused on healthcare professionals and young children or those who may infect young children.
View Update

New guidelines for the monitoring of *S aureus* infections treated with vancomycin
The guidelines include initial dosing for all patients, the best way to monitor vancomycin effectiveness, how to avoid resistance, recommended trough concentrations, a target AUC/MIC, and other information concerning the monitoring of vancomycin.
View Update

Resource Update

2010 edition of *Travelers' Health Yellow Book* is now available...
The CDC's updated version of *Yellow Book* includes new information for traveling safely with health conditions, medical tourism, and expert opinions on popular international places of travel.

New features include information about:

- Diseases that might be unfamiliar to travelers (i.e. anthrax or scabies)
- Mental health and travel
- Drug-drug and drug-vaccine interactions
- Respiratory infections common to travelers
- Common post-travel illnesses

View Yellowbook

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AUGUST 20, 2009

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In this issue...

Special Alert

New H1N1 virus could result in a severe flu season this year
With the emergence of the H1N1 virus earlier this year, the CDC is encouraging people to get the seasonal influenza vaccine as soon as possible. The seasonal flu vaccine is unlikely to provide protection against the H1N1 virus, therefore, the CDC recommends that certain people should also consider taking advantage of the novel H1N1 vaccine that is expected to become available this fall.
View Alert

Recommended Groups for Seasonal Influenza Vaccine* for 2009-2010 Season:
- Children aged 6 months up to their 19th birthday
- Pregnant women
- People 50 years of age and older
- People of any age with certain chronic medical conditions
- People who live in nursing homes and other long-term care facilities
- People who live with or care for those at high risk for complications from the flu, including health care workers and household contacts and out of home caregivers of children less than 6 months of age.

**The seasonal influenza vaccine is not expected to protect against the H1N1 flu virus.*

Recommended Groups for the Novel H1N1 Influenza Vaccine are:
- Pregnant women
- Household contacts and caregivers for children less than 6 months of age
- Healthcare and emergency medical services personnel
- All persons 6 months through 24 years of age
- Persons aged 25 through 64 years who have health conditions associated with higher risk of medical complications from influenza

Reported totals of the H1N1 flu virus in the United States:
- 43,771 confirmed and probable cases (April 15, 2009 to July 24, 2009)
- 7,511 hospitalizations cases as of August 13
- 477 deaths as of August 13

Current status of the novel H1N1 influenza vaccine:
- A novel H1N1 vaccine is expected to be available mid-October, or possibly late September (This will not replace the seasonal flu vaccine)
- Clinical trials testing safety and recommended number of doses are still in progress
- Consumers should be aware that fraudulent novel H1N1 influenza products are being advertised on various internet sites. View More Info
- Vaccine information for pharmacists/health care providers is currently under development. On August 10, 2009, a vaccination planning guide was released by the CDC. View CDC Vaccination Planning Q&A

How can you protect yourself and others during this upcoming flu season?
- Cover your nose and mouth with a tissue when you cough or sneeze.
- Wash your hands often with soap and water.
- Avoid touching your eyes, nose, and mouth.
- Avoid crowds and close contact with sick people.
- If you become sick with a flu-like illness, stay away from others for at least 24 hours after your fever is gone.
- If you become sick, wear a facemask around your home to prevent the spread of the virus to other members of your family.
- Stay informed.

Additional resources regarding the 2009-2010 flu season:
http://www.cdc.gov/h1n1flu/
http://www.cdc.gov/flu/whatyoushouldknow.htm
http://www.cdc.gov/flu/professionals/index.htm

FDA Medwatch Alerts

Falsely elevated blood glucose readings with GDH-PQQ test strips
Patients receiving drug therapy containing non-glucose sugars may obtain falsely elevated blood glucose readings with the use of GDH-PQQ test strips. These strips detect both glucose and non-glucose sugars, leading to elevated readings that could possibly result in potentially life-threatening insulin dosing.
View Alert

CellCept has been linked to PRCA
Patients treated with CellCept may develop a type of anemia known as Pure Red Cell Aplasia (PRCA). In some cases, PRCA was found to be reversible with dose reduction or cessation of therapy.
View Alert

FDA declared a Class 1 recall on various modules of Cardinal Health's Alaris System
Cardinal Health's Alaris System is composed of electronic infusion pumps that deliver controlled amounts of medications or fluids to patients via parenteral administration. Failures observed with these pumps may result in patients experiencing under- or over-infusion.
View Alert

TNF blockers result in an increased risk of lymphoma and other cancers
The FDA has taken action to notify healthcare professionals and warn patients of an increased risk of lymphoma and other cancers, specifically leukemia, associated with the use of tumor necrosis factor (TNF) blockers in children and adolescents. Currently available TNF blockers include Remicade, Enbrel, Humira, Cimzia, and Simponi.
View Alert

Fatal colchicine toxicity has been reported in certain patients
Patients taking standard therapeutic doses of colchicine concomitantly with medications that affect the GI absorption and/or hepatic metabolism of colchicine have developed adverse effects. With the recent approval of a new colchicine product, Colcrys, the FDA urges healthcare professionals to become familiar with safety considerations regarding the use of colchicine.
View Alert

View all Medwatch Alerts

News Items:

Doctor-pharmacist collaborative practice reduces hospitalization
A collaborative practice program in Australia allows pharmacists to make in-home visits to patients referred by their doctor. The pharmacists conduct patient interviews, review medications and report any potential problems. A study in Australia reports that heart failure patients studied in a collaborative practice program required less hospitalization than the control group.
View Article

Study shows increased survival for colorectal cancer patients using aspirin
Patients diagnosed with colorectal cancer who begin taking aspirin post-diagnosis could benefit from therapy, especially in cancer expressing COX-2. Previous studies also showed that aspirin and NSAIDs decrease the chance of developing colorectal cancer.
View Article

Researchers at the University of Utah test gel for the prevention of HIV
Researchers are testing a vaginal gel to prevent the spread of HIV. The gel is designed to change the molecular structure of the virus to provide a protective barrier against this life-threatening disease.
View Article

Withdrawal of PPI therapy may result in new acid-related symptoms
A recent study demonstrated that rebound acid hypersecretion occurs after PPI therapy is withdrawn. When a PPI is stopped, it is proposed that a hypersecretory state develops due to compensatory gastrin release. It is recommended that PPIs should be restricted to certain patients and alternate treatment options should be considered first.
View Article

Enzyme discovery may lead to new treatment for asthma
Researchers have found that a single enzyme, aldose reductase, may be responsible for provoking asthma attacks. It has been proposed that inhibition of aldose reductase will block the activation of the pathway that results in inflammation. This new target for drug therapy may benefit those suffering from asthma, as well as other diseases characterized by inflammation.
View Article

Anti-psychotic drugs may be useful in treating some forms of cancer
It has been observed that people being treated for schizophrenia with anti-psychotics have lower cancer rates. The anti-psychotic, pimozide has been found to kill cancer cells by blocking the synthesis or movement of cholesterol and lipids into the cells.
View Article

Seizures are associated with adverse pregnancy outcomes
A recent study supports the need to treat pregnant women with epilepsy, because the seizures put infants at risk. Women who experience seizures during pregnancy deliver neonates with a greater risk for low birth weight, preterm birth, and small gestational age.
View Article

Certain oral contraceptives put women at greater risk for venous thrombosis
Oral contraceptives containing desogestrel, gestodene, or drospirenone have been associated with a significantly higher risk of venous thrombosis; levonorgestrel was found to have the lowest risk. It is recommended that women who desire oral contraception use a low dose combined pill or a progestogen-only pill.
View Article

Genetic variants may increase childhood risk for ALL
Three genes have been found to increase the risk of developing the most common childhood cancer, acute lymphoblastic leukemia (ALL). Children with ALL have too many immature white blood cells, which increases their risk for infection. This discovery provides insight into how some children develop this life-threatening disease.
View Article

Drug Approvals

FDA approves new once-daily tablet for type 2 diabetes
Onglyza (saxagliptin) was approved as a new DDP-4 inhibitor for the treatment of T2DM. Based on eight clinical trials, Onglyza is not associated with increased risk of cardiovascular events.
View Article

FDA approves new drug for treatment of pulmonary arterial hypertension
The FDA approved Tyvaso (treprostinil) inhalation solution for the treatment of pulmonary arterial hypertension (WHO Group I) and NYHA Class III symptoms. Tyvaso is a prostaglandin vasodilator indicated to increase walking distance in these patients.
View Package Insert

FDA approves new statin
Pitavastatin, to be marketed as Livalo, has been approved by the FDA to help improve cholesterol levels. Kowa Pharmaceuticals claims that pitavastatin will inhibit cholesterol production more effectively that other statins.
View Article

Embeda has been approved for management of moderate to severe pain
The FDA has approved morphine sulfate and naltrexone HCl extended-release capsules to be marketed as Embeda. It is indicated once- or twice-daily for around-the-clock analgesic therapy.
View Article

FDA approves new atypical antipsychotic
Saphris (asenapine) has been approved to treat adults with schizophrenia and/or bipolar I disorder. Similar to other atypicals, Saphris is not approved for older patients with dementia-related psychosis.
View Article

Extavia will be available this fall
FDA approved Extavia (interferon beta-1b) for treatment of patients who have experienced their first clinical episode of multiple sclerosis and for treatment of relapsing forms of the disease. Interferon beta-1b is used as first-line therapy for those suffering with multiple sclerosis.
View Article

Guideline Updates

New guidelines have been released on assessing asthma exacerbations and control

According to the new guidelines released by the American Thoracic Society (ATS) and European Respiratory Society (ERS), no single outcome measure can adequately assess asthma control; instead, a multi-component assessment is needed that focuses on optimizing clinical control while minimizing future adverse events. The new guidelines will help standardize asthma assessment in clinical trials and in practice.
View Update

Updated Guidelines for Management of HIV
Updated IDSA (Infectious Disease Society of America) primary care guidelines for the management of HIV will be published in the September 1 issue of *Clinical Infectious Diseases*. Since the 2004 guideline updates, new information includes an increased focus on primary care issues related to the overall health of HIV patients, such as screening and treatment for chronic conditions. The increased need for patient adherence to comprehensive care versus antiretroviral medication regimens alone is also discussed.
View Update

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SEPTEMBER 10, 2009

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In this issue...

Special Alert

Cocaine/Levamisole: A Dangerous Mix

Many health officials may be unaware of the effects of cocaine laced with levamisole. About 30% of U.S. cocaine seized from July to September 2008 contained levamisole. Authorities suggest that this adulterated cocaine may be traced to manufacturers in Colombia. Some studies suggest that the addition of levamisole elevates dopamine levels adding to the "feel-good" effects of cocaine. Drug traffickers may believe that this additive will add value to a weakened product.

Previously used in humans for rheumatoid arthritis and colorectal cancer, levamisole is currently only available as a veterinary anti-helminthic drug in the U.S. and Canada. Increased cases of agranulocytosis were linked to the wide circulation of cocaine containing levamisole. Agranulocytosis suppresses the immune system making one more susceptible to infection. For those who are unaware of this potentially fatal adverse effect, ingestion of levamisole may lead to unforeseen consequences.

Since most physicians are unaware of this dangerous additive and many patients deny cocaine use, these factors often contribute to the improper diagnosis and subsequent treatment of this emerging problem. Data published from various case reports allow physicians to consider exposure to levamisole-laced cocaine when otherwise healthy patients present with unexplained fever and agranulocytosis.

View Article
View Article (*Annals of Internal Medicine*)

FDA Medwatch Alerts

Neuropsychiatric events have been reported in some patients taking leukotriene inhibitors
Patients and healthcare professionals should be aware of the potential for neuropsychiatric events associated with montelukast (Singulair), zafirlukast (Accolate), and zileuton (Zyflo and Zyflo CR). Some of the neuropsychiatric events reported include anxiousness, hallucinations, depression, and suicidal thinking and behavior.
View Alert

Orlistat may contribute to liver-related adverse events
Thirty-two reports of serious liver injury have been reported; however, the definite association between liver injury and orlistat has not been established by the FDA at this time. Orlistat is currently marketed as prescription-only Xenical and Alli, which is available over-the-counter.
View Alert

Needle may detach from Accusure Insulin Syringes
A voluntary recall of two lots of Accusure Insulin Syringes has been declared because the needles have been found to detach from the syringes. Consumers should stop using the recalled syringes because they may interfere with insulin administration or cause patient harm.
View Alert

HIV patients treated with etravirine may develop severe reactions
Healthcare professionals should be aware of postmarketing reports of severe skin or hypersensitivity reactions associated with Intelence (etravirine), including Stevens-Johnson syndrome and liver failure. Therapy with etravirine should be immediately discontinued when signs and symptoms of a severe reaction develops.
View Alert

Stolen insulin may be dangerous for human use
Vials of Levemir insulin that were stolen months ago may still be on the market. Due to improper storage and handling, patients using a vial from one of the stolen lots may suffer an adverse event related to poor glucose control.
View Alert

Myfortic has been linked to PRCA
Patients treated with Myfortic (mycophenolic acid) may develop a type of anemia known as Pure Red Cell Aplasia (PRCA). In some cases, PRCA was found to be reversible with dose reduction or cessation of therapy.
View Alert

Unlawful OTC topical products containing ibuprofen
FDA will take action against companies marketing unlawful OTC topical products containing ibuprofen. Topical ibuprofen is advertised as a "safer" alternative for pain relief, but its topical use has not been approved by the FDA.
View Article

Summary of drug safety labeling changes
FDA has posted a summary of July 2009 drug safety labeling changes. This list includes 38 different medications.
View List

News Items:

Drug-delivery vehicle with "sugar bugs" currently being studied
Using genetically engineered bacteria in the presence of xylan, human growth factor (KGF-2) may be directly delivered to target sites in irritable bowel conditions. Rodent studies and clinical trials are needed to determine its potential role as a drug-delivery system in humans.
View Article

H1N1 influenza vaccine testing to begin in children
After safety data was reviewed in adults, the National Institute of Allergy and Infectious Disease will begin two trials to test the safety of the vaccine for children 6 months to 17 years of age. One study will enroll up to 650 children for evaluation.
View Article

Study shows that diastolic blood pressure may be linked to cognitive impairment
A study published in *Neurology* discusses the possibility of diastolic blood pressure's effect on memory and thinking skills. The author states it is possible that the prevention or treatment of hypertension may prevent cognitive impairment.
View Article

Automation could allow pharmacists to expand clinical roles
Current and future automation in the pharmacy may help improve workflow while allowing the pharmacist to spend more time counseling patients and fulfilling clinical responsibilities, such as immunizations and MTM services.
View Article

Use of proton-pump inhibitors and antiplatelet drugs
Since earlier studies, the concomitant use of proton-pump inhibitors and antiplatelet drugs, such as clopidogrel and prasugrel, has remained controversial. A recently published study in *The Lancet* notes new findings about this topic. The study did not show an increased risk of cardiovascular adverse events with the combination of these medications.
View Article

Lantus may be linked to breast cancer
When compared to other types of insulin, Lantus (insulin glargine) may increase the risk of breast cancer; however, there have been inconsistencies among published trial results. A definite conclusion cannot be drawn at this time and patients should continue administering their insulin as prescribed.
View Article

Low vitamin D levels may be linked to increased risk of heart disease in diabetics
People with type 2 diabetes are more likely to be deficient in vitamin D. Because of their low vitamin D levels, cholesterol is not processed normally and builds up in their blood vessels. New research shows that it may be possible to slow or reverse the development of atherosclerosis in diabetics by helping them regain adequate vitamin D levels.
View Article

PG9 and PG16 may be the keys to an effective AIDS vaccine
Researchers have found and isolated two new powerful antibodies to HIV. PG9 and PG16 are bNAbs (broadly neutralizing antibodies) and they may be a promising target for an effective AIDS vaccine. Only a small proportion of HIV-infected patients produce bNAbs, which effectively neutralize most types of the life-threatening virus. An effective AIDS vaccine would stimulate one's immune system to induce bNAbs, which would enable the body to protect itself from an HIV infection.
View Article

Low vaccination rates among health care professionals contribute to influenza outbreaks
Annual influenza vaccination of health care providers may reduce influenza-related deaths among patients at high risk for complications; however, the CDC estimates only 40% of the nation's health care providers are vaccinated each year. The FDA urges those providing health care to become educated on the benefits of influenza vaccination.
View Article

Gardisil may no longer be the only vaccine to protect against cervical cancer
Cervarix is a new vaccine that has shown to provide protection against the most common cancer-causing virus types, which include HPV types 16, 18, 31, 33 and 45. Cervarix is still awaiting FDA approval.
View Article

Letrozole may increase survival rates in postmenopausal women with breast cancer
Nolvadex (tamoxifen) and Femara (letrozole) are both used to prevent the recurrence of breast cancer after surgery in postmenopausal women with hormone receptor-positive cancer. Currently, tamoxifen is more widely used; however, a recent study has shown that letrozole is more effective in increasing survival rates in these patients and has fewer side effects.
View Article

Menopausal women may benefit from gabapentin in more ways than one
Gabapentin is currently a treatment option for menopausal women who suffer with hot flashes. Researchers have also found that it may be used to improve sleep quality in this same population in which nearly forty percent of patients experience sleep disruption.
View Article

Drug Approvals

FDA approves new drug to treat infantile spasms
Sabril (vigabatrin) Oral Solution is the first drug in the U.S. approved to treat spasms in children 1 month to 2 years of age. A tablet formulation of vigabatrin has also been approved for adult use in combination with other medications to help treat complex partial seizures. Patients treated with vigabatrin may be at risk of permanent vision damage.
View Article

FDA approves first selective alpha-2A adrenergic receptor agonist for ADHD
INTUNIV (guanfacine) extended-release tablets have been approved for once-daily treatment of ADHD in children and adolescents 6 to 17 years of age. INTUNIV is not a controlled substance and has no known potential for abuse or dependence. Adverse effects observed in clinical trials include hypotension, bradycardia, syncope, sedation and somnolence.
View Article

New Hib vaccine gets accelerated approval
GlaxoSmithKline has released Hiberix, which is a new *Haemophilus influenzae* type b (Hib) vaccine. In an effort to alleviate the current Hib vaccine shortage, the FDA has accelerated the approval of Hiberix. The vaccine is indicated in children ages 15 months through 4 years of age to prevent the Hib disease.
View Article

ASTEPRO Nasal Spray 0.15% will be available in October
ASTEPRO (azelastine HCl) Nasal Spray 0.15% has been FDA-approved for treating symptoms of seasonal and perennial allergic rhinitis. This new formulation is fifty percent more concentrated than original ASTEPRO. It also offers fast-acting relief and convenient once- or twice-daily dosing.
View Article

FDA approves Zenpep™ for the treatment of cystic fibrosis
Zenpep™ (pancrelipase) was recently approved for the treatment of exocrine pancreatic insufficiency in patients with cystic fibrosis or other conditions. The manufacturer states that it is the first and only FDA-approved pancreatic enzyme product clinically tested in patients under 12 years old.
See News Release

Guideline Updates

WHO Guidelines for pharmacological management of H1N1 and other influenza viruses
The World Health Organization (WHO) posted guidelines on August 20 that include treatment and chemoprophylaxis with the use of antivirals.
View guidelines

Updated H1N1 guidelines for using antivirals
The CDC is now advocating watchful waiting to see whether someone will develop flu symptoms instead of immediately prescribing an antiviral drug for prevention. Over-prescribing antiviral medications may make the present situation worse because there is a risk that the 2009 H1N1 influenza virus might mutate to drug-resistant forms. Currently, prophylactic use of an antiviral is only recommended for people with chronic conditions, the very young, the very old and pregnant women.
View Article
View guidelines

New guidelines for managing opportunistic infections among HIV-exposed children
HIV-exposed or HIV-infected children are at an increased risk of developing opportunistic infections (OIs). The new guidelines focus on treating all children born to HIV-infected women. Although a child is born uninfected with HIV, he or she is still at risk of developing an OI through family members with HIV co-infections. The updated guidelines provide recommendations for the most effective strategies for diagnosis, prevention, and treatment of OIs.
View Article

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FYDI

FOR YOUR DRUG INFORMATION

October 5, 2009

Greetings from the Drug Information Center at the University of Louisiana at Monroe College of Pharmacy!

We hope you find this newsletter helpful in keeping you well-informed.

Please contact us and let us assist you with any drug information needs.

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In this Issue…

All About the Flu

H1N1 Vaccinations Expected to start October 6

Of the first 6 million doses of swine flu vaccine, most will be the live virus, nasal spray vaccine. By mid-October, another 45 million doses, including traditional flu shots, will be distributed to states based on population.
View Article

Live versus Inactivated Flu Vaccines

A review of the 2007-2008 flu season concluded that both the inactivated vaccine and the live attenuated virus were effective in preventing symptomatic influenza, with the inactivated being superior.
View Summary
View Article *(N Engl J Med)*

Vaccines may Offer More than Just Flu Prevention for Cardiac Patients

With a review of cases, a prediction was made that influenza virus may trigger cardiac arrest; therefore, the H1N1 and seasonal flu vaccines are expected to offer protection for cardiac patients.
View Summary
View Article *(Lancet Infect Dis)*

Use of Influenza A (H1N1) 2009 Monovalent Vaccine

View Recommendation

Have Additional Questions about the H1N1 Flu?

View Questions & Answers 2009 H1N1 Influenza Vaccine

FDA MedWatch Alerts

Changes to Reference Standard for Heparin Unit Dose

The USP has modified the reference standard for heparin's unit dose to correspond with the World Health Organization's International Standard, which is about 10% less potent than the former USP unit dose. "Although the FDA-approved labeling for heparin has not changed, including the recommended doses, it is essential that health care professionals be aware of the potential difference in potency between the old and new vials of heparin when administering the drug," stated John Jenkins, M.D. director of the Office of New Drugs in the FDA's Center for Drug Evaluation and Research.
View Alert

Boxed Warning for Promethazine Hydrochloride Injection

The FDA now requires a boxed warning to emphasize the risk for severe tissue damage when injected into the artery or under the skin. The preferred route of administration is deep intramuscular.
View Alert

Reports of Acute Pancreatitis associated with Sitagliptin

Acute pancreatitis has been reported in a large number of people who received sitagliptin (Januvia, Janumet). The prescribing information will be revised to highlight the warning and recommend monitoring for pancreatitis with initiation or dose changes of sitaglipti.
View Alert

Tylenol Oral Suspension Products Recalled

Several lots of Tylenol oral suspension have been recalled due to possible contamination of bacteria during the manufacturing process. No reports of subsequent illness have been made.
View Alert
View Recalled Lots

Increased adverse effects with Exjade (deferasirox)

Reports of increased adverse reactions have occurred in patients using Exjade (deferasirox) who have myelodysplastic syndrome (MDS) and are over sixty years old.
View Alert

New Warnings and Precautions for Intelence (etravirine)

Intelence (etravirine) has been reported to cause severe skin or hypersensitivity reactions, which could lead to death or organ dysfunction.
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View Letter

Graduated Oral Syringe should Match Oseltamivir Instructions

Tamiflu suspension prescriptions should be written in milligrams, not milliliters or teaspoons. Pharmacists should ensure that the correct measuring device is given to patients if the prescription has instructions for administration in milliliters.
View Alert
View Manufacturer Letter

News Items

Decrease in Heart attacks with Smoke-free Zones

The number of heart attacks have decreased by 17% in just one year after the smoking ban in North America and Europe. A large study published in *Circulation* projects this number to reach 36% by a three-year period.
View Article

SSRIs Linked to Heart Defects in Newborns

The risk of heart defects in the newborn is increased with administration of antidepressants during the first trimester. These effects were primarily seen with sertraline and citalopram, both of the SSRI group. A study concluded the birth defect may be a class effect of all SSRIs.
View Article
View Article *(BMJ)*

New, Improved Way for CPR without Mouth-to-Mouth

As concluded by a study presented in *Circulation*, the outcomes were substantially better for the cardiac arrest patient who received chest compressions 60 to 80 percent of the time during CPR compared to those who received fewer chest compressions. The American Heart Association updated the CPR guidelines in 2008 recommending the bystanders to only conduct uninterrupted chest compressions. With the new implementation, the "germs" from mouth-to-mouth are not an issue.
View Article

Some Good News with the AIDS Vaccine

More than 16,000 adult volunteers in Thailand were part of the Phase III clinical trial demonstrating the safety and somewhat effectiveness of the investigational HIV vaccines, ALVAC® HIV and AIDSVAX® B/E. The final results concluded a decreased rate of the HIV infection by 31.2% with the combination vaccine as compared to the placebo.
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Angiotensin-Receptor Blockers not effective for Microalbuminuria

Two studies with telmisartan and candesartan concluded the ARBs are no better than placebo in preventing microalbuminuria. ACE inhibitors, that are known to prevent microalbuminuria in people with diabetes, are still considered superior to ARBs.
View Article
View Article I *(Ann Intern Med)*
View Article II *(Ann Intern Med)*

Statins may be in the Future for COPD Treatment

Statins have anti-inflammatory and pleiotropic effects in addition to the lipid lowering effects, which have been proven beneficial in numerous studies. The evidence is not considered strong enough and more studies are needed to determine if a place for statins exists in the COPD treatment regimen.
View Article

Confusion for Diabetics with Phenergan Elixir

The statements "sugar-free" and "not suitable for diabetics" are both printed on the label of Sanofi-aventis' Phenergan Elixir 5mg/5ml, 100ml. The product does not contain sucrose, glucose or fructose, so technically it is sugar-free and there is no risk of dental caries. But, it does contain hydrogenated glucose, which is not suitable for diabetic patients.
View Drug Safety Information Letter

Use Of Diabetes Drug Linked To Higher Risk Of Bone Fractures

The study concluded that fracture risk is increased during periods of exposure to thiazolidinediones (rosiglitazone and pioglitazone) compared with unexposed periods. The increased risk is observed in both men and women and at a range of fracture sites. The risk also increases with longer duration of use.
View Article

Drug Approvals

FDA Approves First Drug for Treatment of Peripheral T-cell Lymphoma

The FDA has approved Folotyn (pralatrexate), the first treatment for a form of cancer known as Peripheral T-cell Lymphoma (PTCL). It is approved for patients who have relapsed, or have not responded well to other forms of chemotherapy.
View FDA News Release

FDA Approves New Drug to Treat Psoriasis

The FDA approved Stelara (ustekinumab), a biologic product for adults who have a moderate to severe form of psoriasis.
View FDA News Release

Combo antihypertensive Valturna approved by the FDA

The FDA has approved Valturna (aliskiren and valsartan) tablets. Valturna is indicated for the treatment of high blood pressure in patients not adequately controlled on aliskiren or angiotensin receptor blocker monotherapy and as initial therapy in patients likely to need multiple drugs to achieve their blood pressure goals.
View Novartis News Release

Safer Colchicine Dosing Regimen Approved

The FDA has approved the first single-ingredient oral colchicine product, Colcrys, for the treatment of familial Mediterranean fever and acute gout flares. The FDA-approved label includes more detailed drug interaction warnings and recommended dosing adjustments.
View Article
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View Prescribing Information

ULM
COLLEGE OF PHARMACY
Drug Information Center

The Louisiana Drug Information Center (DIC), which became operational in 1995, is located on the first floor of the College of Pharmacy (COP) Bienville Building of the University of Louisiana at Monroe (ULM). The operation objectives of the DIC are centered around the three core components of the University mission of service, teaching and scholarship, with a primary focus on service. These objectives are as follows:

- To provide current, comprehensive, objective and need-specific information to the healthcare professional community of the State of Louisiana for clinical decision making and for the delivery of quality patient care.
- To serve as an information resource center for faculty, students, and healthcare professionals.
- To teach pharmacy students, pharmacists, and other healthcare providers the skills of efficient literature retrieval, critical evaluation of the information, and accurate communication of a response.
- To conduct research for the advancement of drug information and pharmacy practice.

The service component makes up the largest portion of the DIC operation and includes providing assistance with areas such as literature retrieval, evidence-based recommendations and off-label use of medications. We respond to drug information requests from healthcare professionals regarding the following areas:

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

Currently, the DIC has a new phone number and a healthcare provider-focused service for the State of Louisiana. As of September 2007, the DIC discontinued public services and provides information services exclusively to healthcare professionals. 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

University of Louisiana at Monroe College of Pharmacy
Drug Information Center
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