# FYDI

FOR YOUR DRUG INFORMATION

January 15, 2010

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, such as full-text article retrieval. In this issue, find out more about the services the DIC has to offer.


ULM
COLLEGE OF PHARMACY
Drug Information Center

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**In this issue…**


FDA MedWatch Alerts
News Items
Drug Approvals
New Guidelines


## FDA MedWatch Alerts

**New monitoring recommendations for Rapamune**
Therapeutic drug monitoring results for Rapamune (sirolimus) will vary based on assay used and the laboratory where the tests were performed. Therefore, the results must be adjusted with these factors taken into consideration.
View Alert

**Pregnant women and others advised to avoid Nzu**
Nzu, a morning sickness remedy, has been found to contain large amounts of arsenic and lead, which may cause birth defects. The FDA and the Texas Department of State Health Services are urging consumers to stop using this product and contact their healthcare providers.
View Alert

**Atlas Operations Inc. and FDA recall sexual enhancement supplements**
FDA labs have detected the chemical, Sulfoaildenafil, within Atlas Operations products. Sulfoaildenafil is an analogue of Sildenafil, which is the active ingredient in the prescription drug, Viagra®. Because of potential health concerns associated with Viagra®, the FDA has recalled several products made by Atlas Operations.
View Alert

**Alka-Seltzer Plus Day-and-Night® formulation incorrect packaging**
One lot of Alka-Seltzer Plus Day-and-Night® was packaged with the blister pack labeling swapped. This will mislead the consumer as to which tablets are to be taken at night as opposed to daytime.
View Alert

**Lexiva® (fosamprenavir calcium) information letter**
Makers of Lexiva® and the FDA have issued a letter to prescribers informing them of increased lipids and potential associated cardiac events linked to Lexiva® use. The letter focuses on the importance of lipid monitoring both before and while on Lexiva®.
View Alert

**Norpramin® (desipramine hydrochloride) information letter**
Makers of Norpramin® and the FDA have issued a letter to prescribers informing them of sudden cardiac death associated with Norpramin®.
View Alert

**Tylenol Arthritis Pain® 100-count bottles are on voluntary recall status for all lots**
The popular easy-open "red cap" 100-count Tylenol Arthritis Pain® bottles are all on voluntary recall status by McNeil Healthcare and the FDA due to unwanted adverse events such as nausea and other GI disturbances caused by a packing chemical used on wooden pallets involved in the packing process.
View Alert

**Slim-Fast® …Not-so-fast!!**
Slim-Fast® has placed a recall on **all** ready-to-use metal can shakes regardless of flavor, lot number, or best by date due to possible contamination with a bacterial organism that may cause GI upset.
View Alert

**Valproic Acid and Birth Defects**
The FDA has issued a warning about the risk of serious birth defects associated with the use of valproate sodium and other related products such as valproic acid and divalproex sodium during pregnancy.
View Alert

**Voltaren® gel post-marketing Hepatic Effects**
The FDA, Endo, and Novartis are informing physicians and pharmacists of the newly revised Hepatic Effects section of the labeling due to new post-marketing data involving increased hepatic injury.
View Alert
Dear Healthcare Professional Letter - View

## News Items

**APhA's picks for the top news stories of 2009**
The American Pharmacists Association has compiled the top news stories of 2009 with issues ranging from health care reform to health information technology.
View Article

**Questionable Antidepressant Efficacy in Mild/Moderate Depression**
New meta-analysis published in *JAMA* suggests that antidepressant therapy is significantly more effective in severe depression rather than moderate and/or mild forms of depression. The analysis consisted of 6 randomized, placebo controlled trials with over 700 patients. This meta-analysis calculated the following numbers-needed-to-treat: 16 for *mild-to-moderate*, 11 for *severe*, and only 4 for *very severe*.
View Abstract (Full-text may require subscription.)

**Does Mobic® have Anti-tumor Properties?**
Pilot study shows promise for meloxicam in the treatment of extra abdominal desmoid tumors. This study, published in the *Journal of Clinical Oncology*, consisted of 22 patients, none of which required surgery over study period.
View Article

**Is Ginkgo really Effective in the Aging Population?**
Numerous claims have been made that the herbal supplement Ginkgo biloba aids in prevention of cognitive decline in the aging population, but a recent 3,069-patient, double blind, placebo-controlled randomized trial published in *JAMA* suggests otherwise!
View Abstract (Full-text may require subscription.)

**Immediate Aggrenox® therapy just as safe as Aspirin Alone**
New randomized, open-label, blinded endpoint trial funded by the makers of Aggrenox® suggests that early intervention (within first 7 days) with aspirin plus extended-release dipyridamole after an ischemic event is just as safe and effective as monotherapy with aspirin alone.
View Abstract (Full-text may require subscription.)

**MAO-I's show Promise in Heart Failure!**
John Hopkins researchers are breaking 'new ground with old meds' with regard to Heart Failure! A recent report published in *Circulation Research* shows that MAO-I's can blunt and even reverse muscular patterns and pump function deficiency in mice with Heart Failure.
View Article

**Statin use in individuals with normal cholesterol levels**
The FDA is currently considering the recommendation of an advisory panel to approve rosuvastatin for use in individuals with normal cholesterol levels but who have other risk factors for heart disease, such as elevated levels of C-reactive protein.
View Article

**Increased risk of type 2 diabetes short-term after smoking cessation**
According to an article published in the *Annals of Internal Medicine*, individuals who stop smoking have a transient increased risk of developing type 2 diabetes. The study found that individuals have the highest risk of developing diabetes in the first three years after smoking cessation and that the risk decreased to normal at 12 years.
View Abstract (Full-text may require subscription.)

**Use of household spoons results in dosing errors**
The use of household spoons to measure medications increases the risk of dosing errors according to an article published in the *Annals of Internal Medicine*. The study found that the size of the spoon used to measure the dose could result in overdosing or underdosing of medications.
View Article

**Erythropoiesis-stimulating agents may increase adverse cardiovascular events**
According to an article in the *New England Journal of Medicine*, several studies have shown that erythropoiesis-stimulating agents increase the risk of adverse cardiovascular events and more randomized trials are necessary to determine the most appropriate use of these medications.
View Article

## Drug Approvals

**FDA approves long-acting Zyprexa injection**
Zyprexa Relprevv (olanzapine), an extended release injectable suspension, has been approved by the FDA to treat schizophrenia.
View Item

**Flu-Zone High-Dose has been FDA approved for use in seniors**
The FDA has approved Flu-Zone High-Dose for use in people 65 years of age and older. The inactivated vaccine has a higher dose to produce a stronger immune response, which will provide increased protection against the flu.
View Item

**FDA approves Kalbitor for the treatment of hereditary angioedema**
The FDA has approved Kalbitor (ecallantide) for the treatment of potentially life-threatening fluid build-up in people with hereditary angioedema.
View Item

View all 2009 FDA-approved drugs at CenterWatch.com

## New Guidelines

**New Osteoporosis Guidelines**
The North American Menopause society has released new guidelines on osteoporosis management in postmenopausal women. The focus of these guidelines is identifying women with risk factors for osteoporosis and using both lifestyle changes and medications to modify these risk factors.
View Guidelines

**Guidelines for Psoriasis Treatment with Phototherapy and Photochemotherapy**
The American Academy of Dermatology has released new guidelines for psoriasis treatment. The focus of these guidelines is ultraviolet light therapy as treatment for psoriasis.
View Guidelines

**2010 Childhood and Adolescent Immunization Schedules**
The American Academy of Pediatrics, the Advisory Committee on Immunization Practices, and the American Academy of Family Physicians have released the 2010 childhood and adolescent immunization schedules. Changes include new recommendations for the use of combination vaccines and revaccination recommendations for meningococcal conjugate vaccine.
View Guidelines

**2010 Adult Immunization Schedule**
The Advisory Committee on Immunization Practices has released the 2010 adult immunization schedule. Changes to the adult schedule include the approval of a bivalent HPV vaccine (HPV2) for use in females. The quadrivalent HPV vaccine (HPV4) has now been approved for use in males.
View Guidelines

**New Breast Cancer Screening Guidelines**
New guidelines released by the *American College of Radiology* and the *Society of Breast Imaging* recommend that average-risk women should begin mammogram screening at 40 years of age rather than the 50-year mark recommended by the recent guidelines set forth by the *U.S. Preventitive Service Task Force*.
View Guidelines

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## COLLEGE OF PHARMACY
## Drug Information Center

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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.
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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**

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University of Louisiana at Monroe College of Pharmacy
Drug Information Center
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Please click on the following link to unsubscribe or reply to this newsletter with
CANCEL FYDI as the subject.

# FYDI
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February 11, 2010

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## FDA MedWatch Alerts

**FDA issues warning for Videx and Videx EC (didanosine)**
Didanosine has been associated with a rare, dangerous condition of the liver known as non-cirrhotic portal hypertension.
View Alert

**HAPPYTOT and HAPPYBABY Meals Recalled**
Nurture Inc. and the FDA are conducting a recall on certain HAPPYTOT stage 4 meals and HAPPYBABY stage 1 and 2 meals. The products are at risk of bacterial contamination due to a defect in the packaging.
View Alert

**FDA Commissioner of Food and Drugs Says that H1N1 Vaccine is Safe**
The FDA and other agencies say that the H1N1 vaccine is safe, and adverse events are being rigorously monitored. High risk individuals are still being encouraged by the FDA to receive the vaccine.
View letter to healthcare professionals

**Tylenol Recall Expanded**
McNeil Consumer Healthcare and the FDA are expanding their previous recall of Tylenol Arthritis to include certain lot numbers of several additional products.
View Alert
View list of affected products

**Recall of MuscleMaster.com Dietary Supplements**
MuscleMaster.com and the FDA are recalling 17 different types of dietary supplements sold between June 1, 2009 and November 17, 2009 because these products may contain steroids.
View Alert

**FDA issues warning about counterfeit Alli**
The FDA and GlaxoSmithKline, the maker of Alli, have found that a counterfeit version of Alli is being sold over the internet. The counterfeit version contains twice the maximum daily dose of sibutramine instead of orlistat, the legitimate active ingredient in Alli.
View Alert

**FDA instructs Meridia manufacturer to add new contraindication**
Following a safety review, the FDA has announced that the use of Meridia in patients with cardiovascular disease increases their risk of heart attacks and strokes. The use of this medication will now be contraindicated in this patient population.
View Alert

**Recall of Nipro GlucoPro Insulin Syringes**
The FDA and Nipro Medical Corporation have issued a recall of all GlucoPro insulin syringes with an expiration date before November 2011 because the needles may detach from the syringes.
View Alert

**Velcade Dosage Adjustments in Hepatic Impairment**
The FDA and Takeda Oncology are notifying healthcare professionals about the recent changes to the prescribing information for Velcade. Reduced dosages are recommended for patients with hepatic impairment.
View Alert

**Updates to Zyprexa prescribing information**
There have been updates relating to the use of Zyprexa in pediatrics and adolescents. Prescribers are encouraged to consider other therapeutic options due to the increased risk of weight gain and hyperlipidemia.
View Alert

**Risk of PML increases with increasing number of Tysabri infusions**
The FDA has announced that the risk of developing progressive multifocal leukoencephalopathy increases as the number of Tysabri infusions received increases.
View Alert

## News Items

**Simplified auxiliary labels improve patient understanding**
A study published in the *Archives of Internal Medicine* found that patients' comprehension of prescription warning labels is increased when the labels are simplified and contain icons. The study was carried out in Chicago, Illinois and Shreveport, Louisiana and had 500 participants.
View Abstract (Full-text may require subscription.)

**Risk of Alzheimer's Disease and Dementia Reduced with ARB Use**
According to a study published in *BMJ*, angiotensin receptor blockers may reduce the risk of Alzheimer's disease and dementia. The study, a prospective cohort analysis, was conducted in 819,491 veterans.
View Article

**Stroke Reduction with Statins Proportional to Reduced Cholesterol Levels**
According to a meta-analysis in the *Journal of the American College of Cardiology*, stroke reduction with statins is proportional to the percentage reduction of total cholesterol and LDL. The study included 78 randomized clinical trials with over 250,000 patients.
View Summary (Full-text may require subscription)

**Is Metformin now considered Safe in Heart Failure?**
A recent cohort study that took place from 1994 to 2008 with 401 patients showed that metformin use in HF patients appeared safe and actually showed a trend toward better outcomes with HF patients being treated with metformin.
View Abstract (Full-text may require subscription)

**New NSAID that may actually lower BP**
Naproxinod is a new NSAID that has recently completed phase 3 clinical trials. It has a nitric oxide component within its formulation which is thought to act as a vasodilator and actually lower BP rather than increase BP like other NSAIDS.
View Article

**Walgreens' Diabetes Management Program**
Walgreens has announced that it will be launching a DM counseling pilot study to learn if pharmacist counseling will improve patient outcomes.
View Article

**New study threatens clopidogrel in PCI treatment**
AstraZeneca has a new anti-platelet agent, ticagrelor, that has shown superior efficacy for early planned invasive treatment over clopidogrel. However, while it has shown superior efficacy in terms of cardiovascular outcomes, there are significant concerns about its propensity to cause intracranial bleeding…
View Abstract

**IV fish oil??**
A small study showed that omega-3 in TPNs may improve patient outcomes in sepsis due to improved gas exchange and inflammatory cytokine concentration modulation.
View Abstract

**Comparison of Ustekinumab and Etanercept for Moderate-to-Severe Psoriasis**
A new study published in the *NEJM* showed that Ustekinumab was superior to Etanercept for psoriasis treatment over a 12 week period.
View Abstract (Full-text may require subscription)

**FDA declares Spiriva safe for the cardiovascular system!**
The FDA has announced that there is no increase in risk of MI, stroke, or death associated with Spiriva use.
View Announcement

**USP recalls new USP-NF**
United States Pharmacopeial Convention has announced that the USP33-NF28 is being recalled due to monograph errors that arose from attempts to redesign monographs.
View Article

**Is Omega-3 the new Fountain of Youth?**
New scientific research published in *JAMA* suggests that omega-3 may significantly lengthen the natural life-cycle of human cells!
View Abstract (Full-text may require subscription)

**HTN drugs and A-fib**
A new nested case-control study published in the *Annals of Internal Medicine* suggests that ACE-I's, ARB's, and Beta Blockers have significantly less risk of A-fib associated with them when compared to calcium channel blockers.
View Abstract (Full-text may require subscription)

**Joint Commission Issues Sentinel Alert on Preventing Maternal Deaths**
The Joint Commission has issued an alert to encourage healthcare providers to follow certain steps to reduce the risk of maternal death during and after pregnancy.
View Article

**Crestor receives FDA approval for new indication**
The FDA has approved Crestor for use in individuals with normal cholesterol who have high levels of C-reactive protein and at least one other cardiovascular risk factor.
View Article

## Drug Approvals

**FDA approves Actemra for rheumatoid arthritis**
Actemra (tocilizumab) has been approved to treat moderate to severe rheumatoid arthritis in adults. This medication is reserved for individuals who have failed other therapies due to side effects.
View Item

**Ampyra receives FDA approval for multiple sclerosis**
Ampyra (dalfampridine) has been approved by the FDA to improve walking in multiple sclerosis patients.
View Item

**Victoza approved as adjunct for DM-2**
The FDA announced its approval of yet another injectable diabetes medication. Victoza® (liraglutide) is an analogue of glucagon-like peptide-1 that has a half-life long enough to be administered once-a-day. It was approved for adjunct therapy only and will most likely compete with the popular drug, Byetta®.
View Announcement

**Xiaflex receives FDA approval for Dupuytren's contracture**
The FDA has approved Xiaflex (collagenase clostridium histolyticum) to treat Dupuytren's contracture, a condition that limits patients' ability to both straighten and use their fingers.
View Item

**FDA approves Oleptro for major depressive disorder**
The FDA has approved Oleptro (trazodone hydrochloride) extended release tablets to treat major depressive disorder.
View Item

View all FDA-approved drugs at CenterWatch.com

## New Guidelines

**New obesity screening recommendations for children and adolescents**
The U.S. Preventive Services Task Force has released a recommendation statement encouraging obesity screening in children six years of age and older.
View Guideline

**New Science Advisory on Androgen Deprivation Therapy**
The American Heart Association, American Cancer Society, and American Urological Association have released a science advisory focusing on possible increased cardiovascular risk in patients receiving androgen deprivation therapy for prostate cancer.
View Guideline

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Institutional Review Board Support
Investigational/Foreign Drugs
IV Compatibility
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# FYDI

FOR YOUR DRUG INFORMATION

July 27, 2010

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## FDA MedWatch Alerts

**Herbal Supplement Joyful Slim Recalled**
Joyful Slim herb supplement contains the ingredient desmethyl sibutramine, an FDA-approved weight loss drug. The FDA recommends consumers return this product due to the risk of increased pulse and blood pressure associated with this medication.
View Alert

**FDA Recall on Vialipro**
Vialipro is a dietary supplement intended to treat erectile dysfunction in males. The FDA found this supplement to include sulfoindenafil, a form of the FDA-approved drug Viagra (sildenafil).
View Alert

**Recall on Slim- 30 Herb Supplement**
The undeclared drug Sibutramine was found in Slim-30 herbal supplement. The FDA states that this medication has been shown to increase blood pressure and pulse rate.
View Alert

**Warning on Advair Diskus**
In 2009 Advair Diskus inhalers were stolen and are now showing up in some pharmacies. The FDA cannot account for the safety and storage conditions of these inhalers.
View Alert

**Reviewing the Cancer Risk of Angiotensin Receptor Blockers (ARBs)**
The FDA is investigating information based on a meta-analysis released last month stating that ARBs increase the risk of cancer. Currently, the FDA does not believe ARBs cause cancer, and the benefits of this medication far offset the possible risks.
View Alert

**Recall on 1 mg Coumadin Blister Packs**
The level of the preservative isopropanol may not be at sufficient levels to sustain active ingredient coumadin. Health care professionals and consumers are advised to report adverse events.
View Alert

**Boxed Warning on Arava**
Arava (leflunomide) has been shown to cause severe to fatal liver damage in patients with prior liver disease and when used with other medications that cause liver damage. Patients with elevated liver enzymes should not take this medication.
View Alert

**Recall on McNeil Over-The-Counter Products (Update)**
The products McNeil and the FDA are recalling include Benadryl, Tylenol, Motrin, Children's Tylenol, etc. There have been reports of a musty or moldy odor coming from the medications. The odor could be associated with trace amounts of 2,4,6-tribromoanisole (TBA). Read article for further drug and lot information.
View Alert

**Recall on Que She Herbal Supplement due to Multiple Medications**
The FDA has found fenfluramine (a drug ingredient taken off of the market), propranolol, sibutramine, and ephedrine in the Que She herbal supplement. All of these medications are regulated by the FDA. This product was primarily sold over the internet.
View Alert

**FDA Warning Qualaquin and Nighttime Leg Cramps**
Qualaquin is a malaria treatment drug commonly used for nighttime leg cramps, an off-label use for the medication. The FDA warns of severe adverse reactions such as thrombocytopenia, kidney damage, and death. Prescribers should not use this medication for the off-label use of nighttime leg cramps.
View Alert

**Recall on Cepheid Xpert MRSA/SA Blood Culture Assay**
The blood culture assay has been displaying several false negatives, which could lead to a delay in treatment. The company Cepheid has issued a Class I recall.
View Alert

**Market Withdrawal of Mylotarg**
Mylotarg (gemtuzumab ozogamicin) is used for the treatment of acute myeloid leukemia. A recent clinical trial determined that this medication did not show sufficient safety and efficacy in treating patients with cancer. The drug was approved via the accelerated approval program.
View Alert

**Magic Power Coffee Recall**
The FDA and INZ distributors, Inc. are issuing a recall for Magic Power Coffee. The product contains a drug ingredient similar to sildenafil and could affect patients currently taking nitrates.
View Alert

**Counterfeit Tamiflu on the Internet**
The FDA found a generic version of Tamiflu sold over the internet actually contained cloxacillin and not oseltamivir, the active ingredient in Tamiflu. This product could potentially be harmful for patients with penicillin allergies.
View Alert

**Safety Review of Benicar**
Benicar (olmesartan) is being investigated by the FDA due to results from two clinical trials showing an increase in cardiovascular deaths in patients with type 2 diabetes taking Benicar. At this time the FDA believes that Benicar's benefits far outweigh the possible risks.
View Alert

**Medication Use Error with Vitamin D Supplements**
Parents can possibly give their infants harmful doses of Vitamin D with some liquid products that contain large dose droppers. The FDA recommends the use of products with droppers that only allow up to 400 IU of Vitamin D at one time.
View Alert

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## News Items

**Cardiovascular Outcomes with Strict Blood Pressure Control in Diabetes**
In an observational analysis, patients with diabetes and coronary artery disease, whose blood pressure was tightly controlled, did not have fewer cardiovascular events compared to the control.
View Summary Article

**Low Back Pain Not Helped by Glucosamine**
Chronic low back pain in patients with osteoarthritis was not helped by the supplement glucosamine. A controlled trial found no difference in pain scores between the placebo group and glucosamine group.
View Summary Article

**Improved Blood Pressure control with Self-management**
A controlled trial was conducted to determine if patient-management of blood pressure led to better control of blood pressure. Patients with uncontrolled hypertension were able to titrate their own medications with the monitoring of a doctor over the phone.
View Article

**Diabetic Mortality Risk and Low Vitamin D**
An observational study was conducted that looked at vitamin D levels in diabetic patients for over 20 years. Patients with extremely low levels of vitamin D were found to have an increase in mortality.
View Article

**Antibodies that Prevent Infection of Most HIV Strains Found**
Scientists have found two human antibodies that can kill up to 90 percent of identified HIV forms. This breakthrough can lead to further treatment options and possibly preventative vaccinations.
View Article

**The Latest on Avandia**
Recently, the US advisory panel met to discuss the status of Avandia. In the end, the committee recommended to keep Avandia on the market and to add more stringent warning labels.
View Article
The TIDE trial, comparing pioglitazone to rosiglitazone, can continue but can no longer recruit more patients.
View Article

**The FDA looking into Cancer risk of Angiotensin Receptor Blockers**
The FDA is investigating information based on a meta-analysis released last month stating that ARBs increase the risk of cancer. Currently, the FDA does not believe ARBs cause cancer, and the benefits of this medication far offset the possible risks.
View Article

## Drug Approvals

**FDA Approves Tribenzor: 3-in-1 for Resistant Hypertension**
Tribenzor is an antihypertensive medication containing 3 drug ingredients including a thiazide diuretic, angiontensin receptor blocker, and calcium channel blocker. Patients with uncontrolled hypertension on two of these medications will give the indication for this medication.
View Article

**FDA Approves Generic Opana ER**
Oxymorphone hydrochloride 30 mg extended release tablets (Opana ER) has been approved by the FDA. It is indicated for the treatment of moderate to severe pain.
View Article

**FDA Approves First Generic Lovenox**
The FDA has approved a generic version of the anticoagulant drug Lovenox (enoxaparin). Enoxaparin will have the same cautions as the brand, including increased risk of bleeding and bruising during an epidural or spinal procedure.
View Article

**FDA Approves Buprenorphine as a 7-Day Pain Patch**
The FDA has approved a 7-day pain patch for moderate to severe chronic pain containing buprenorphine. It is indicated for patients requiring continuous opioid analgesic pain control, but it is not indicated for acute, mild, or postoperative pain.
View Article

**FDA Approves Vimovo (naproxen + esomeprazole)**
Vimovo is approved for arthritis in patients with an increased risk of NSAID induced ulcers.
View Article

**FDA Approves Intranasal Formulation of Ketorolac**
Sprix (ketorolac tromethamine) is in an intranasal form and has been approved by the FDA for the short-term treatment (no more than 5 days) of moderate to severe pain.
View Article

**Natazia Approved for Oral Contraception**
The FDA approved Natazia (estradiol valerate/dienoges) as another option in oral contraception. This form of oral contraception is the first four-phasic system.
View Article

**FDA Approved Jalyn for Benign Prostatic Hyperplasia**
Jalyn (dutasteride/tamsulosin) was approved for the treatment of benign prostatic hyperplasia.
View Article

**New Medication for the Treatment of Osteoporosis**
Prolia (denosumab) has been approved by the FDA for the treatment of osteoporosis in postmenopausal women. This medication will be recommended for women with an increased risk of fractures.
View Article

View all FDA-approved drugs at CenterWatch.com

## New Guidelines

**2010 HIV Treatment Guidelines**
The International AIDS Society has issued updated HIV treatment recommendations. These guidelines cover from initial treatment to long-term treatment strategies.
View Guidelines

**New Postmenopausal Hormone Therapy Guidelines**
The Endocrine Society has released a statement on postmenopausal hormone therapy. The purpose of this statement is to make recommendations by analyzing and grading studies based on degree of evidence and safety of therapy.
View Guidelines

**Exercise Guidelines for Cancer Survivors**
The American College of Sports Medicine has discussed guidelines for cancer survivors. They feel that the survivors may benefit from increased activity during and after cancer treatment. In the past, doctors recommended a decrease in activity and rest.
View Abstract

**Position Statement on Optimizing Acute Presenting Pain**
The American Society for Pain Management Nursing (ASPMN), the Emergency Nurses Association (ENA), the American College of Emergency Physicians (ACEP), and the American Pain Society (APS) collaborated to publish a position statement on optimizing acute presenting pain.
View Guidelines

**New Comprehensive Heart Failure Practice Guidelines**
The Heart Failure Society of America has released comprehensive practice guidelines on heart failure. These guidelines expanded many sections including end of life care as well as adding a section on genetic evaluations.
View Guidelines

**New Cardiopulmonary Exercise Testing Guidelines**
The American Heart Association has issued a clinician's guide for the applications, technology, current and emerging uses, and interpretation of cardiopulmonary exercise testing.
View Guidelines

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Drug Information Center

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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 Comparisons
Therapeutic Drug Monitoring
Therapeutic Uses/Drugs of Choice
Toxicology
Travel/Health Information

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# FYDI
FOR YOUR DRUG INFORMATION

September 3, 2010


ULM
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Drug Information Center

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## In this issue...


FDA MedWatch Alerts
News Items
Drug Approvals
New Guidelines


## FDA MedWatch Alerts

**Cubicin (Daptomycin) Associated With Risk Of Eosinophilic Pneumonia**
The risk for developing eosinophilic pneumonia while on the drug Cubicin is being made public to patients.
View Alert

**Unintended Exposure Of Children and Pets To Evamist (Estradiol Transdermal Spray)**
Unintentional exposure to Evamist may cause premature puberty and unwanted side effects in children.
View Alert

**Label Change for Afluria Influenza Virus Vaccine**
Afluria is associated with an increased risk of fever or febrile seizures in children under 5 in Australia.
View Alert

**Serious Medication Errors from Intravenous Administration of Nimodipine Oral Capsules**
The FDA released warnings that nimodipine should only be administered orally, and that other methods of use have continued to result in fatalities.
View Alert

**OTC Supplements Recalled by FDA for Containing Analogs of Sildenafil**
Multiple OTC supplements have been found to contain analogs of sildenafil. The FDA recalled some of those products and warned consumers against the others.
Reviderect Extra Strength, Prolatis, Mr. Magic Male Enhancer, MaxXtreme Capsules, XXTREME and stimulant II

**Octagam (Immune Globulin Intravenous (Human)) 5% Liquid Preparation Withdrawn from Market**
Octapharm USA Inc. initiated a voluntary market withdrawal of selected lots of Octagam as a result of an increased number of reported thrombotic events, some of which were serious.
View Alert

**Risk of Aseptic Meningitis Development with Use of Lamictal**
The FDA is reporting that the anti-seizure and bipolar medication Lamictal may be linked to development of meningitis, not associated with bacterial infections.
View Alert

**Acetaminophen Linked to Asthma, Rhinoconjunctivitis, and Eczema In Adolescents**
In a study published by the *American Journal of Respiratory and Critical Care Medicine*, researchers found that the recent use of acetaminophen was associated with an exposure-dependent increased risk of current asthma, rhinoconjunctivitis, and eczema symptoms.
View Abstract

**FDA Proposes Withdrawal of Midodrine Hydrochloride**
Withdrawal of midodrine hydrochloride, used to treat orthostatic hypotension, has been proposed because the required post-approval studies that verify the clinical benefit of the drug were not done.
View Alert

**Ongoing Safety Evaluation of Stalevo by FDA**
The FDA is evaluating clinical trial data that suggest patients taking Stalevo (carbidopa/levodopa and entacapone) may be at an increased risk for cardiovascular events compared to those taking carbidopa/levodopa.
View Alert

**First Report of Progressive Multifocal Leukoencephalopathy Linked to Infliximab**
The first reported case of progressive multifocal leukoencephalopathy (PML) linked to infliximab therapy has been published in *Arthritis & Rheumatism*.
View Summary, View Article

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Medwatch Voluntary Reporting Form

## News Items

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**Linezolid and Vancomycin Effectiveness Compared for Patients with MRSA**
A recent study found that the treatment with linezolid was as effective as vancomycin, which is the gold standard for MRSA.
View Summary

**Reducing Risk of Preeclampsia by Starting Aspirin Early in Pregnancy**
A recent study found that aspirin started at 16 weeks of gestation or less could reduce the risk of pre-eclampsia in pregnant women.
View Summary

**Risk for Myocardial Infarction Raised by Calcium Supplements**
A recent meta analysis revealed that calcium supplements are associated with the risk of increased myocardial infarction.
View Article

**Vaccine Boosts Survival for Men with Advanced Prostate Cancer**
A new study shows that Provenge, a vaccine for prostate cancer, extended the lives of men with metastatic tumors resistant to standard hormonal treatment. It improved survival by about four months compared with no treatment and was less toxic than chemotherapy.
View Summary

**Heart Failure Outcomes Improved in Gout Patients Taking Allopurinol**
In research published in the *Archives of Internal Medicine*, researchers concluded that allopurinol reduces adverse outcomes in patients with heart failure and a recent or past history of gout.
View Abstract

**Eli Lilly Halts Development of Alzheimer's Drug**
The development of semagacestat was stopped because preliminary results from late-stage studies showed the drug did not slow the progression of Alzheimer's, and it was associated with a worsening of clinical measures.
View Article

**Alogliptin and Pioglitazone for Patients with Untreated Type 2 Diabetes**
This phase III study investigated the effects of initial combination therapy with alogliptin and pioglitazone versus monotherapy with either component in patients with untreated type 2 diabetes. The authors concluded that initial combination treatment appears to be safe and effective in the short term.
View Article

**Carboplatin Plus Paclitaxel with or without Gemcitabine as First-Line Treatment of Epithelial Ovarian Cancer**
When investigating the safety and effectiveness of this first-line therapy, the authors concluded that the addition of gemcitabine to carboplatin plus paclitaxel increased treatment burden, reduced progression free survival time, and did not improve overall survival in patients with advanced epithelial ovarian cancer.
View Article

**Increase in Length of Valganciclovir Prophylactic Therapy for Adult Kidney Transplant Patients Approved by the FDA**
The FDA's supplemental approval was based on data from the IMPACT study showing that longer prophylaxis with valganciclovir reduced the incidence of cytomegalovirus disease in high-risk adult kidney transplant patients.
View Summary

**Meta-analysis Shows Beneficial Results When STEMI Treated with Early Invasive Procedures**
A new meta-analysis shows that patients who have a STEMI and have received fibrinolytic therapy have lower mortality rates and risk of re-infarction when early invasive measures are taken.
View Summary, Article

**Low Loading Dose for Clopidogrel is Better According to Meta-Analysis**
Recent evidence suggests that a 600mg loading dose before a PCI for ACS is more beneficial than giving a 300mg dose.
View Summary Article

**A Phase III study Shows Eltrombopag's Use for Chronic Immune Thrombocytopenia**
A phase III study has shown that eltrombopag appears to be an effective treatment for the management of chronic immune thrombocytopenia (CITP). It could be potentially beneficial for patients who have not responded to splenectomy or previous treatment.
View Article Summary

**US FDA Rejects Ceplene (Histamine Dihydrochloride) for Acute Myeloid Leukemia**
A New Drug Application (NDA) for Ceplene™ (histamine dichloride) for the remission maintenance and prevention of relapse of patients with acute myeloid leukemia (AML) in first remission, has been denied by the FDA. The FDA concluded that the application did not establish Ceplene's therapeutic contribution and requested that an additional trial confirming its survival benefit is conducted.
View Article

**Sunitinib Fails to Achieve Primary Endpoint in Non-Small Cell Lung Cancer (NSCLC) Trial**
Pfizer's drug sunitinib (Sutent) failed to reach its primary goal in the SUN 1087 study. The study assessing sunitinib in combination with erlotinib versus erlotinib alone showed no significant improvement in overall survival. The study did meet its secondary endpoint; the drug significantly improved progression-free survival in patients with previously treated NSCLC.
View Article

**A Study Comparing the Cardiovascular Risks of Rosiglitazone and Pioglitazone**
In a recent study published in *Circulation: Cardiovascular Quality and Outcomes*, the risks of the composite cardiovascular endpoints were the same for patients taking rosiglitazone and pioglitazone. The results of this study were in contrast to earlier studies which had found a greater risk of heart attack among rosiglitazone users compared to patients receiving other treatments or placebo.
View Article

## Drug Approvals

**FDA Approves Amgen's Prolia (Denosumab)**
Prolia has been approved for the treatment of postmenopausal women with osteoporosis at high risk for fracture. It is the first and only FDA-approved RANK Ligand inhibitor and is administered every 6 months subcutaneously by a health care professional.
View Article

**Brilinta (Ticagrelor) is recommended for approval by FDA Advisory Committee**
The FDA Advisory Committee recommended ticagrelor be approved to reduce the risk of thrombotic events in those patients with Acute Coronary Syndromes.
View Article

**Merz's Xeomin has Received FDA Approval**
A new treatment for specific focal dystonias has been approved by the FDA.
View Article Summary

**Protection in Young Children is Expanded by New 13-Valent Pneumococcal Vaccine**
PCV13 and PCV7 were evaluated for safety and tolerability in toddlers.
View Abstract, Contact the Drug Information Center for full text

**Ella Tablet is Approved by FDA for Emergency Contraception**
The FDA has approved ulipristal acetate (Ella) for use within 120 hours (5 days) after failure of standard contraception or after unprotected intercourse. It is available only by prescription.
View Article
View all FDA-approved drugs at CenterWatch.com

## New Guidelines

**Use of Anthrax Vaccine in the United States: Recommendations from Advisory Committee on Immunization Practices**
The 2010 Anthrax vaccine guidelines for vaccine use are now available
View Guidelines

**U S. Medical Eligibility Criteria for Contraceptive Use, 2010; Adapted from the World Health Organization Medical Eligibility Criteria for Contraceptive Use, 4th edition**
The fourth edition of the MEC is has been released and provides the latest updates.
View Guidelines

**Recommendations for the Treatment and Prevention of Glucocorticoid-Induced Osteoporosis from the American College of Rheumatology 2010**
2010 updated ACR guidelines are available, and reflect changes made to the 2001 report.
View Guidelines

**Guidelines for Pediatric HIV Infection and Antiretroviral Agent Use**
These guidelines include updates and changes made to the 2009 version.
View Guidelines

**World Health Organization's Guidelines for H1N1 Post-Pandemic Period**
WHO has released guidelines that outline the H1N1 flu's new status as a seasonal virus, and what to expect as we move into the post-pandemic period.
View Guidelines

**Guidelines for Prevention and Control of Influenza, 2010**
The CDC's updates of the 2009 recommendations for preventing and controlling Influenza through vaccination.
View Guidelines

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# FYDI
FOR YOUR DRUG INFORMATION

October 15, 2010

# ULM COLLEGE OF PHARMACY
## Drug Information Center

Amanda Dannheim, PharmD Candidate
Erin Powell, PharmD Candidate
Gregory W. Smith, PharmD, Director

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**In this issue…**

Flu Season Update
FDA MedWatch Alerts
News Items
Drug Approvals
New Guidelines

## Flu Season Update

**UPDATE: FLU SEASON 2010-2011** -

Each year, strain selection is updated according to laboratory tests, surveillance, and trends. In February of this year, the World Health Organization (WHO) established three of the most probable strains to provide maximum flu coverage:

- An influenza B strain
- H3N2
- H1N1

The indications for the influenza vaccine are slightly different than what has commonly been advised in the past. The population recommendation has expanded to include all persons age 6 months and older. Also, it is important to note that even patients who contracted the 2009 H1N1 should still receive the 2010-2011 seasonal flu vaccine.

**Useful Links:**
CDC 2010-2011 Seasonal Influenza
Health Care Professional Resources
Seasonal Flu Patient Information
Current Flu Activity
National Influenza Vaccination Week: Dec. 5-11, 2010

## FDA MedWatch Alerts

**Lipitor 40mg Recall Due to Odor**
Due to reports of an uncharacteristic odor from bottles of Lipitor 40mg, the FDA recommends that any patient who notices an odor return their pills to their local pharmacist.
View Alert

**Withdrawal of Meridia (sibutramine) Due to Risk of Serious Cardiovascular Events**
This weight loss drug has voluntarily been pulled from the market by the FDA and Abbott laboratories after review of study results done by the SCOUT trial.
View Alert

**Undeclared Drug Ingredient in Slimming Beauty Bitter Orange Slimming Capsules**
The FDA has recommended that the public discontinue use of Slimming Beauty capsules due to the discovery of an undisclosed active ingredient in the preparation only: sibutramine. This drug was recently withdrawn due to adverse cardiovascular events as listed above.
View Alert

**Epogen and Procrit (epoetin alfa) Recall**
Thin and barely visible flakes of glass have been found in some lots of Epogen and Procrit. Health care professionals are advised to return all lots of these vials to ensure patient safety.
View Alert

**Tygacil (tigecycline) Increased Mortality Risk**
The FDA has updated sections of the Tygacil label to include higher risks seen in patients with hospital-acquired pneumonia and skin structure diseases. Increased risks have been seen through combined analysis of clinical trials, and Tygacil is therefore not approved for hospital-acquired pneumonia or diabetic foot infections.
View Alert

**Aromatase Inhibitors Marketed as Dietary Supplements Recalled**
The FDA has recalled dietary supplements containing aromatase inhibitors because these products do not meet the definition of a dietary ingredient and also carry many risks and associated adverse events, including but not limited to: infertility, kidney/liver failure, and decreased maturation of bone.
View Alert

**FDA Significantly Restricts Access to Avandia**
Due to increased cardiovascular risks associated with the use of Avandia its use will be restricted. Glaxo/Smithkline will be required to develop a REMS. The REMS will limit the use of Avandia to patients who cannot take Actos and are unable to reach glucose goals with other medications. Patients already taking Avandia will be allowed to continue to do so if they desire
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## News Items

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**Tiotropium Bromide Step-Up Therapy for Adults with Uncontrolled Asthma**
Alternate therapies are needed for patients with uncontrolled asthma. When added to an inhaled glucocorticoid, one trial showed tiotropium bromide improved symptoms and lung function in patients with inadequately controlled asthma, with effects equivalent to salmeterol.
View Article

**Is Antidepressive Use Associated with Increased Risk of Diabetes?**
One study's findings show a relationship between continuous antidepressant medication use and the risk of developing diabetes.
View Article

**Study Suggests Aliskiren/Grapefruit Juice Interaction**
A small pharmacokinetic study has recommended that the combination of grapefruit juice and aliskiren be avoided due to an interaction with an influx transporter. This is the first study to demonstrate that grapefruit juice may inhibit the influx of a certain transporter (OATP2B1), which is necessary for aliskiren absorption.
View Article

**Toremifene May Reduce Fracture Risk in Men Receiving Androgen Deprivation Therapy**
Men receiving androgen deprivation therapy (ADT) for prostate cancer may be at higher risk for vertebral fractures. Drugs that work on estradiol receptors are critical to bone formation and bone resorption in men. Toremifene is a selective estrogen receptor modulator that has had promising results in Phase III clinical studies.
View Article

**Is Colchicine Effective in the Prevention of Post-Pericardiotomy Syndrome?**
A multi-center, randomized trial shows that colchicine may be safe and effective in preventing post-pericardiotomy syndrome (PPS). These results may be beneficial considering that there is currently no other drugs proven safe and effective in preventing PSS.
View Article

**Viagra Used to Treat Prostate Cancer**
Researchers have found that combining sildenafil with an anti-cancer drug (doxorubicin) can effectively treat prostate cancer. Adding sildenafil to the regimen helps to protect against heart damage without compromising the effects of doxorubicin. Plans for clinical trials are underway.
View Article

**Apixaban Could More Than Halve Stroke Risk Versus Aspirin**
Apixaban is an oral Factor Xa inhibitor that was studied in patients with atrial fibrillation (AF) who were unable to take warfarin. Safety and risk of major bleeding was also shown to be comparable to aspirin. Currently awaiting final publication of the study.
View Summary

**Isoniazid Resistance Increases Death Risk in Tuberculous Meningitis**
Tuberculous meningitis is the most severe manifestation of tuberculosis (TB), and a treatment combination of four drugs is standard. A large study suggests that one of the four drug combination, isoniazid, may increase fatalities. Though the only severely bacteria drug option that crosses the blood-brain barrier, resistance on initial susceptibility testing was associated with an increased risk of death.
View Article

**B Vitamins May Slow Progression of Dementia**
A British clinical trial supports the use of B vitamins as a way to slow down the shrinkage of brain cells in disease like dementia and Alzheimer's.
View Article

**Bleeding Risk with Warfarin, Aspirin, and Clopidogrel Therapy Comes in Patients with Atrial Fibrillation**
The combination of clopidogrel and/or aspirin to warfarin monotherapy may increase the risk of fatal and non-fatal bleeding in patients with atrial fibrillation (AF), according to the results of a large observational cohort study. Also, there were no apparent benefits in the prevention of ischemic stroke.
View Article

**Long-Term Use of Anti-Inflammatory Drugs May Increase Risk of Chronic AF**
According to study findings, there may be a link between NSAIDs and increased risk of developing chronic atrial fibrillation. However, the authors did note that there may possibly be correlation between inflammatory conditions and atrial fibrillation, and may not be due to NSAID use.
View Article

**Roche Stops Trials of Tasoguitide Due to Adverse Reactions**
Roche has stopped further research of Phase III trials of tasoquitide with the interest of patients in mind. A high-rate of reports of gastrointestinal (GI) intolerability and serious hypersensitivity reactions are the basis for discontinuation of studies for this drug.
View Article

**For High-Risk Patients, Clopidogrel May Not Add to Low-Dose Aspirin for Stroke Prevention**
A sub-analysis of the CHARISMA trial suggests that in high vascular risk patients, the addition of clopidogrel to low-dose aspirin therapy did not improve stroke outcomes.
View Article

**Results of the MONALISA Study**
A study has shown moxifloxacin to be as safe and effective as levaquin plus metronidazole in the treatment of uncomplicated pelvic inflammatory disease.
View Article

**Drug Trials in Alzheimer's Disease are Failing**
A review in The Lancet Neurology summarizes the issues with drug development in Alzheimer's disease.
View Article

**Blockbuster Cancer Drug May Offer Clue to Alzheimer's Cure**
Gleevac may be a key to developing Alzheimer's treatment. Studies have shown that when Gleevac binds to GSAP in reduces beta-amyloid production. Beta-amyloids are responsible for producing the cell death-causing plaques found in the brains of most Alzheimer's patients.
View Article

**Antipsychotic Medication/Psychosocial Intervention Combo Improves Outcomes of Early-Stage Schizophrenia**
A study published in the Archives of General Psychiatry reported that the addition of psychosocial intervention to medication regimens leads to a lower rate of relapse, improved insight, quality of life, and social functioning, as well as, lower treatment discontinuation rates than treatments consisting of medication only.
View Article

**Antidepressant Medication Use Risk Factor for Weight Gain and Type 2 Diabetes Mellitus**
A study done to evaluate the use of antidepressant medications as a risk factor for type 2 diabetes and weight gain concluded that there is a slight relative risk of type 2 diabetes with continual antidepressant use.
View Article

**Study Shows Persistent Statin Use May Delay Onset of Rheumatoid Arthritis**
A retrospective population-based cohort study suggests taking statins may reduce the risk of RA.
View Article

## Drug Approvals

**FDA Approves Tekamlo**
Tekamlo (aliskiren/amlodipine) has been approved for patients who require multiple drug therapy to achieve blood pressure goals.
View Summary

**FDA Approves New Drug for Gout**
Krystexxa (pegloticase) has been approved for the treatment of gout in patients who are intolerant to or do not respond to conventional therapy.
View Article

**FDA Approves Combination Contraceptive Containing Folate**
Beyaz, an oral combination contraceptive containing a folic acid metabolite, has been FDA approved for the prevention of pregnancy, PMDD, & the treatment of acne vulgaris.
View Article

**FDA Approves First Oral Drug to Reduce MS Relapses**
The FDA has approved Gilenya (fingolimod) to reduce the frequency of symptoms and delay the amassing of physical disability in patients with relapsing multiple sclerosis (MS).
View Article

**FDA Approves Ozurdex for Uveitis**
Ozurdex (dexamethasone intravitreal implant) is a biodegradable implant approved for the indication of noninfectious uveitis affecting the posterior segment of the eye and also for macular edema following retinal vein occlusion.
View Article

**FDA Approves Aridol**
Aridol (mannitol) is a prescription-only inhalation powder that comes as a challenge kit to assess the bronchial hyperresponsitivity in children 6 years and older. This is intended as an additional tool to help physicians identify asthma, and should not be used as a stand-alone tool for diagnosis.
View Article

**FDA Approves Atelvia**
Atelvia (risedronate sodium) is a delayed-release tablet indicated for the treatment of postmenopausal osteoporosis.
View Article

**FDA Approves Vivitrol**
The FDA has approved an extended-release naltrexone formulated to be administered by intramuscular injection once a month.
View News Release

## New Guidelines

**NICE Issues Clinical Guidance on the Management of Hypertension During Pregnancy**
The National Institute for Health and Clinical Excellence has issued new guidelines on the management of hypertensive disorders during pregnancy.
View Guidelines

**New US Guidelines on the Management of Depression**
The 3rd edition of guidelines for Major Depressive Disorder were approved in May of 2010 and recently published by the American Psychiatric Association.
View Guideline

**Impact of Smokeless Tobacco Products on Cardiovascular Disease: Implications for Policy, Prevention, and Treatment**
The American Heart Association has assessed the risk of cardiovascular events in smokeless tobacco products and has found that there may be higher risks for fatal MI and stroke with long-term use. Currently the AHA does not recommend smokeless tobacco as an alternative to cigarette smoke cessation.
View Guideline

**The Diagnosis and Management of Anaphylaxis Practice Parameter: 2010 Update**
The Journal of Allergy and Clinical Immunology has published an update to the guidelines for identifying and treating anaphylaxis.
View Guideline

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