

FYDI  
- For Your Drug Information –  
An Update from the  
ULM Drug Information Center  
January 17, 2008

**Public Health Advisory:**

Nonprescription Cough and Cold Medicine Use in Children

FDA Recommends that Over-the-Counter (OTC) Cough and Cold Products not be used for Infants and Children under 2 Years of Age

[http://www.fda.gov/cder/drug/advisory/cough\\_cold\\_2008.htm](http://www.fda.gov/cder/drug/advisory/cough_cold_2008.htm)

**Drug Information Resources Update:**

We have access to an excellent selection of drug information resources through our College of Pharmacy. A question was recently raised regarding the online access to resources for herbal and other Complementary & Alternative Medicine (CAM). Our subscribed resources include the following databases which offer an extensive collection of monographs and evidence-based literature for CAM products:

Fact & Comparisons®

Review of Natural Products

Lexicomp Online™

Natural Products

Micromedex®

AltCareDex® Alternative Medicine Education

AltMedDex® Evaluations

AltMedDex® Consults

RPS Herbal Medicines: A guide for Health-Care Professionals

We also have online access to full-text articles from several hundred journals through our subscriptions with Iowa Drug Information (IDIS), OVID and the ULM library.

The login information for these resources can be found on our ULM COP reference webpage at:

<http://rxweb.ulm.edu/pharmacy/reference.html>

With popup stopper disabled, click 'COP Password Protected Sites' and enter password 'ulmcp'

Please feel free to come by the Drug Information Center (Bienville #130) for assistance in accessing or using these resources.

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Fentanyl Patch Recall

PriCara has voluntarily recalled all lots of 25mcg/hr *Duragesic*® Patches and all 25mcg/hr Fentanyl Patches sold by Sandoz Inc. The products may have a cut in the reservoir within the patch that could release a potentially fatal dose of the drug transdermally.

See the press release for details:

[http://www.pricara.com/pricara/pages/021208\\_press\\_release.jsp](http://www.pricara.com/pricara/pages/021208_press_release.jsp)

Shortage of *Digibind*® and *DigiFab*®

Manufacturers are reporting limited availability of these digoxin immune fab products used to treat potentially life-threatening digoxin overdoses.

See details:

<http://www.fda.gov/CBER/shortage/shortage.htm>

USA Today Investigates Causes for Medication Errors

The investigation examined policies and alleged errors at major chain pharmacies, including lawsuits and pharmacy board disciplinary actions in 10 states.

[http://www.usatoday.com/money/industries/health/2008-02-11-prescription-errors\\_N.htm?loc=interstitialskip](http://www.usatoday.com/money/industries/health/2008-02-11-prescription-errors_N.htm?loc=interstitialskip)

Vaccine Mismatch May Compromise Flu Protection

According to Dr. Joe Bresee of the CDC's influenza division, nearly half of the influenza virus strains reported are not well covered by this flu season's vaccine.

See the full transcript of the news conference at:

<http://www.cdc.gov/od/oc/media/transcripts/2008/t080208.htm>

Safety of Botulinum Products Under Investigation

The FDA is investigating reports of possible botulism in patients that have been treated with botulinum toxin type A (Botox® and Botox Cosmetic®) and type B (Myobloc®) for both approved and unapproved conditions. Serious adverse effects including respiratory compromise and death occurred mostly in children treated for cerebral palsy-associated limb spasticity.

See the FDA early communication:

[http://www.fda.gov/cder/drug/early\\_comm/botulinium\\_toxins.htm](http://www.fda.gov/cder/drug/early_comm/botulinium_toxins.htm)

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February 22, 2008

In this week's issue...

- News Items by PharmD Candidates, Keeli Cutrer and Phi Leach
- Resources Update by Greg Smith, PharmD

### **News Items**

#### **Help the American Heart Association Celebrate American Heart Month in February**

Heart disease is the primary cause of deaths in the United States. Since February is American Heart Month, the American Heart Association along with the National Heart, Lung, and Blood Institute have implemented a new operation known as "Act in Time" in an effort to enhance the knowledge of the public regarding signs and symptoms of heart attacks. More information about the "Act in Time" campaign can be obtained from the following web address:

<http://www.nhlbi.nih.gov/actintime/index.htm>

#### **FDA Ordered a Halt on Intravenous Heparin Purchased from Baxter Manufacturers**

FDA has recommended that all health care professionals either stop using IV heparin made by Baxter manufacturers or switch to a different manufacturer of heparin. It has been reported that serious adverse events including allergic reaction and low blood pressure have resulted from the use of heparin in multiple-dose vials.

More details about this topic can be found at the following web address:

<http://www.fda.gov/bbs/topics/NEWS/2008/NEW01797.html>

#### **New Research Shows Promise in Targeting New Therapeutic Areas in Patients with MS**

Ms. Patricia A. O'Looney, vice president of biomedical research from the National Multiple Sclerosis Society, has announced that new research has been conducted in using FDA-approved drugs to help with the inflammation associated with MS.

More details about the research are available at the following web address:

<http://www.healthfinder.gov/news/newsstory.asp?docid=612713>

#### **Nexavar® Rejected in Lung Cancer Trial**

Bayer HealthCare Pharmaceuticals and Onyx Pharmaceuticals have terminated the research of a possible cancer drug Nexavar® for the treatment of non-small cell lung cancer (NSCLC).

Find out why in article:

<http://www.medicalnewstoday.com/articles/97792.php>

#### Childhood CNS Infections Tied to Later Psychoses

Research suggests that certain psychosis disorders in adults may have been linked to central nervous system (CNS) viral infections in childhood.

Click link for details:

[http://www.nlm.nih.gov/medlineplus/news/fullstory\\_61258.html](http://www.nlm.nih.gov/medlineplus/news/fullstory_61258.html)

#### FDA Approves Treatment for Hemophilia A

The FDA has granted the approval of the drug, Xyntha®, to treat patients who present with hemophilia A. Xyntha® is part of a treatment known as Xyntha Antihemophilic Factor (Recombinant) Plasma/Albumin Free, which is genetically engineered to produce a version of the protein clotting factor known as factor VIII.

More details about this topic can be found at the following web address:

<http://www.fda.gov/bbs/topics/NEWS/2008/NEW01799.html>

#### Next Year's Flu Vaccine May Get Total Overhaul

World Health Organization (WHO) recommends the flu vaccines to be changed for next year's vaccines. The flu vaccines will have an overhaul of all three strains due to a dramatic change in the mix of circulating flu.

Norman Baylor, director of the FDA's Office of Vaccine Research and Review, said "I can't remember when we've changed all three."

Find out more:

[http://www.usatoday.com/news/health/2008-02-21-flu-vaccine\\_N.htm?loc=interstitialskip](http://www.usatoday.com/news/health/2008-02-21-flu-vaccine_N.htm?loc=interstitialskip)

#### Google Will Store Health Records

Google is offering a new service that involves storing patients' health records on their database so patients can readily access the files at home.

This raises privacy concerns for some individuals.

Read more:

[http://www.usatoday.com/tech/products/services/2008-02-21-google-health-records\\_N.htm](http://www.usatoday.com/tech/products/services/2008-02-21-google-health-records_N.htm)

## **Resources Update**

An online podcast review of our subscribed information resources is available for viewing. This podcast was created primarily for the Pharmacotherapy Forum course; however it is available to anyone that might find it useful.

<http://www.ulm.edu/~grsmith/DI-Resources/DIResourcesReview.html>

Review Topics:

Micromedex

Facts and Comparisons

Lexi-Comp

PubMed

Ovid

IDIS

Other resources

College of Pharmacy - Reference Resources

<http://rxweb.ulm.edu/pharmacy/internet.html>

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March 12, 2008

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In this week's issue...

- **News Items** by PharmD Candidates, Brent Cantrelle and Rusty Manuel
- **Resources Update** by Greg Smith, PharmD  
Kinetidex® kinetics software installation instructions

## **News Items**

### **Very Early Indicator Of Type 2 Diabetes Is Low Levels Of PYY Hormone**

Soon it may be possible to take a simple blood test and predict whether or not someone is predisposed to develop Type 2 diabetes. Read more:

<http://www.medicalnewstoday.com/articles/100218.php>

### **Aspirin cuts breast cancer risk**

Taking drugs like aspirin regularly can significantly reduce the risk of breast cancer. The use of non-steroidal anti-inflammatory drugs (NSAIDs) could cut the incidence of the cancer by 20 percent.

Read More:

<http://www.news.com.au/story/0,23599,23338809-23109,00.html>

### **FDA Issues Alert on Tussionex, a Long-Acting Prescription Cough Medicine Containing Hydrocodone**

The FDA has issued an alert on the safe and correct use of Tussionex Pennkinetic Extended-Release Suspension in response to numerous reports of adverse events--including death. Read More:

<http://www.fda.gov/bbs/topics/NEWS/2008/NEW01805.html>

### **Nationally Representative CDC Study Finds 1 in 4 Teenage Girls Has a Sexually Transmitted Disease**

The two most common STDs overall were human papillomavirus (18 percent), and chlamydia (4 percent). Read More:

<http://www.cdc.gov/STDConference/2008/media/release-11march2008.htm>

### **Gulf War Illness Strongly Linked To Chemical Exposure**

A scientific review finds that 26 to 32 percent of personnel deployed to the Persian Gulf have chronic health problems associated with exposure to a class of chemicals, known as acetylcholinesterase inhibitors.

[http://www.nlm.nih.gov/medlineplus/news/fullstory\\_62043.html](http://www.nlm.nih.gov/medlineplus/news/fullstory_62043.html)

### **Unapproved Over The Counter Drugs Marketed for Prevention and Treatment of STDs**

FDA advised healthcare professionals and consumers that the Agency issued Warning Letters to six U.S. companies and one foreign individual for marketing unapproved and misbranded drugs over the internet to U.S. consumers for the prevention and treatment of sexually transmitted diseases.

<http://www.fda.gov/bbs/topics/NEWS/2008/NEW01803.html>

### **Statins Exert Class Effect In Heart Failure**

Research shows that statins, as a class appear to reduce death among elderly people with congestive heart failure at relatively low doses.

[http://www.nlm.nih.gov/medlineplus/news/fullstory\\_62012.html](http://www.nlm.nih.gov/medlineplus/news/fullstory_62012.html)

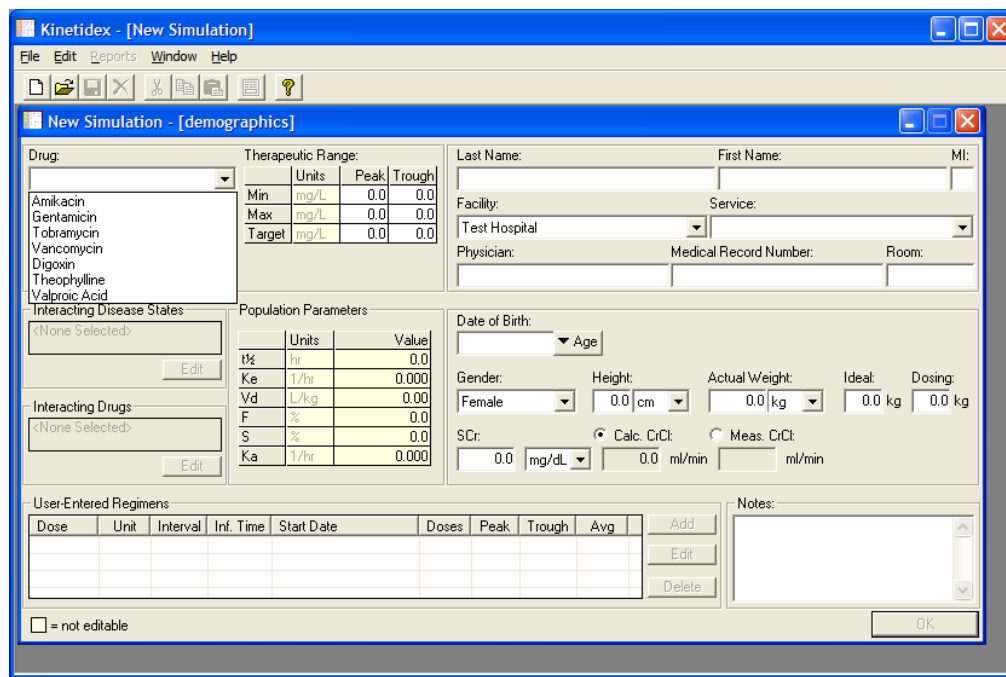
### **Studying Mutations in Non-Hodgkin Lymphoma Yields Clues For Potential New Therapies**

The discovery of DNA mutations found in a type of non-Hodgkin lymphoma has led to new cancer treatment research. The scientists found that all of the mutations caused changes in amino acids in a small segment of the CARD11 protein, which spontaneously activates the NF- $\kappa$ B signaling pathway, thereby promoting survival of the malignant cell.

<http://www.nih.gov/news/health/mar2008/nci-06.htm>

## Resources Update

KINETIDEX<sup>®</sup> System by Thomson Micromedex is an easy-to-use, pharmacokinetic program to help you calculate drug dosages for the most frequently monitored drugs. We have access to this software as part of our Micromedex subscription. See below for installation instructions.



To install Kinetidex<sup>®</sup>:

1. Click on the link below and select 'Save' to begin download:  
<http://www.ulm.edu/~grsmith/kinetidex.zip>
2. Make note of where the kinetidex.zip file has been downloaded to your computer.
3. Open the kinetidex.zip folder and doubleclick on 'setup.exe'.  
Note: To see full file names, it may be necessary to click on the 'View' menu tab and select 'Details'.
4. Click 'Run', and complete the steps for a Standalone Installation.  
Note: See installation guide names 'KDX\_Installation.pdf' in the documents folder if installation help is needed.
5. During the installation process you will be prompted to enter the following:  
Customer ID: 101961004  
Activation Code: 615D-37B7

For more information visit:

[http://www.micromedex.com/products/kinetidex/kinetidex\\_brochure.pdf](http://www.micromedex.com/products/kinetidex/kinetidex_brochure.pdf)



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In this week's issue...

- **News Items** by PharmD Candidates, Brent Cantrelle and Rusty Manuel
- **Resource Update** by Greg Smith, PharmD  
The National electronic Library for Medicines (NeLM)

## **News Items**

### **FDA Tightens Borders to Heparin Suppliers**

FDA announced that the major importers of heparin for the United States have agreed to test all heparin shipments for the contaminant that has been linked to patient deaths.

Read more:

[http://www.ashp.org/s\\_ashp/article\\_news.asp?CID=167&DID=2024&id=24644](http://www.ashp.org/s_ashp/article_news.asp?CID=167&DID=2024&id=24644)

### **Obesity Linked to Poor Prognosis for Some Breast Cancer Patients**

A recent study suggested that women who are overweight or obese are more likely to be diagnosed with a rare, aggressive type of breast cancer, called inflammatory breast cancer.

Read more:

[http://www.nlm.nih.gov/medlineplus/news/fullstory\\_62241.html](http://www.nlm.nih.gov/medlineplus/news/fullstory_62241.html)

### **Scientists Identify New Leads for Treating Parasitic Worm Disease**

A research team had identified chemical compounds that hold potential for the treatment of schistosomiasis, a parasitic worm that affects over 200 million people worldwide.

Read more:

<http://www.nih.gov/news/health/mar2008/nhgri-16.htm>

### **Vitamin E and C Do Not Reduce Dementia Risk**

In a study that followed adults ages 65 years and older for five years suggested that taking Vitamin E and C, alone or in combination, did not reduce the risk of getting dementia and Alzheimer's Disease.

Read more:

[http://www.nlm.nih.gov/medlineplus/news/fullstory\\_62205.html](http://www.nlm.nih.gov/medlineplus/news/fullstory_62205.html)

### **Early Communication about an Ongoing Safety Review of Tiotropium**

The FDA and the drug company are investigating a possible increase in risk of stroke among patients who use the Spiriva®. The data from UPLIFT trial is expected to be available in June 2008, which will help confirm or dismiss the trends noticed among 29 clinical trials involving Spiriva®.

Read more:

[http://www.fda.gov/cder/drug/early\\_comm/tiotropium.htm](http://www.fda.gov/cder/drug/early_comm/tiotropium.htm)

### **New Study Shows Colorectal Cancer Screening Rates Increasing Among U.S. Adults**

The percentage of U.S. adults aged 50 years and older getting screened for colorectal cancer is increasing according to a study released by the Centers for Disease Control. Screening prevalence was lower among all racial and ethnic minorities studied compared to whites.

Read more:

<http://www.cdc.gov/od/oc/media/pressrel/2008/r080313.htm>

### **Emergency Contraception Case Lands in Illinois Supreme Court**

Pharmacists shouldn't be forced to dispense the "morning-after pill," a form of emergency contraception known as Plan B. They say the requirement violates a state law that prohibits making health care

decisions over moral objections. A similar law in Washington state is also working its way through the courts.

Read more:

[http://blogs.wsj.com/health/2008/03/19/emergency-contraception-pharmacy-rule-lands-in-illinois-supreme-court/?mod=googlenews\\_wsj](http://blogs.wsj.com/health/2008/03/19/emergency-contraception-pharmacy-rule-lands-in-illinois-supreme-court/?mod=googlenews_wsj)

### **Early retirement may mean earlier death**

Researchers found that those who were retired at enrollment were 51 percent more likely to die during the study period than their same-age counterparts who were still working. Each 5-year increase in the age at retirement was associated with a 10 percent reduction in mortality risk.

Read more:

[http://www.nlm.nih.gov/medlineplus/news/fullstory\\_62206.html](http://www.nlm.nih.gov/medlineplus/news/fullstory_62206.html)

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## **Resource Update**

The National Library of Health's National electronic Library for Medicines (NeLM), formerly known as DrugInfoZone is an excellent online resource that provides the latest relevant information on medicines from FDA alerts to product shortages.

RSS feeds and email updates from NeLM also offer practical information including answers to questions such as:

Why must some drugs be taken with or after food?

<http://www.nelm.nhs.uk/Record%20Viewing/vR.aspx?id=543975>

Why must some drugs be taken on an empty stomach?

<http://www.nelm.nhs.uk/Record%20Viewing/vR.aspx?id=543974>

Why can't over-the-counter hydrocortisone cream or ointment be used on the face?

<http://www.nelm.nhs.uk/Record%20Viewing/vR.aspx?id=544064>

Does cannabis interact with antidepressants or lithium?

<http://www.nelm.nhs.uk/Record%20Viewing/vR.aspx?id=543831>

See more: <http://www.nelm.nhs.uk/home/default.aspx>

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## **FYDI**

# For Your Drug Information

March 28, 2008

University of Louisiana at Monroe, College of Pharmacy, Drug Information Center

In this week's issue...

- **FDA Medwatch Alerts**
  - **News Items** by PharmD Candidates, Brent Cantrelle and Rusty Manuel
  - **Resource Update** by Greg Smith, PharmD  
The National electronic Library for Medicines (NeLM)
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## **FDA Medwatch Alerts**

**Data analyses indicates a higher risk of heart attack in HIV-1 patients taking Ziagen or Videx.**

<http://www.fda.gov/medwatch/safety/2008/safety08.htm#abacavir>

**Increased risk of death from cancer in diabetic patients using Regranex Gel.**

<http://www.fda.gov/medwatch/safety/2008/safety08.htm#Regranex>

**FDA Investigation: Possible Link Between Singulair and Suicidal Behavior**

<http://www.fda.gov/medwatch/safety/2008/safety08.htm#Singulair>

**Read More:** <http://www.fda.gov/medwatch/index.html>

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## **News Items**

**TB Drug Treatment Can Lead To Severe Pneumonia**

A study conducted in South Africa suggests that the use of fluoroquinolones to treat multidrug-resistant pneumonia in children can result in the development of pneumonia infections.

[http://www.nlm.nih.gov/medlineplus/news/fullstory\\_62545.html](http://www.nlm.nih.gov/medlineplus/news/fullstory_62545.html)

**Many Phase 3 Cancer Drug Trials Yield Effective Medicines**

According to American researchers, 25 percent to 50 percent of cancer treatments currently in Phase III clinical trials have been shown to be effective.

[http://www.nlm.nih.gov/medlineplus/news/fullstory\\_62556.html](http://www.nlm.nih.gov/medlineplus/news/fullstory_62556.html)

**Free Drug Samples Hike Out-of-Pocket Costs**

A new study shows that patients who receive free drug samples end up paying higher out-of-pocket costs for prescription medications compared to patients who do not receive free drug samples.

<http://www.healthfinder.gov/news/newsstory.asp?docid=613786>

**Drug Therapy Boosting Heart-Attack Survival Rates**

A study spanning ten years reports a steady increase in the long-term survival rate of elderly patients who have heart attacks, with drug therapy being a major factor.

<http://www.healthfinder.gov/news/newsstory.asp?docid=613709>

**More Vitamin D in Childhood Cuts Later Diabetes Risk**

Children who take vitamin D supplements may be less likely to develop type-1 diabetes later in life. Children who were given additional vitamin D were about 30 percent less likely to develop type-1 diabetes. Read more:

[http://www.nlm.nih.gov/medlineplus/news/fullstory\\_62507.html](http://www.nlm.nih.gov/medlineplus/news/fullstory_62507.html)

### **Brain stimulation may relieve cluster headaches**

Deep brain stimulation may relieve chronic cluster headaches that do not respond to standard medication. The process involves surgically implanting electrodes that deliver a small electric current into a targeted area of the brain. Read more:

[http://www.nlm.nih.gov/medlineplus/news/fullstory\\_62475.html](http://www.nlm.nih.gov/medlineplus/news/fullstory_62475.html)

### **New Drug Approved for Chronic Lymphocytic Leukemia**

The FDA has approved Treanda (bendamustine hydrochloride), a chemotherapy drug for chronic lymphocytic leukemia. 59% of the patients taking Treanda had their disease significantly reduced by the drug. Read more:

[http://www.cancer.org/docroot/NWS/content/NWS\\_1\\_1x\\_New\\_Drug\\_Approved\\_for\\_Chronic\\_Lymphocytic\\_Leukemia.asp](http://www.cancer.org/docroot/NWS/content/NWS_1_1x_New_Drug_Approved_for_Chronic_Lymphocytic_Leukemia.asp)

### **Tuberculosis rate in US lowest ever in 2007**

The rate of tuberculosis in the US fell to its lowest point ever 4.4 cases per 100,000 people. Foreign-born individuals have a 9.7-times higher rate of TB compared with US-born individuals. Read more:

[http://www.nlm.nih.gov/medlineplus/news/fullstory\\_62425.html](http://www.nlm.nih.gov/medlineplus/news/fullstory_62425.html)

### **Study of CT Screening for Lung Cancer Supported by Tobacco Money**

The *Times* reports that the authors' foundation in a 2006 study received some \$3.6 million from the parent company of the Liggett Group, a cigarette maker.

Read more:

[http://www.nytimes.com/2008/03/26/health/research/26lung.html?\\_r=1&oref=slogin](http://www.nytimes.com/2008/03/26/health/research/26lung.html?_r=1&oref=slogin)

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## **Resource Update**

### **TRIP Database**

The aim of the TRIP (Turning Research Into Practice) Database is to allow health professionals to easily find the highest-quality material available on the web to help support evidence-based practice. This database helps the researcher find answers to clinical questions quickly and efficiently by searching multiple web-based resources simultaneously, instead of moving from website to website. A search will yield relevant results including systematic reviews, guidelines or Medline articles sorted by therapy, diagnosis, prognosis and etiology.

Try this resource at <http://www.tripdatabase.com>

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To view previous issues of the FYDI newsletter visit <http://rxweb.ulm.edu/pharmacy/dicpubs.html>.

For comments and suggestions please email [grsmith@ulm.edu](mailto:grsmith@ulm.edu)

## **FYDI**

### **For Your Drug Information**

July 16, 2008

University of Louisiana at Monroe, College of Pharmacy, Drug Information Center

PharmD Candidates, Courtney Griffin and Anees Kanorwala  
Gregory W. Smith, PharmD.

In this issue...

- **FDA Medwatch Alerts**
  - **News Items**
  - **Resource Update**
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#### **FDA Medwatch Alerts**

**Roxane Laboratories, Inc reports two lots of Sodium Polystyrene Sulfonate Suspension that have tested positive for yeast.**

<http://www.fda.gov/medwatch/safety/2008/safety08.htm#SPSS>

**FDA issues boxed warnings concerning systemic fluoroquinolone antibiotics and the potential risk of tendonitis and tendon rupture.**

More Information for Healthcare Professionals on Fluoroquinolone Antimicrobial Drugs is available at:

<http://www.fda.gov/cder/drug/InfoSheets/HCP/fluoroquinolonesHCP.htm>

**Avastin® may increase the risk of developing microangiopathic hemolytic anemia (MAHA) in patients with solid tumors when used in combination with sunitinib.**

<http://www.fda.gov/medwatch/safety/2008/safety08.htm#Avastin>

**Vials of Herceptin® and BWFI (bacteriostatic water for injection) diluent should be inspected carefully before administration due to increased complaints of broken or damaged vials.**

<http://www.fda.gov/medwatch/safety/2008/safety08.htm#Herceptin>

**Amgen and Wyeth Pharmaceuticals has revised prescribing information for Enbrel®, including a boxed warning concerning the potential risk for serious infections and adverse event updates regarding increased tuberculosis occurrence in clinical studies.**

<http://www.fda.gov/medwatch/safety/2008/safety08.htm#Enbrel>

Read More FDA Medwatch Alerts: <http://www.fda.gov/medwatch/index.html>

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#### **News Items**

##### **Public Health Advisory-Albuterol Inhalers**

An alert has been issued from the FDA to the public and healthcare professionals concerning the future transition of chlorofluorocarbon (CFC) propelled albuterol inhalers to hydrofluoroalkane (HFA) propelled albuterol inhalers. This transition to HFA inhalers is currently underway, and CFC inhalers will no longer be available for use as of December 31, 2008.

[http://www.fda.gov/cder/drug/advisory/albuterol\\_cfc.htm](http://www.fda.gov/cder/drug/advisory/albuterol_cfc.htm)

For more information concerning CFC inhalers and other ozone-depleting drug products:

<http://www.fda.gov/cder/mdi/albuterol.htm>

### **Measles Outbreak Largest in Ten Years**

About 127 measles cases have occurred in 15 states since May 2008, largely due to infected overseas travelers returning to the United States. The Centers for Disease Control and Prevention recommends vaccination against measles for children despite the current public concerns regarding pediatric vaccinations and the development of autism.

View article here:

<http://www.foxnews.com/story/0,2933,379388,00.html>

For more information concerning measles prevention and vaccination, please visit the Center for Disease Control and Prevention at:

<http://www.cdc.gov/vaccines/vpd-vac/measles/default.htm>

### **E-Prescribing On the Rise**

A recent article in the New England Journal of Medicine states that electronic prescription writing is steadily increasing. In one study, about 7% of office-based physicians submitted e-prescriptions, with 73% of U.S. pharmacies both receiving and filling them. High start-up costs, adoption of technology, and restrictions implemented by the DEA may limit this rise in e-prescriptions.

[http://www.kaisernetwork.org/daily\\_reports/rep\\_index.cfm?DR\\_ID=53229](http://www.kaisernetwork.org/daily_reports/rep_index.cfm?DR_ID=53229)

### **First Generic Risperdone Approved**

The FDA has approved the first generic formulation of Ortho-McNeil-Janssen's Risperdal® tablet. The newly-approved versions of risperdone may differ in labeling due to certain patent protection; however, the same boxed warning concerning dementia-related psychosis in the elderly will be applied.

<http://www.fda.gov/bbs/topics/NEWS/2008/NEW01855.html>

### **Benefits of Dexamethasone for Acute Migraines**

A new study has shown that dexamethasone is no more effective than placebo for acute migraine relief, but may be more likely to reduce the occurrence of relapsing headaches within 72 hours.

<http://emergency-medicine.jwatch.org/cgi/content/full/2008/711/2>

### **Non-Refrigerated Coagulation Product Approved**

The FDA has approved NovoSeven RT®, a newly revised version of the genetically engineered coagulation factor VIIa that requires no refrigeration. This product has been shown effective with maintained stability at room temperature for up to two years.

<http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/psn/transcript.cfm?show=77#2>

### **PhRMA Revises Voluntary Guidelines Concerning Gifts to Physicians**

The Pharmaceutical Research and Manufacturers of America (PhRMA) has released guidelines banning gifts, including restaurant dinners, entertainment, and recreation, from pharmaceutical companies to physicians.

[http://www.kaisernetwork.org/daily\\_reports/rep\\_index.cfm?DR\\_ID=53252](http://www.kaisernetwork.org/daily_reports/rep_index.cfm?DR_ID=53252)

### **Pentacel® Vaccine Approval**

Sanofi Pasteur's Pentacel® vaccine has recently gained FDA approval for active immunization against diphtheria, tetanus, pertussis, poliomyelitis and invasive disease caused by *Haemophilus influenzae* type b. It is recommended for administration in infants and children 6 weeks through 4 years of age (prior to fifth birthday).

<http://www.fda.gov/cber/products/pentacel.htm>

### **Updated HIV Recommendations**

The Public Health Service Task Force and the Perinatal HIV Guidelines Working Group, along with CDC, have updated recommendations regarding the use of anti-retroviral drugs in pregnant HIV-infected women to reduce potential risks of perinatal transmission and promote maternal health.

Updated guidelines may be accessed at:

<http://aidsinfo.nih.gov/contentfiles/PerinatalGL.pdf>

More Guideline updates may be accessed at:

<http://guidelines.gov/whatsnew/newthisweek.aspx>

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## Resource Update

Where to find information for international drugs...

**MARTINDALE: The Complete Drug Reference** *from Thomson Micromedex®* is the electronic version of the highly respected Martindale reference book from the Pharmaceutical Press, London, UK. The program offers extensive unbiased, evaluated information on drugs and related substances used worldwide.

The Martindale reference contains summaries of over 70,000 proprietary products from more than 25 countries with information on brand names, manufacturers, country of origin, active constituents, and licensed uses. More than 600 disease reviews and product ingredients are cross-reference linked to corresponding drug monographs within the Micromedex® Healthcare Series.

Martindale includes:

- Generic drugs names including U.S., British, and international approved names
- Synonyms/chemical names
- Molecular formula/molecular weight, CAS registry numbers
- Pharmacopeias
- Physical characteristics
- Adverse effects and their treatment
- Precautions, including contraindications
- Interactions
- Pharmacokinetics
- Uses and Administration, including pharmacology and dosage
- Preparations and brand names
- 5300 drug monographs
- 70000 proprietary preparations
- 6000 manufacturers
- 600 disease treatment reviews
- 200 herbal medicine monographs
- 5000 herbal preparations

To access Martindale, log on to the Micromedex® Healthcare Series and select "Specific Database Search" from the Drugs tab...



\*

And check the MARTINDALE box to search within the reference...

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**Search checked databases:**  
[Check All](#) [Uncheck All](#)

<input type="checkbox"/> DRUGDEX® System <a href="#">i</a>	<input checked="" type="checkbox"/> MARTINDALE <a href="#">i</a>
<input type="checkbox"/> P&T QUIK® Reports <a href="#">i</a>	<input type="checkbox"/> Alternative Medicine <a href="#">i</a>
<input type="checkbox"/> REPRORISK® System <a href="#">i</a>	<input type="checkbox"/> Summary Documents <a href="#">i</a>

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\*Excerpts from <http://www.thomsonhc.com/hcs>

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To view previous issues of the FYDI newsletter, visit <http://rxweb.ulm.edu/pharmacy/dicpubs.html>.

For comments and suggestions please email [druginfo@ulm.edu](mailto:druginfo@ulm.edu).



## **FYDI**

### **For Your Drug Information**

July 25, 2008

University of Louisiana at Monroe, College of Pharmacy, Drug Information Center

PharmD Candidates, Courtney Griffin and Anees Kanorwala  
Gregory W. Smith, PharmD.

In this issue...

- **FDA Medwatch Alerts**
- **News Items**
- **Guidelines Update**
- **Resource Update**

#### **FDA Medwatch Alerts**

##### **FDA Issues Warning- Abacavir Hypersensitivity Reactions More Common in Particular Patients.**

<http://www.fda.gov/cder/drug/InfoSheets/HCP/abacavirHCP.htm>

##### **FDA Updates Warnings and Contraindications for Micro-bubble Contrast Agents.**

<http://www.fda.gov/cder/drug/InfoSheets/HCP/microbubbleHCP.htm>

##### **FDA Issues Warning Concerning Electronic Medical Device Malfunction Due to X-ray Use During CT Examinations.**

<http://www.fda.gov/cdrh/safety/071408-ctscanning.html>

Read More FDA Medwatch Alerts: <http://www.fda.gov/medwatch/index.html>

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#### **News Items**

##### **FDA Lifts Warnings On Tomatoes, Jalapeno Pepper Is New Culprit**

The FDA's June 7<sup>th</sup> warning to avoid certain types of red raw tomatoes has been lifted. At this time raw jalapeno and serrano peppers are being linked to the infectious *Salmonella* Saintpaul. High risk patients, including children, elderly, and immunocompromised individuals, should avoid eating these types of peppers.

<http://www.fda.gov/bbs/topics/NEWS/2008/NEW01862.html>

##### **Genes May Play A Role in Efficacy of Anti-Depressant Medication**

A new study published in the *American Journal of Medical Genetics Part B: Neuropsychiatric Genetics* shows new evidence that genetic variance may predict a patient's response to anti-depressant drugs, namely SSRIs. In the future, genetic makeup may play a larger role in medication efficacy due to America's steadily increasing use of anti-depressants.

[http://www.nlm.nih.gov/medlineplus/news/fullstory\\_67133.html](http://www.nlm.nih.gov/medlineplus/news/fullstory_67133.html).

##### **New Study Fails to Show Cardiovascular Benefit of Vytorin**

The SEAS (Simvastatin and Ezetimibe in Aortic Stenosis) trial, which evaluated effects of Vytorin (ezetimibe and simvastatin) in patients with aortic stenosis, has not shown any benefit or effect on aortic valve events when compared to placebo. According to trial results, Vytorin reduced atherosclerotic events, but did not reduce chances of developing heart valve problems and need for related surgical procedures.

[SEAS press release](#) (pdf)

<http://www.nytimes.com/2008/07/22/business/22drug.html>

### **NSAIDs Do Not Reduce the Risk of Ovarian Cancer**

A newly released study has debunked the theory that the use of anti-inflammatory agents, such as aspirin and ibuprofen, may reduce the occurrence of ovarian cancer. This theory originated from previous studies' claims, which linked ovarian cancer to inflammatory pathways.

[http://www.nlm.nih.gov/medlineplus/news/fullstory\\_67057.html](http://www.nlm.nih.gov/medlineplus/news/fullstory_67057.html).

### **FDA Recruits Scientists and Other Professionals For New Fellowship Program**

October 2008 will mark the first entering class of the FDA's newest program; the purpose of this fellowship is to provide many different science professionals, including pharmacists, with extensive training in scientific analysis. This analysis should help to improve regulations and safety decisions made by the FDA in order to provide both patients and health care providers with knowledgeable data and advice.

<http://www.fda.gov/bbs/topics/NEWS/2008/NEW01861.html>

### **JAMA Study: Viagra® May Help Women During Antidepressant Use**

A new article released by the Journal of the American Medical Association reports that women experiencing sexual dysfunction due to antidepressant use may benefit from effects of Viagra® (sildenafil). The small study performed in women taking antidepressants did not improve their arousal or desire; however, improvements were seen with orgasm. Pfizer Inc., manufacturer of Viagra®, does not plan to seek FDA approval for any indication for use in females.

<http://www.cnn.com/2008/HEALTH/conditions/07/22/viagra.women.ap/index.html>

### **Sucrose May Not be Enough for Treating Pain in Newborns**

The Canadian Medical Association Journal has released new reports concerning the use of sucrose solution as an analgesic in newborns. Sucrose is generally used to reduce overall pain within the first two days after birth. However, it has been shown that sucrose may be more useful as a calming agent after certain procedures, such as venipuncture, than use as an analgesic during these painful procedures.

[http://www.nlm.nih.gov/medlineplus/news/fullstory\\_67113.html](http://www.nlm.nih.gov/medlineplus/news/fullstory_67113.html).

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## **Guidelines Update**

### **Updated Influenza Guidelines**

New and updated recommendations for the use of influenza vaccine and antiviral agents for the upcoming 2008-2009 flu season found here:

[http://www.cdc.gov/mmwr/preview/mmwrhtml/rr57e717a1.htm?s\\_cid=rr57e717a1\\_e/](http://www.cdc.gov/mmwr/preview/mmwrhtml/rr57e717a1.htm?s_cid=rr57e717a1_e/)

### **New Guidelines on Antithrombotic Therapy**

The eighth edition of the ACCP guidelines for Antithrombotic and Thrombolytic Therapy are now available.

[http://www.chestjournal.org/content/vol133/6\\_suppl/](http://www.chestjournal.org/content/vol133/6_suppl/)

Executive Summary:

[http://www.chestjournal.org/cgi/content/full/133/6\\_suppl/71S](http://www.chestjournal.org/cgi/content/full/133/6_suppl/71S)

### **AHA Issues First Guidelines for Management of Stroke in Children**

Available here:

<http://stroke.ahajournals.org/cgi/reprint/STROKEAHA.108.189696v1>

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## **Resource Update**

**The Clinician's Ultimate Reference – GlobalRPh.com**

[www.globalrph.com](http://www.globalrph.com)

The Clinician's Ultimate Reference provides many useful pharmaceutical applications to reduce the amount of research time spent by pharmacists and other healthcare professionals. This free public site contains popular links to drug abbreviations, tables, and medical calculations. There are also quick navigation options to locate information concerning drug dosages and renal dosing, IV dilutions, and normal lab values.

In addition, this site posts health videos for consumers and includes a quick list of search topics for medical professionals. Along with vast amounts of information located at this site, medical software is available through GlobalRPh for handheld devices.

A variety of services available through GlobalRPh.com include:

- Common medical abbreviations
- Medical calculators, including anion gap, body mass index, creatinine clearance, and much more
- IV dilution guidelines
- Drug class tables
- Latest health news
- Infectious disease database
- Disease management tools and calculators
- Medical reference tools and guidelines
- Consumer health tools including videos and helpful links
- Professional medical health topics
- Renal dosing protocols
- RX List <sup>®</sup> drug look up
- Comprehensive website search through multimedia and professional libraries
- Symptom checker
- Description of tests and procedures
- Forum discussion board
- Medical dictionary
- Medical links for aseptic technique, clinical links and tables, continuing education, drug-food reactions, geriatric pharmacokinetics, lab interpretation, and urine studies
- Support group links
- US pharmacy school links

Although there is much information available through GlobalRPh, healthcare professionals should always use caution in solely relying on information from a commercial website. However, GlobalRPh does comply with the HONcode standard for trustworthy health information. To receive the HONcode accreditation, websites must comply with eight different principles issued by the Health On the Net (HON) Foundation. For more information concerning the HONcode, please visit [www.hon.ch/HONcode/Conduct.html](http://www.hon.ch/HONcode/Conduct.html).

In the next issue of FYDI, watch for more information on using the HONcode and other tips for evaluating web-based resources.

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For comments and suggestions please email [druginfo@ulm.edu](mailto:druginfo@ulm.edu).

## **FYDI**

### **For Your Drug Information**

July 31, 2008

University of Louisiana at Monroe, College of Pharmacy,  
Drug Information Center



PharmD Candidates, Courtney Griffin and Anees Kanorwala  
Gregory W. Smith, PharmD.

In this issue...

- [FDA Medwatch Alerts](#)
- [News Items](#)
- [Guidelines Update](#)
- [Resource Update](#)

### **FDA Medwatch Alerts**

**FDA issues recommendations for cardiac monitoring and possible detection of cardiac toxicity in patients taking mitoxantrone hydrochloride (Novantrone®).**

<http://www.fda.gov/medwatch/safety/2008/safety08.htm#Mitoxantrone>

More information for health care professionals is available at:

<http://www.fda.gov/cder/drug/InfoSheets/HCP/mitoxantroneHCP.htm>

**Jack Distribution LLC, has issued a nationwide recall of Rize 2 The Occasion and Rose 4 Her capsules, supplements used for erectile dysfunction, due to a potentially harmful, unknown analog of sildenafil.**

<http://www.fda.gov/medwatch/safety/2008/safety08.htm#Rize>

**Label changes for ongoing Erythropoiesis Stimulating Agents (ESAs) safety review have been issued by the FDA.**

<http://www.fda.gov/cder/drug/infopage/RHE/default.htm>

**FDA Center for Drug Evaluation and Research has issued the June 2008 label revision summary, including changes to boxed warnings, contraindications, warnings, precautions, adverse reactions, and/or package insert sections.**

A list of drugs and their revisions can be found at:

[http://www.fda.gov/medwatch/safety/2008/jun08\\_quickview.htm](http://www.fda.gov/medwatch/safety/2008/jun08_quickview.htm)

Read More FDA Medwatch Alerts: <http://www.fda.gov/medwatch/index.html>

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### **News Items**

#### **Home Medication Deaths On the Rise**

An analysis of U.S. death certificates has shown that home medication mistakes have dramatically risen in the last two decades, resulting in 1,132 deaths in 1983 to a staggering 12,426 deaths in 2004. The increasing use of prescription analgesics with alcohol and other illicit drugs may be partially responsible for this drastic rise in mortality.

<http://www.cnn.com/2008/HEALTH/07/28/fatal.drug.errors.ap/index.html>

#### **Serrano Pepper Consumer Warning**

*Salmonella* Saintpaul has been traced to samples of serrano peppers and irrigation water from a farm in Tamaulipas, Mexico. As a result, the FDA has extended warnings issued regarding raw consumption and avoidance of jalapeno and serrano peppers.

<http://www.fda.gov/bbs/topics/NEWS/2008/NEW01869.html>

### **Generic Depakote® Approval**

The first generic version of Depakote® (divalproex sodium) delayed-release tablets has been released by the FDA. This generic form has been labeled with the same safety warnings and precautions as Depakote®, with indications for the treatment of bipolar disorder, migraines, and seizure occurrence.

<http://www.fda.gov/bbs/topics/NEWS/2008/NEW01867.html>

### **Potassium and Blood Pressure Reduction**

New research shows that increases in dietary potassium intake may help prevent blood pressure elevation in normal adults and may actually lower blood pressure in hypertensive patients. Hypertensive patients should be advised to reduce sodium intake while increasing potassium intake, along with proper diet and exercise.

[http://www.nlm.nih.gov/medlineplus/news/fullstory\\_67539.html](http://www.nlm.nih.gov/medlineplus/news/fullstory_67539.html)

### **Rotavirus Update**

A new rotavirus vaccine, Rotarix®, was approved in early 2008 following RotaTeq®, the first licensed effective rotavirus vaccine approved in 2006. RotaTeq® is a bovine recombinant vaccine while Rotarix® contains attenuated human strain; however, both have shown efficacy in larger studies. Rotarix® will be available later this year and vaccination guidelines will include both vaccines.

[http://pediatrics.jwatch.org/cgi/content/full/2008/730/1?q=etoc\\_jwpeds](http://pediatrics.jwatch.org/cgi/content/full/2008/730/1?q=etoc_jwpeds)

### **Cancer Identification Test Cleared For Marketing**

The Pathwork Tissue of Origin test has been evaluated for its ability to identify malignant tumor cell types. This analysis compares patients' genetic tumor profiles to a database containing different malignant tumor types, including bladder, breast, and colorectal tumors, and their genetic information. Further testing and research may prove this device's ability to assist in the diagnosis of various cancer types.

<http://www.fda.gov/bbs/topics/NEWS/2008/NEW01870.html>

### **Illegal Fentanyl Kills Over One Thousand**

The CDC has made public over 1,013 American deaths attributed to an illegal version of the popular opiate analgesic fentanyl. Overdoses have increased due to a rise in the illegal distribution of powdered fentanyl, which is often mixed with cocaine and heroin or used as a replacement for heroin. This is the highest occurrence of fentanyl related deaths since the 1980s, and these numbers may still be increasing.

[http://www.nlm.nih.gov/medlineplus/news/fullstory\\_67357.html](http://www.nlm.nih.gov/medlineplus/news/fullstory_67357.html)

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## **Guidelines Update**

### **Rheumatoid Arthritis Recommendations Update**

Recommendations for the treatment of rheumatoid arthritis have been updated by the American College of Rheumatology. Recommendations include disease-modifying agents, both biologic and non-biologic, and should be used only as recommendations for treatment rather than set guidelines.

<http://firstwatch.jwatch.org/cgi/content/full/2008/728/1>

Full text recommendations issued by the American College of Rheumatology are available at:

<http://www.rheumatology.org/publications/guidelines/recommendations.asp?aud=prs>

### **Update Screening for Prostate Cancer Synthesis**

New recommendations from the American College of Preventative Medicine (ACPM) have been included in the latest National Guideline Clearinghouse™ guideline synthesis for prostate cancer screening. Guidelines from the American Cancer Society (ACS), University of Michigan Health System (UMHS), and ACPM are included in this synthesis, and tables have been provided comparing each organization's specific recommendations.

Areas of agreement and difference are included in these comparisons, along with specific practices, to assist healthcare providers in providing the most appropriate care and screening to male patients. <http://www.guideline.gov/Compare/comparison.aspx?file=PROSCREEN9.inc>

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## **Resource Update**

**Health On the Net (HON) Foundation** at <http://www.hon.ch/>

HON is a non-governmental Swiss organization whose mission is to guide medical users and medical practitioners, via the HONcode, to useful and reliable online medical and health information. The HONcode consists of eight principles that support the quality of the information for a particular site, if they are met. Sites that have obtained approval by HON will display the HONcode logo as evidence of quality.

The HonCode principles mentioned in last week's newsletter are clearly defined for websites submitting applications for accreditation by Health On the Net Foundation. Listed below is a summary of the eight principles established by the foundation for website approval and accreditation.

1. **Authoritative-** states that all medical information listed within a website must reference a particular author, either a healthcare professional, medical specialist, or other contributor, and their title, qualifications, and specialty. If the author referenced is not a healthcare professional, this must be plainly stated on the website.
2. **Complementary-** all information available through the website should be used as an additional tool for healthcare professionals and consumers. The website is not meant to serve as a replacement for physician-patient relationships, and its purpose and mission must be described in full for intended users.
3. **Privacy-** all websites, regardless of information provided, must describe processes for keeping all user information completely private. Descriptions should be available regarding access privileges and use of confidential information by website owners.
4. **Attribution-** all sources of material posted to the website must be documented, cited, and dated. References should be cited using posted bibliographies and html links when available. Updated material should be consistent and timely, but dates of updated site information should not default to current date.
5. **Justifiability-** along with the fourth principle, site editors must justify any information provided regarding efficacy of any available product or treatment. Unless the website is advertising certain products, alternate therapies should be mentioned in addition to recommended treatment options.
6. **Transparency-** information provided by the web publisher should be clear, concise, and easily accessed. Current e-mail addresses should be clearly posted for website users who would like to request more information regarding particular topics of interest.
7. **Financial Disclosure-** a statement is required listing the contributors of all services, financial supporters, pharmaceutical companies, government-based agencies, non-profit organizations, and other financial entities.
8. **Advertising Policy-** all merchandise or products advertised within the website should be clearly identified and distinguishable from other information. Policies on advertising must be visibly posted and easily accessible.

Complete versions of these principle guidelines may be accessed by visiting: [www.hon.ch/HONcode/Conduct.html](http://www.hon.ch/HONcode/Conduct.html).

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Another point to consider is the three-letter extension at the end of the URL for a website that can provide a basis to evaluate the authority and objectivity of a source.

.com	Commercial (often used for product promotion and sales); generally, regardless of their quality, they exist primarily to advertise and sell products and/or services.
.edu	Educational sources that range from respected research institutions to casual student sites
.gov	Government (generally objective and dependable)
.net	Network (may provide services to commercial or individual customers)
.org	Organization (non-profit institutions, but may have biased agendas)

Evaluation of the quality and applicability of internet site content follows many of the general principles for the evaluation of healthcare literature. The essential applicable process still assesses the inherent quality of the information provided, the interpretation of that information in light of professional standards, and ultimately its applicability to specific patient needs.

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For comments and suggestions please email [druginfo@ulm.edu](mailto:druginfo@ulm.edu).

## **FYDI**

### **For Your Drug Information**

August 28, 2008

University of Louisiana at Monroe, College of Pharmacy,  
Drug Information Center



PharmD Candidates, Gilda Jefferson and Pratik Shah  
Gregory W. Smith, PharmD.

In this issue...

- [FDA Medwatch Alerts](#)
- [News Items](#)
- [Guidelines Update](#)
- [Resource Update](#)

### **FDA Medwatch Alerts**

#### **Tysabri (natalizumab)**

The FDA has issued a MedWatch alert for Tysabri. This came after occurrence of progressive multifocal leukoencephalopathy (PML) in two patients in Europe treated with Tysabri monotherapy for multiple sclerosis for more than a year. Tysabri is a recombinant humanized monoclonal antibody that is indicated for treatment of relapsing multiple sclerosis and Crohn's disease. Prescribing information for the medication will be revised to include information about PML cases and the FDA recommends healthcare providers to monitor patients for signs and symptoms of PML. More information available at:

<http://www.fda.gov/medwatch/safety/2008/safety08.htm#Tysabri2>

#### **Vytorin (simvastatin and ezetimibe combination)**

Preliminary results from the Simvastatin and Ezetimibe in Aortic Stenosis (SEAS) trial show an increased prevalence of cancer with Vytorin use. The FDA is awaiting publication of the final results of the trial before making any final recommendations to the public. Until then, it is recommended that healthcare professionals and caregivers continue to monitor those taking Vytorin and report side effects to the FDA's MedWatch Adverse Event Reporting program.

[http://www.fda.gov/cder/drug/early\\_comm/ezetimibe\\_simvastatin\\_SEAS.htm](http://www.fda.gov/cder/drug/early_comm/ezetimibe_simvastatin_SEAS.htm)

#### **Byetta (exenatide)**

The FDA has received more reports of hemorrhagic or necrotizing pancreatitis in users of Byetta following issuance of a precautionary notice describing such adverse reactions in October 2007. Byetta is used parentally in adults for the treatment of type 2 diabetes. Acute hemorrhagic or necrotizing pancreatitis is devoid of signs and symptoms; therefore, if pancreatitis is suspected discontinue Byetta. Other medications used in the treatment of diabetes should be considered in those with a history of pancreatitis.

<http://www.fda.gov/medwatch/safety/2007/safety07.htm#Byetta>

#### **Vivitrol (naltrexone)**

The FDA has received 196 reports of injection site reactions (cellulitis, induration, hematoma, abscess, sterile abscess, and necrosis) following injection of naltrexone. This has prompted the FDA to issue notification to healthcare professionals about detection and appropriate management of these side effects.

The FDA recommendations to healthcare providers can be found at the following link:

<http://www.fda.gov/cder/drug/InfoSheets/HCP/naltrexoneHCP.htm>

#### **Simvastatin Used With Amiodarone**

Concurrent administration of simvastatin with amiodarone increases the risk of rhabdomyolysis. This risk is dose-related and increases when a dose of simvastatin greater than 20 mg per day is given with amiodarone. A 2002 revision of Simvastatin labeling provides this precaution to healthcare



providers. Nevertheless, the FDA continues to receive reports of the above-mentioned adverse event. Therefore, the FDA has finally issued the following notice informing healthcare providers about the interaction between amiodarone and Simvastatin.

[http://www.fda.gov/cder/drug/InfoSheets/HCP/simvastatin\\_amiodaroneHCP.htm](http://www.fda.gov/cder/drug/InfoSheets/HCP/simvastatin_amiodaroneHCP.htm)

Read More FDA Medwatch Alerts: <http://www.fda.gov/medwatch/index.html>

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## **News Items**

### **Seeding trials**

Investigation of internal documents released as a result of legal proceedings reveals evidence of a "seeding trial":

Seeding trials, presented as clinical trials, are primarily designed and performed as a marketing tool to increase utilization of a drug. Recent legal actions against MERCK & Co. regarding cardiovascular safety of Vioxx have revealed internal documents suggesting ADVANTAGE (Assessment of Differences between Vioxx and Naproxen To Ascertain Gastrointestinal Tolerability and Effectiveness), a clinical trial to determine GI safety of Vioxx, may have been a seeding trial. For more information click on the link below:

[http://www.ncbi.nlm.nih.gov/pubmed/18711155?ordinalpos=2&itool=EntrezSystem2.PEntrez.Pubmed.Pubmed\\_ResultsPanel.Pubmed\\_RVDocSum](http://www.ncbi.nlm.nih.gov/pubmed/18711155?ordinalpos=2&itool=EntrezSystem2.PEntrez.Pubmed.Pubmed_ResultsPanel.Pubmed_RVDocSum)

### **PERISCOPE**

Results of the Pioglitazone Effect on Regression of Intravascular Sonographic Coronary Obstruction Perspective Evaluation (PERISCOPE) show that pioglitazone treatment in type 2 diabetes significantly lowers the rate of progression of coronary atherosclerosis compared to treatment with glimeperide.

[http://www.ncbi.nlm.nih.gov/pubmed/18378631?ordinalpos=1&itool=EntrezSystem2.PEntrez.Pubmed.Pubmed\\_ResultsPanel.Pubmed\\_DiscoveryPanel.Pubmed\\_RVAbstractPlus](http://www.ncbi.nlm.nih.gov/pubmed/18378631?ordinalpos=1&itool=EntrezSystem2.PEntrez.Pubmed.Pubmed_ResultsPanel.Pubmed_DiscoveryPanel.Pubmed_RVAbstractPlus)

### **Xenazine**

The FDA approves Xenazine (tetrabenazine) for treatment of chorea associated with Huntington's disease. Xenazine depletes dopamine at brain synapses and helps control chorea (abnormal movements) in Huntington's disease. Because of increased risk of depression and suicidal thoughts and actions, the drug must be accompanied with a Risk Evaluation and Mitigation Strategy (REMS) to determine benefits and risks of the treatment. More information available at:

<http://www.fda.gov/bbs/topics/NEWS/2008/NEW01874.html>

### **Nplate**

The FDA approves romiplostim (Nplate) for treatment of thrombocytopenia in chronic immune thrombocytopenic purpura (ITC) in patients who have had an insufficient response to corticosteroids, immunoglobulins or splenectomy. For more information see:

<http://www.fda.gov/cder/Offices/OODP/whatsnew/romiplostim.htm>

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## **Guidelines Update**

### **Influenza Immunizations**

Keeping abreast is of the utmost importance in the medical profession; hence, the purpose of guidelines. There has been an update to the influenza virus guideline entitled Prevention and Control of Influenza: Recommendations of the Advisory Committee on Immunization Practices (ACIP), 2008 - July 17, 2008. <http://www.cdc.gov/mmwr/preview/mmwrhtml/rr57e717a1.htm>

Further, the week of December 8-14, 2008 has been declared National Immunization Vaccination Week by the Center for Disease Control and Prevention (CDC). The purpose of this occasion is to

emphasize the significance of ongoing vaccination, especially the influenza vaccine. The hope is to promote usage of the influenza vaccine through the month of December and beyond. There is specific information for healthcare providers as well as special populations. <http://www.cdc.gov/flu/>

### **Antithrombotic and Thrombolytic Therapy**

The American College of Chest Physicians (ACCP) has made changes to the guidelines pertaining to the treatment of thromboembolic disorders. The link below is to the Executive Summary entitled: American College of Chest Physicians Evidence-Based Clinical Practice Guidelines (8<sup>th</sup> Edition) for specifics.

[http://www.ncbi.nlm.nih.gov/pubmed/18574259?ordinalpos=7&itool=EntrezSystem2.PEntrez.Pubmed.Pubmed\\_ResultsPanel.Pubmed\\_RVDocSum](http://www.ncbi.nlm.nih.gov/pubmed/18574259?ordinalpos=7&itool=EntrezSystem2.PEntrez.Pubmed.Pubmed_ResultsPanel.Pubmed_RVDocSum)

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## **Resource Update**

**LabTestsOnline** at [www.labtestsonline.org](http://www.labtestsonline.org).

LabTestsOnline.org gives listings and explanations of the laboratory tests conducted in treating various diseases, including tests performed as monitoring parameters for various medications. The website is maintained by various professional societies and non-profit organizations representing clinical laboratory sciences community. The website is intended to help patients understand and interpret the lab tests as well as provide resources in advancements in laboratory sciences for healthcare providers. The website is available for free on the World Wide Web and does not require registration.

- Abides by Health On the Net (HON) Code of Conduct and has HON code logo at the bottom of each webpage. [http://labtestsonline.org/site/pb\\_honcode.html](http://labtestsonline.org/site/pb_honcode.html)
  - The American Association for Clinical Chemistry (AACC) structured the data therein; hence, the endorsement of both domestic and international professional partners and supporters. [http://labtestsonline.org/site/m\\_partners.html](http://labtestsonline.org/site/m_partners.html) and [http://labtestsonline.org/site/n\\_sponsors.html](http://labtestsonline.org/site/n_sponsors.html)
  - Consumer Reports gives its stamp of approval via Web Watch, a web-based site that evaluates other sites for 'credibility'. A set of guidelines that are used in determining the accuracy of data provided on other web-sites; the link below provides direct access to the afore mentioned guidelines. <http://www.consumerwebwatch.org/consumer-reports-webwatch-guidelines.cfm>
- 

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## **FYDI**

### **For Your Drug Information**

September 19, 2008

University of Louisiana at Monroe, College of Pharmacy,  
Drug Information Center



PharmD Candidates, Gilda Jefferson and Pratik Shah  
Gregory W. Smith, PharmD.

In this issue...

- [FDA Medwatch Alerts](#)
- [News Items](#)
- [Guidelines Update](#)
- [New and Generic Drug Approvals](#)
- [Resource Update](#)

### **FDA Medwatch Alerts**

#### **Rituxan Receives Revision to Prescribing Information**

Revisions to prescribing information for Rituxan happened as a result of the death of a rheumatoid arthritis patient receiving it in a long-term study. The patient developed progressive multifocal leukoencephalopathy (PML) secondary to JC virus. PML should be considered in those treated with Rituxan; hence, neurologist consults, brain MRIs and lumbar punctures should be performed.

[MedWatch Safety Information](#)

#### **Health Information Advisory Issued by FDA**

Reports of contaminated milk-based products in China have prompted the FDA to issue a health information advisory on infant formulas. The manufacturers whose formulas are reported are not approved to sell their products in the US; however, there is a concern that the products have been disseminated in the Asian community. For more information click the link below for a list of manufactures who are adhering to the FDA standards.

<http://www.fda.gov/bbs/topics/NEWS/2008/NEW01883.html>

#### **Medications Identified by FDA as Having Potential Problems**

Quarterly the FDA releases a list to identify medications having a "potential safety issue". This information is taken from reports filed with the Adverse Event Reporting System (AERS). The FDA is not recommending physicians stop prescribing nor the patient stop taking the medications, they are simply seeking to heighten awareness of the possibility enabling one to make a more informed decision. For more information click on the following link: [FDA News](#)

#### **Four Arthritis Medications Get Stronger Warning Labels**

Due to several deaths, the FDA mandates that the manufacturers of tumor necrosis factor alpha blockers (TNF-alpha blockers) strengthen the warnings on their labeling to include "the risk of developing opportunistic fungal infections". Humira, Cimzia, Enbrel, and Remicade are the four medications affected by this directive. For more information see [FDA News](#) and the additional link at the bottom of the page, specific to healthcare providers.

#### **Gardasil Receives New Indications**

Additional indications for the prevention of certain vaginal and vulvar cancers are added to Gardasil. The FDA approved these indications after research indicated they are caused by Human Papillomavirus (HPV) types 16 and 18, which accounts for most cervical cancer cases. It is important to receive the vaccination prior to exposure as it is indicated for prevention and not treatment. For additional information click on link below.

<http://www.fda.gov/bbs/topics/NEWS/2008/NEW01885.html>

### **Medications for Rare Neurological Disease Receives Orphan Drug Approval**

Chronic inflammatory demyelinating polyneuropathy (CIDP) is a rare autoimmune disease. Recently the FDA approved Gamunex, an immune globulin, for this disorder which is depicted by chronic weakness and impaired sensory function in the legs and arms. More information regarding this disease as well as the drug is available via link.

<http://www.fda.gov/bbs/topics/NEWS/2008/NEW01884.html>

### **FDA Issues Recall**

There has been a Class I recall of LifePak CR Plus Automated External Defibrillators issued by the FDA. This recall is due to the inability to provide shock therapy to aid patients in cardiopulmonary arrest because the button to do so is inaccessible.

[FDA Recall](#)

Read More FDA Medwatch Alerts: <http://www.fda.gov/medwatch/index.html>

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## **News Items**

### **No link found between MMR vaccine and autism in recently published case-control study.**

There have been concerns about increased incidence of autism in children immunized with MMR vaccines. Findings of measles virus (MV) RNA in the intestinal tissue of children who had autistic spectrum disorders (ASD) and gastrointestinal (GI) disorders suggested a link between MV colonization of the intestine and increased risk of ASD. A recently published case-control study showed there was no link between MV RNA in the intestinal tissue or MMR vaccination and development of ASD. Further information on the study available at [PubMed](#)

### **A clinical trial finds no difference between aspirin+extended release dipyridamole (Aggrenox) against clopidogrel (Plavix) in prevention of stroke recurrence.**

The Prevention Regimen for Effectively Avoiding Second Stroke (PRoFESS) trial evaluated the above mentioned two medications in prevention of stroke recurrence. The randomized, active-placebo controlled, multi-center trial, which lasted for 2.5 years found no difference between the two medications in preventing stroke recurrence. For more information click on the following link:

[PubMed](#)

### **A clinical trial finds telmisartan (Micardis) ineffective in prevention of recurrent stroke.**

The published study was a part of the 2 X 2 factorial PRoFESS trial, the other part being a head-to-head comparison between Aggrenox and Plavix in prevention of recurrent stroke (mentioned above). The trial found that telmisartan was not any better than a placebo in preventing recurrence of stroke. More information on the trial available at: [PubMed](#)

### **Medical, statistical and clinical pharmacology reviews of pediatric studies available at FDA.**

Most of the current medications are studied and approved for adult population. Therefore utilization of these medications in pediatric population often becomes problematic due to lack of appropriate dosing and monitoring strategies. In addition to the package inserts and various drug information sources, the FDA site is devoted to providing reviews of clinical, pharmacological and statistical data of pediatric studies of drugs may help in appropriate treatment of children. Click following link to see the webpage. [http://www.fda.gov/cder/pediatric/BpcaPrea\\_full\\_review.htm](http://www.fda.gov/cder/pediatric/BpcaPrea_full_review.htm)

### **FDA issues import alert for drugs manufactured in two plants in India operated by Ranbaxy Laboratories Inc.**

In its recent efforts to protect the general public from substandard pharmaceutical imports, the FDA issued warning letters and import alerts for drugs manufactured at two facilities of Ranbaxy Laboratories Inc. in India. The FDA found that these two plants deviated substantially from US

current good manufacturing practices (cGMP); hence, the products of these facilities may not meet safety and efficacy requirements. To see the issued warning letters click on following link.

<http://www.fda.gov/bbs/topics/NEWS/2008/NEW01886.html>

### **FDA issues a warning letter to the manufacturer of Bystolic regarding false claims made in a journal ad.**

The FDA's Division of Drug Marketing, Advertising and Communications (DDMAC) has issued a letter of warning to the manufacturer of Bystolic (nebivolol) regarding claims made in a journal advertisement. According to the letter, the ad makes unproven pharmacological and efficacy claims. Further, the ad leaves out important safety information and minimizes the risks of side-effects. The letter demands the manufacturer to retract the advertisement and issue corrections to false claims and omissions. Click following link to see the FDA issued letter:

<http://www.fda.gov/cder/warn/warn2008.htm>

### **Bisphenol A used in plastic food containers may be associated with increased risk of cardiovascular diseases and diabetes.**

A recently published study in the Journal of American Medical Association (JAMA) suggests increased risk of cardiovascular diseases and diabetes in those who have higher levels of urinary bisphenol A (BPA). Bisphenol A is commonly used in many plastic products, including food storage containers. Therefore, the overall exposure to BPA is high in humans. A cross-sectional analysis of urine BPA level in 1455 adults, aged 18 to 74, showed greater incidence of cardiovascular diseases and diabetes. See the [Pubmed](#) abstract of the study, or access the full article for free at the JAMA homepage.

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## **Guidelines Update**

### **The American College of Physicians publishes guidelines for treatment of osteoporosis for prevention of fracture.**

The American College of Physicians (ACP) has published guidelines for pharmacologic treatment for prevention of fracture in those with osteoporosis. The major highlights of the guidelines are:

- Pharmacologic treatment should be offered to those who have established osteoporosis and have experienced fracture in past.
- Pharmacologic treatment should be considered for those at risk of osteoporosis.
- Further research should be conducted to evaluate treatment of osteoporosis.

The guidelines are available for free at the Annals of Internal Medicine website or at [PubMed](#).

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## **New and Generic Drug Approvals**

(Click on link and Browse by drug name)

- [Alendronate Sodium](#) tablets are a generic equivalent of Fosamax. It is a bisphosphonate used in the treatment and prevention of osteoporosis in postmenopausal women as well as to increase bone density in men with osteoporosis.
- [Galantamine Hydrobromide](#) extended-release is a generic equivalent of Razadyne™; Razadyne™ ER; Reminyl®. It is indicated for mild to moderate dementia in Alzheimer's disease. It is metabolized by CYP2D6 and CYP3A4; therefore, monitor for interactions with inducers and inhibitors of these systems.
- [Keppra XR](#) (levetiracetam) extended-release tablets is an antiepileptic medication used as adjunctive treatment of partial onset seizures. It is indicated specifically for epileptic patients aged 16 and older.
- [Ketotifen Fumarate](#) Ophthalmic Solution is a generic over-the-counter medication indicated to temporarily prevent itching of eyes associated with allergic conjunctivitis.
- [Ramipril](#) Capsules, this generic equivalent to Altace is used in the treatment of hypertension either as monotherapy or concurrently with thiazide diuretics. It is also used in the treatment of left ventricular dysfunction following a MI, to reduce the risk of MI, stroke, and death.

- [Ranitidine](#) (ranitidine hydrochloride) Syrup, a generic equivalent to prescription Zantac, is used in short-term and maintenance therapy of various ulcers, gastroesophageal reflux, and pathological hypersecretory conditions. It is also used with other medications for eradication of *H. pylori*.
- [Risperidone](#) is a generic equivalent of: Risperdal® Consta®; Risperdal® M-Tab®. They are used in the treatment of schizophrenia, acute mania or mixed episodes associated with bipolar I disorder (as monotherapy in children or adults, or in combination with lithium or valproate in adults) and of irritability/aggression associated with autistic disorder.
- [Sancuso](#) (granisetron) is a 3.1-mg transdermal system approved for the treatment of nausea and vomiting induced by chemotherapy. It provides relief for up to 5 consecutive days; also it is the only product on the market with this approved indication.
- [Valtrex](#) (valacyclovir hydrochloride) caplets, manufactured by GlaxoSmithKline, receives a patient population alteration. The new prescribing information now includes the indication for treatment of chicken pox in children from 2 to <18 years of age.

[View all Drug Approval Reports by Month](#)

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## **Resource Update**

**DailyMed:** <http://dailymed.nlm.nih.gov/dailymed/about.cfm>

DailyMed is an online database providing information about prescription and non-prescription medications. The database is maintained by the National Library of Medicine (NLM) and the National Institutes of Health (NIH). Majority of the drug information is collected from package inserts provided by manufacturers and updates provided on respective drugs by the FDA. The access to the website is free and does not require registration.

- The layout of the website is easy to follow and intuitive.
- The website gives options of either performing an alphabetical search or of performing a name search.
- The website is accredited by HON Foundation. The HON Code logo appears at the lower right hand corner of the home page.
- Information about drugs is listed as it appears in package inserts. The information can be accessed by clicking on tabs titled with respective sections (e.g., mechanism of action, metabolism and elimination under the Clinical Pharmacology section).
- In addition, the following information is provided with each drug monograph:
  - Link to FDA's MedWatch to report adverse drug events.
  - Medline Plus link to additional information about the drug.
  - A link to ClinicalTrials.gov about ongoing and past clinical trials.
  - Link to drugbank.ca for biochemical data on the drug
  - Link to Pubmed to search articles on the drug
  - Link to Lactmed database available through ToxNet. This database provides lactation-related information about drugs.
  - There is a dictionary tool, supported by Merriam-Webster, on webpage of drug monographs. Clicking it turn on the tool and highlights certain medical terms in the monograph (e.g., hypertension, schizophrenia). Clicking on the highlighted terms provides definitions in pop-up windows.

Since the monographs are collection of package inserts, a lay person may have trouble understanding and evaluating information provided. Although the website does try to reduce the likelihood of such misinterpretation by providing medical dictionary tool, help of health-care professional may be needed for accurate understanding of the information provided. Overall, the website is an excellent source of quick reference for health-care professionals and a tool to enhance self-care for general public.

**DrugBank:** <http://www.drugbank.ca/>

DrugBank is a database that combines bioinformatics and chemoinformatics data with detailed drug information (pharmacology, metabolism, elimination etc.) to give information about drugs targets, such as enzymes and proteins, in human body. The database is supported by the departments of computing sciences and biological sciences at the University of Alberta in Canada, and Dr David Wishart, a professor of biological and computing sciences at the university. In addition to drugs, the database also includes some neutraceuticals and herbal products.

- The database allows an alphabetical search or name specific search
- The results for searches are presented in tables with link to "DrugCard" for each drug molecule.
- Clicking on Drugcard link opens the webpage for the respective drug. Information is categorized and color-coded by drug field, target field and enzyme field.
- Some of the unique features are 2-dimensional and 3-dimensional structures of the molecule, major Phase I and Phase II metabolizing enzymes and their protein sequences, as well as target enzymes with their protein sequences.

The webpage is targeted to scientific research and is not intended to help in clinical practice. However, detailed information on drug metabolizing enzymes and target proteins may help in understanding drug-drug, drug-disease interactions and adverse events caused by medications.

**USP-Drug Error Finder:** <http://www.usp.org/hqi/similarProducts/choosy.html>

The United States Pharmacopeia in cooperation with Institution for Safe Medication Practices maintains Medication Errors Reporting Program to collect actual and potential medication errors. With the data collected from reporting of these errors, a database known as Drug Error Finder has been created. This database allows searching for medication errors caused by look-alike or sound-alike names. Upon performing search for a specific medication the results are displayed as follows.

- Drugs for which medication errors have been reported appear in a table.
- The table also lists the types and severity of errors:
  - Potential for error
  - Intercepted error
  - Error with no harm
  - Error with harm
  - Error with Death
- A cross under a category represents at least one report of medication error.

The database is developed by volunteer reporting from healthcare providers. Therefore, it is prone to underreporting. Furthermore, the results do not indicate prevalence of errors. Nevertheless, the database can help as an important tool in formulating guidelines and policies in minimizing medication errors caused by drugs which look similar or have names that sound similar.

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To view previous issues of the FYDI newsletter, visit <http://rxweb.ulm.edu/pharmacy/dicpubs.html>.

For comments and suggestions please email [druginfo@ulm.edu](mailto:druginfo@ulm.edu).

## **FYDI**

# For Your Drug Information

October 6, 2008

University of Louisiana at Monroe, College of Pharmacy,  
Drug Information Center



PharmD Candidates, Gilda Jefferson, Pratik Shah and Katie Swayze  
Gregory W. Smith, PharmD.

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- [FDA Medwatch Alerts](#)
- [News Items](#)
- [Guidelines Update](#)
- [New and Generic Drug Approvals](#)
- [Resource Update](#)

## **FDA Medwatch Alerts**

### **Statin drugs and amyotrophic lateral sclerosis (ALS)**

The use of statins does not increase incidence of amyotrophic lateral sclerosis (ALS) according to a new FDA analysis, which is based on data from 41 long-term controlled clinical trials. Results of the trials showed no increased occurrence of ALS, also known as "Lou Gehrig's Disease", in patients receiving a statin compared to patients receiving placebo.

[News Release](#)

### **Epoetin alfa**

Preliminary safety findings from a clinical trial in Germany have been brought to the attention of the FDA. The trial investigated the use of epoetin alfa as treatment for acute ischemic stroke. Higher doses than those recommended for the treatment of anemia were employed. These findings show an increase in number of deaths in patients receiving epoetin alfa compared to patients receiving placebo. The FDA expects more information in the upcoming weeks and will release recommendations at that time.

[Early Communication about an Ongoing Safety Review](#)

### **Ammonul (sodium phenylacetate and sodium benzoate) Injection 10%/10%**

The presence of particulate matter has been identified in Ammonul Injection 10%/10%. The use of Millex Durapore GV 33 mm Sterile Syringe Filter (0.22 µm) is recommended during the admixture process. [Letter](#)

### **Tarceva (erlotinib)**

Tarceva has been reported as causing hepatic failure and hepatorenal syndrome with fatalities; further, those with baseline hepatic impairment are at increased risk and should be monitored closely. Refer to the revised prescribing label for new information from a pharmacokinetic study as well as additional recommendations. OSI and Genentech--[Letter](#)

### **New warnings for Phosphocol P 32 (Chromic Phosphate P 32 Suspension)**

The manufacturers of Phosphocol P 32 have issued letters to prescribers informing of the risk of leukemia in children using this drug. The medication is approved for intracavitary infusion in peritoneal and pleural effusion associated with metastatic diseases. Two cases of acute lympholytic leukemia occurred in children given intra-articular infusion of the medication. In addition, in post-marketing surveillance, radiation injury to the small bowel, cecum and bladder were observed after using Phosphocol P 32. Warnings against these adverse events will be included in the package insert. Click on following link to see the letter issued to health-care providers. [Letter](#)

Read More FDA Medwatch Alerts: <http://www.fda.gov/medwatch/index.html>

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## **News Items**

### **New HIV drug class**

Maraviroc is the first of a new class of HIV drugs that blocks the R5 protein on host CD4 cells, preventing attachment of certain types of HIV. According to studies in the *New England Journal of Medicine*, Maraviroc is effective against some HIV subtypes. In two clinical trials, patients treated with Maraviroc had lower levels of HIV RNA and larger increases in CD4 counts compared to those treated with placebo. [Abstract](#)

### **Long-term combination Alzheimer's therapy slows decline**

According to a study published in *Alzheimer Disease and Associated Disorders*, cognitive and functional decline was significantly slowed in Alzheimer's disease patients on long-term combination therapy with acetylcholinesterase inhibitors and memantine. Patients receiving long-term combination therapy showed slowed disease progression and better maintenance of activities of daily living as compared to patients receiving either drug alone or placebo.

[Link](#)

### **Foods to get COOL**

Until now, consumers have had no idea where the food they were purchasing originated. A new law known as the "COOL" law mandates that certain foods be labeled with their country-of-origin. The law does have many exceptions for labeling but will be helpful when a new health concern, such as a food from a certain region causing salmonella, arises. The law went into effect on September 30, 2008.

[Foods to get COOL: Country-of-origin labeling](#)

### **FDA advisory on melamine contamination**

Due to potential contamination with melamine, the FDA is notifying consumers that seven Mr. Brown instant coffee and milk tea products are being recalled. It is recommended by the FDA that the public not consume any of these recalled products. Visit the link below for a full list of the recalled products.

[FDA Updates Health Information Advisory on Melamine Contamination](#)

### **Colonoscopy screenings: who is more likely to have large polyps?**

According to a *JAMA* study, black men and women have disproportionately larger polyps, greater than 9mm, than whites. There is a large disparity between black women and white women; further, white men aged 50-59 have similar rates as black women less than 50 years of age. It's concluded that, while awaiting confirmation, heightened screening of black patients "would seem to be prudent." [JAMA article](#)

### **Drug-eluting stents proven better than bare-metal stents**

A prospective cohort study published in the *New England Journal of Medicine* indicates that drug-eluting stents appear superior to bare-metal stents. The study included 7217 acute myocardial infarction patients in which percutaneous coronary intervention was performed. After 2 years of receiving the drug-eluted stents, there was a significantly lower mortality rate in all participants; further, they were linked to lowering the risk for recurrent MI in those with non-ST-elevation MI, as well as recurrent revascularization in all participants. Larger, long-term, randomized studies are needed to confirm these findings. [NEJM article](#)

### **Comparisons between clinical trials of ezetimibe do not prove link between ezetimibe and cancer**

The results of the SEAS trial have raised concerns of cancer with ezetimibe. To gain more definitive data on this issue, results of the SEAS trial were compared with data from two ongoing trials: 1) Study of Heart and Renal Protection (SHARP) and 2) Improved Reduction of Outcomes: Vytorin Efficacy International Trial (IMPROVE-IT). The results of the comparisons failed to show sufficient

evidence of cancer risk with ezetimibe use. [Pubmed](#). The full-text study is also available for free at the New England Journal of Medicine website.

**A tool to help in evaluation of direct-to-consumer prescription drug advertisements:**

The Center for Drug Evaluation and Research of the FDA has prepared a web page that assists consumers in evaluating direct-to-consumer prescription drug advertisements. The web page gives examples of the correct way and the misleading ways of making claims in those advertisements. Click on following link to see the webpage: <http://www.fda.gov/cder/ethicad/index.htm>

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## **Guidelines Update**

**Guidelines for testing for Hepatitis B updated by the CDC.**

Previous CDC guidelines recommended screening for hepatitis B in pregnant women, babies of HBsAg-positive mothers, household contacts and sexual partners of those infected, people with needlestick injuries, victims of sexual assault, those HIV-positive and those born in regions with HBsAg prevalence of 8% or higher. An update to the guidelines now include men who have sex with men, injection-drug users, those who receive cytotoxic or immunosuppressive therapy, those with liver disease and those who are born in regions with HBsAg prevalence of at least 2%. Click on following link to see the updated guidelines. [MMWR article](#)

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## **New and Generic Drug Approvals**

**Generic coronary artery disease imaging agent approved**

The FDA has approved Covidien's ANDA for its kit used for the preparation of technetium Tc-99m sestamibi for injection, a myocardial perfusion imaging agent used for detecting coronary artery disease. The product is generically equivalent to *Cardiolite* by Lantheus Medical Imaging.

**Tumor-imaging agent approved**

GE Healthcare's *AdreView* (Iobenguane I 123) injection has been approved by the FDA for the detection of rare neuroendocrine tumors in children and adults. *AdreView* allows detection of tumors at initial diagnosis and when relapse or recurrence is suspected.

**Nasacort AQ receives expanded labeling**

Sanofi-Aventis' *Nasacort AQ* (triamcinolone acetonide) nasal spray labeling has been expanded. It is now recommended in children aged 2 to 5 for both seasonal and perennial allergic rhinitis associated nasal symptoms.

**Retrovir revised labeling approved**

*Retrovir* (zidovudine), manufactured by GSK, has added a pediatric efficacy supplement to its syrup, tablet and capsules to allow more suitable twice daily dosing in children with HIV. This regimen is for those 6 weeks to 18 years of age and based on body surface area or body weight. Prior dosing was three times daily using only body surface area.

[View all Drug Approval Reports by Month](#)

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## **Resource Update**

**Center for Veterinary Medicine**

The Center for Veterinary Medicine is a unique entity managed by the FDA. There are links to a variety of resources to include: antimicrobial resistance, biotechnology, aquaculture, bovine spongiform encephalopathy (BSE) also known as "mad cow disease", and The Green Book. The Green Book, a FDA approved animal products list, is published annually in January and updated monthly. For additional information regarding this and other resources click on the link that follows. <http://www.fda.gov/cvm/default.html>

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For comments and suggestions please email [druginfo@ulm.edu](mailto:druginfo@ulm.edu).

## **FYDI**

# For Your Drug Information

October 17, 2008

University of Louisiana at Monroe, College of Pharmacy,  
Drug Information Center



Katie Swayze, PharmD Candidate  
Gregory W. Smith, PharmD.

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- [FDA Medwatch Alerts](#)
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## **FDA Medwatch Alerts**

### **FDA Recall of Dextroamphetamine Sulfate 5 mg Tablets**

Three batches of dextroamphetamine sulfate 5 mg tablets have been recalled by the FDA and Ethex Corp. This recall is due to the possible presence of "oversized tablets" which may include up to double the labeled amount of active ingredient. An increased amount of active ingredient can lead to increased side effects for the patient. The FDA and Ethex Corp urge against the use of any "oversized" dextroamphetamine sulfate tablets.

[Recall Notice](#)

### **Modification of OTC Cough and Cold Labels**

OTC cough and cold medication labels have been revised by the Consumer Healthcare Products Association (CHPA) to now read "do not use" in children less than 4 years old. These labels were modified in order to "help prevent and reduce misuse" of these products.

[OTC Cough and Cold](#)

### **Spiriva (tiotropium bromide) HandiHaler**

It was reported in two current trials that patients using tiotropium or other inhaled anticholinergics were at increased risk of cardiovascular events and death. The recent preliminary data from the UPLIFT (Understanding the Potential Long-Term Impacts on Function with Tiotropium) trial states otherwise. These results demonstrate that patients receiving tiotropium bromide are at no higher risk of stroke than those patients receiving placebo. The anticipated date of the complete report of the UPLIFT trial is November 2008.

[Spiriva \(tiotropium bromide\) HandiHaler](#)

### **FDA Class I Recall of the Nebion HLX-8 Magnetic Resonance Device**

The FDA has recalled the Nebion HLX-8 Magnetic Resonance Device, which claimed to treat a myriad of conditions and diseases. The device was not manufactured under current good manufacturing practices, lacked data on safety and efficacy, and was not approved by the FDA.

[Recall Notice](#)

### **FDA Class I Recall of Medtronic Neuromodulation INDURA One-Piece Intrathecal Catheters, Sutureless Pump Connector Revision Kit, and Intrathecal Catheter Pump Segment Revision Kit**

Numerous Medtronic intrathecal catheters and catheter revision kits used with the implanted Medtronic SyncroMed II, SynchroMed EL, and IsoMed infusion pumps have been recalled by the FDA and Medtronic. Possible misconnections between the catheter and the catheter port have resulted in various catheter obstructions and disconnections.

[Recall Notice](#)

## **News Items**

### **B Vitamins Fail to Slow Cognitive Decline in Alzheimer's Disease**

According to a study in *JAMA*, the cognitive decline of Alzheimer's disease patients is not slowed by homocysteine-lowering vitamin B supplementation. Although homocysteine levels did decrease significantly in the treatment group compared to the placebo group, there was no difference in the degree of cognitive decline between groups.

[Pubmed Link](#)

### **Cardiovascular Risks of Rofecoxib (Vioxx) Confirmed**

According to a study in *Lancet*, rofecoxib's increased risk of cardiovascular events was verified. An analysis was conducted that gathered follow-up information on cardiovascular events in participants of the APPROVe trial, which was stopped prematurely due to the increased risk of cardiovascular events with rofecoxib. The analysis showed that rofecoxib was linked to "an early increase in risk (for the combined incidence of myocardial infarction, stroke, and death from cardiovascular, hemorrhagic, and unknown causes) that seems to persist for about 1 year after 3 years of treatment."

[Link](#)

### **Pneumococcal Vaccine and Risk of MI**

A case-control study in the *Canadian Medical Association Journal* shows a link between pneumococcal vaccination and risk of MI. Patients studied were considered at risk of MI. Two years after exposure to the pneumococcal vaccine, vaccination was correlated with a greater than 50% reduction in the rate of MI.

[Pubmed Link](#)

### **Tiotropium Alleviates Symptoms, Doesn't Reduce Rates of FEV<sub>1</sub> Decline in COPD**

A large double-blind trial in the *New England Journal of Medicine* showed that tiotropium, an inhaled bronchodilator, failed to show any difference in rates of decline in FEV<sub>1</sub> or mortality compared to placebo. Tiotropium did, however, decrease exacerbations, improve lung function, and increase quality of life. There is speculation that FEV<sub>1</sub> alone may not be an appropriate measure of COPD severity.

[PubMed Link](#)

### **High BMI, Hyperinsulinemia Associated with Prostate Cancer Mortality**

According to a prospective study in *Lancet Oncology*, overweight or obese men had a greater risk of dying of prostate cancer than did men of normal weight. Men with large amounts of C-peptide, which is an insulin secretion marker, were also more likely to die from prostate cancer than men with lower amounts of the marker. Men with both a high BMI and hyperinsulinemia had four times the risk of prostate cancer mortality compared to men with neither factor.

[Pubmed Link](#)

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## **Guidelines Update**

### **AAP Updates Guidelines on Influenza Vaccination**

The American Academy of Pediatrics has updated its April 2008 guidelines on influenza vaccination. It is now recommended that all children, healthy or at increased risk, 6 months old to 18 years old be vaccinated. Also, all household contacts and caregivers of children less than 5 years old or high risk children should receive the vaccine. Healthcare professionals and women that may be pregnant during the influenza season should receive the vaccine as well.

[Link](#)

### **AAP Updates Guidelines on Vitamin D Intake**

The American Academy of Pediatrics has updated its 2003 guidelines on vitamin D intake. It is now recommended that infants, children, and adolescents receive 400 IU vitamin D daily, instead of the previously recommended 200 IU daily. Those children at higher risk for rickets may require more vitamin D than 400 IU daily.

[Link](#)

### **ACIP Offers Guidelines on Recently Approved Combination Vaccines for Children**

Recommendations have been issued by the Advisory Committee on Immunization Practices (ACIP) for use of two combination vaccines, DTaP-IPV (Kinrix) and DTaP-IPV/Hib (Pentacel), for children. DTaP-IPV (Kinrix) is a combined diphtheria and tetanus toxoids, acellular pertussis and inactivated poliovirus vaccine, while DTaP-IPV/Hib (Pentacel) is a combined diphtheria and tetanus toxoids, acellular pertussis, inactivated poliovirus, and *Haemophilus influenzae* type B conjugate vaccine. For these guidelines, see the links below.

[Pubmed-Kinrix](#) , [Pubmed-Pentacel](#)

### **USPSTF Colorectal Cancer Screening Guideline Updates**

The 2002 U.S. Preventive Services Task Force colorectal cancer screening guidelines have been updated. It is now recommended that newer, high-sensitivity fecal occult blood testing, colonoscopy, or sigmoidoscopy with interval fecal occult blood testing be used for screening. Also, it is recommended that people 76 to 85 years of age who have had constant negative tests since the age of 50, and people over 85 years of age should not be routinely screened.

[Link](#)

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## **New and Generic Drug Approvals**

### **Raptiva (efalizumab)**

The FDA has update labeling of the drug Raptiva (efalizumab) to include a Boxed Warning. Raptiva, a once-weekly injection for the treatment of psoriasis, has been linked to increased risks of opportunistic infections, such as progressive multifocal leukoencephalopathy (PML).

[FDA Link](#)

### **Rapaflo (silodosin)**

The FDA has approved a new drug, Rapaflo (silodosin), for the treatment of symptoms due to BPH. Rapaflo works as a blocker of alpha-1 adrenoceptors in the urethra, bladder, and prostate and will be available as a capsule taken once daily.

[FDA Link](#)

### **Kogenate FS**

Kogenate FS, a version of clotting factor VIII, has been approved for a new use by the FDA. It is now approved to decrease bleeding incidences and to prevent joint destruction in children with severe hemophilia, an uncommon bleeding syndrome in which factor VIII is diminished.

[FDA Link](#)

### **Cinryze**

The FDA has approved the first U.S. drug for prevention of hereditary angioedema (HAE) attacks, Cinryze. Derived from human plasma, Cinryze is a C1-esterase inhibitor product that controls inflammatory and clotting reactions. Intravenously administered Cinryze can be used every 3-4 days.

[FDA Link](#)

[View all Drug Approval Reports by Month](#)

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## **Resource Update**

### **TRIP Database**

The Turning Research Into Practice (TRIP) Database at [www.tripdatabase.com](http://www.tripdatabase.com) is a very helpful database that aids in answering clinical questions with evidence-based medicine. One can search the database under 3 tabs: "evidence based medicine", "medical images", or "patient information leaflets". The site allows one to search by "specialist sites", which help narrow the search to the topic of interest, while providing the latest news in that area of specialty.

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ULM COLLEGE OF PHARMACY  
DRUG INFORMATION CENTER

NOVEMBER 20, 2008

## **FYDI FOR YOUR DRUG INFORMATION**

KATIE SWAYZE, JESSICA RENÉ & SHELLEY WISENOR  
PHARM D CANDIDATES 2009  
GREGORY W. SMITH, PHARM D



### **In this issue...**

- FDA Medwatch Alerts
- News Items
- Guidelines Update
- New and Generic Drug Approvals
- Resource Update

### **FDA Medwatch Alerts**

#### **Voluntary National Recall of Topical Acne Cream**

CSI USA, Inc. issued a voluntary nationwide consumer product recall of all lots of 1 ounce tubes of 10% Benzoyl Peroxide Acne Cream with the following names:

- DG Maximum Strength Acne Medicated Gel (sold at Dollar General)
- Kroger Acne Gel 10% Benzoyl Peroxide Acne Medication (sold at Kroger)
- Equate: Medicated Acne Gel (sold at Wal-Mart)

#### **Recall Notice**

#### **Urgent Voluntary Nationwide Recall Of Infants' Mylicon Gas Relief Dye Free Drops Due To Possible Metal Fragments**

Johnson & Johnson-Merck Consumer Pharmaceuticals Company has issued a voluntary recall of *Infants' Mylicon Gas Relief Dye Free* drops (lot no. SMF007 and SMF008) sold in one ounce plastic bottles that were distributed nationwide after October 5, 2008. The product was recalled due to the possibility that some bottles may include metal fragments generated during the manufacturing process. Caregivers of infants exposed to the recalled product should contact their primary care provider.

#### **Recall Press Release**

#### **Nationwide Voluntary Recalls of Specific Lots of Five Generic Products Due to the Potential for Oversized Tablets:**

- Propafenone HCl Tablets - 150 mg, 225 mg, and 300 mg
- Isosorbide Mononitrate Extended Release Tablets – 30 mg and 60 mg
- Morphine Sulfate Extended Release Tablets - 15 mg
- Morphine Sulfate Immediate Release Tablets - 15 mg and 30 mg
- Dextroamphetamine Sulfate Tablets - 10 mg

Oversized tablets may contain more than the labeled amount of active drug, which could result in delivery of as much as twice the intended dosage of these drugs. Increased active drug also increases the risk of adverse drug reactions, which



for these recalled drugs may include: arrhythmias (propafenone HCl), low blood pressure (propafenone, isosorbide mononitrate, morphine sulfate), and respiratory depression (morphine sulfate).

[Recall Press Release](#)

### **FDA Reports Class I Recall of Mislabeled ReliOn Insulin Syringes**

Covidien has issued a nationwide recall of one lot of *ReliOn* (lot no. 813900) sterile, single-use, disposable, hypodermic syringes with permanently affixed hypodermic needles. The mislabeled syringes may lead to patients receiving an overdose of as much as 2.5 times the intended dose, causing serious and possibly life-threatening consequences, including low blood sugar. The syringes are sold only by Wal-Mart or Sam's Club pharmacies from August 2008 to October 2008. The lot number can be found on the back panel of the 100-count syringe carton or on the white paper backing of each individual syringe "peel-pack."

[Recall Notice](#)

### **FDA Warns Bayer About Two Unapproved Aspirin Products**

FDA has sent warning letters to Bayer HealthCare regarding two OTC products that combine aspirin with a dietary supplement into a single pill.

[FDA Link](#)

[Read More FDA Medwatch Alerts](#)

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## **News Items**

### **Combination Treatment of Anxiety in Children With CBT and Sertraline**

According to a study in the *New England Journal of Medicine*, combination treatment with cognitive behavioral therapy (CBT) and sertraline improves anxiety in children better than either treatment alone. This study included 500 children with generalized anxiety disorder, social phobia, or separation anxiety disorder. The children were randomized to receive sertraline 25 mg/day titrated to 200 mg/day by 8 weeks, 14 sessions of CBT, a combination of the two, or placebo. Children receiving combination therapy showed a greater improvement in anxiety than did the other treatment groups (81% combo group versus 60% in CBT group, 55% in sertraline group, and 24% in placebo group). The authors state that all three treatments may be used in children but many factors, such as cost, should be considered.

[PubMed Link](#)

### **Beta-Blockers Linked to Increased Risk of Cardiovascular Events**

A meta-analysis in the *Journal of the American College of Cardiology* shows that hypertensive patients taking beta-blockers may be at an increased risk of cardiovascular events and death. Nine studies were assessed containing a total of 68,000 patients: 34,000 patients taking beta-blockers and 34,000 patients taking other antihypertensive medications or placebo. It was concluded that slower heart rates due to beta-blockers were associated with an increased risk of cardiovascular events (MI and heart failure) and death, after a follow-up period of 3.5 years. The authors attribute this increased risk to a possible "increase in central aortic pressure or pulse pressure". The authors also state that additional research is warranted to prove a causal link.

[Pubmed Link](#)

### **Benefit of New Weight Loss Drug Seen in Early Trial**

According to a phase II study in *Lancet*, a new weight loss drug, tesofensine, may cause more weight loss than approved obesity medications. Tesofensine is a noradrenaline, dopamine, and serotonin presynaptic uptake inhibitor. Tesofensine 0.25, 0.5, or 1 mg or placebo daily for 24 weeks was randomly assigned to approximately 200 obese adults in the study. At the end of the study, tesofensine patients had lost a larger amount of body weight than placebo patients. Weight loss in the 0.5 and 1 mg tesofensine patients was about twice the amount of weight lost with medications presently approved for obesity. Although a large amount of weight was lost with 1 mg tesofensine, it was associated with more side effects, such as increased blood pressure and gastrointestinal problems.

[PubMed Link](#)

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### **Guidelines Update:**

#### **ACP Offers Guidelines on Second-Generation Antidepressants**

The American College of Physicians has released clinical practice guidelines on using second-generation antidepressants to treat depressive disorders in adults. These guidelines appear in the *Annals of Internal Medicine* and were formed from an analysis of nearly 30 years' worth of published research on 12 drugs: bupropion, citalopram, duloxetine, escitalopram, fluoxetine, fluvoxamine, mirtazapine, nefazodone, paroxetine, sertraline, trazodone, and venlafaxine.

The principal recommendations follow:

Since all of the drugs are about equally effective, consider adverse-effect profiles, costs, and patient preferences when choosing among them. Assess the patient's status regularly, beginning within 2 weeks after starting therapy. Modify treatment if desired response does not occur within 2 months. Successful treatments of first episodes of major depression should continue for about 4 to 9 months; patients with a history of two or more episodes may benefit from treatment for much longer periods.

[Link](#)

#### **Guidelines for Management of Hyperglycemia in Type 2 Diabetes Updated by ADA**

The 2006 treatment algorithm for hyperglycemia in types 2 diabetes patients has been updated by The American Diabetes Association and the European Association for the Study of Diabetes. The updated algorithm can be found in *Diabetes Care*. The updates include: no longer recommending rosiglitazone due to elevated risk of myocardial infarction and considering exenatide or pioglitazone for patients in whom hypoglycemia is especially unfavorable, such as those having a hazardous occupation.

[PubMed Link](#)

#### **New Recommendation for Pneumococcal Vaccine by ACIP**

According to the Associated Press, smokers under the age of 65 are now recommended by the federal Advisory Committee on Immunization Practices to receive the pneumococcal vaccine. It is estimated that "some 30 million U.S. smokers will be eligible under the new recommendation". The authors state that this recommendation should be confirmed in the future by the CDC in *MMWR*.

[Link](#)

#### **GERD Management Guidelines Released**

Gastroesophageal reflux disease (GERD) guidelines have been issued by The American Gastroenterological Association in *Gastroenterology*. Some of the high points of the new guidelines include information on the most effective treatment

and efficient dosing schedules.

[PubMed Link](#)

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## **New and Generic Drug Approvals**

### **Banzel® (rufinamide)**

The FDA has approved Banzel® (rufinamide) for the adjunctive treatment of seizures associated with Lennox-Gastaut syndrome in children 4 years and older and adults. Rufinamide is a triazole derivative structurally unrelated to currently marketed antiepileptic drugs. Its suggested mechanism of action is prolongation of the inactive state of sodium channels.

Treatment should be initiated at a daily dose of 400- - 800 mg/day administered in two equally divided doses. The dose should be increased by 400- - 800 mg/day every 2 days until a maximum daily dose of 3200 mg/day, administered in two equally divided doses is reached. Banzel® is available as 200 mg and 400 mg tablets. The most common adverse effects associated with Banzel® therapy are somnolence and dizziness. Banzel® is contraindicated in patients with Familial Short QT syndrome.

[Link](#)

### **Toviaz® (fesoterodine)**

A new anticholinergic drug has been approved by the FDA for treatment of overactive bladder in adults. Toviaz® (fesoterodine) decreases urinary frequency and incontinence through relaxation of the bladder smooth muscle. The recommended dosage is a once daily administration of a 4 mg or an 8 mg extended-release tablet. The most common side effects seen in controlled clinical trials were dry mouth and constipation.

Toviaz® should not be used by those with impaired kidney function that is severe, urinary or gastric retention, uncontrolled narrow-angle glaucoma, or severe liver impairment. Its use should also be avoided in those taking medications, such as ketoconazole, that hinder metabolism of fesoterodine. Patients with severe constipation should use this medication with caution.

[Link](#)

### **New Premarin® indication**

The FDA has approved Premarin®(conjugated estrogens) 0.5 mg vaginal cream to treat moderate to severe postmenopausal dyspareunia. The FDA also approved the medication for twice-daily dosing. Premarin® vaginal cream is also indicated for the treatment of atrophic vaginitis and kraurosis vulvae.

[Link](#)

### **New Ranexa® indication**

The FDA has approved Ranexa®(ranolazine) extended-release tablets as a first-line treatment for chronic angina, alone or in combination with other traditional therapies. The new prescribing information includes information on Ranexa®'s ability to reduce arrhythmias (including ventricular arrhythmias), new onset atrial fibrillation, and bradycardia in patients with coronary artery disease. The new labeling also includes information on Ranexa®'s ability to reduce hemoglobin A1<sub>c</sub> (HbA<sub>1c</sub>) in patients with diabetes.

[Link](#)

[View All Drug Approval Reports by Month](#)

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## **Resource Update**

### **New FDA Drug Safety Resource Page**

The FDA has consolidated key product information onto one webpage, <http://www.fda.gov/cder/drugSafety.htm>, which can guide searchers to a wealth of information on approved medications. Included on this webpage is: product recalls and warnings, products and their medication guides, package inserts, approved drug labeling, and the MedWatch adverse event reporting system. The new page allows for a quicker and easier location of needed information in a more navigable form.

#### **FDA news release**

<http://www.fda.gov/cder/drugSafety.htm>

### **PharmGKB**

PharmGKB is a publicly available Internet research tool developed by Stanford University with funding from the National Institutes of Health (NIH). It is part of the NIH Pharmacogenetics Research Network (PGRN), a nationwide collaborative research group. Its goal is to help researchers in understanding how genetic variation among individuals contributes to differences in patients' reactions to drugs.

The PharmGKB database is a central database for genetic, genomic, molecular and cellular phenotype data and clinical information about people who have participated in pharmacogenomics research studies. The data includes clinical and basic pharmacokinetic and pharmacogenomic research in the cardiovascular, pulmonary, cancer, pathways, metabolic and transporter domains. All data given is fully referenced with PubMed links.

#### **Link**

### **HIV Pharmacogenomics Database**

The HIV Pharmacogenomics Database is a comprehensive resource that provides information on the underlying genetic factors that determine response to HIV pharmacotherapy. The Databank is searchable by gene, metabolizing enzyme, drug transporter, toxicity type, or treatment response. A better understanding of the pharmacogenomics of HIV therapy could lead to better patient outcomes.

#### **Link**

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### FDA Medwatch Alerts

#### Ongoing Safety Review of Innohep (tinzaparin sodium injection)

Innohep has been approved for use in the United States in July, 2000. In July 2008, the company changed the prescribing information to restrict the use of Innohep in patients 90 years of age or older instead of 70 years and older. FDA is concerned that the preliminary data from the IRIS study suggest that the increased risk of mortality is not limited only to patients 90 years of age or older. Therefore, FDA has requested that the company revise the labeling for Innohep to better describe the overall study results which suggest that, when compared to unfractionated heparin, Innohep increases the risk of death for elderly patients (i.e., 70 years of age and older) with renal insufficiency.

[FDA Link](#)

#### Urgent Nationwide Recall of Starcaps Dietary Supplement Capsules

Balanced Health Products, Inc. Conducts voluntary urgent recall that is effective immediately and is being undertaken because a certain lot of STARCAPS contains an undeclared drug ingredient, Bumetanide, which is a diuretic available by prescription only. Bumetanide is also not listed on the product label as an ingredient in this product. This recall applies only to Lot 12/2011 – 84810.

[FDA Link](#)

#### Voluntary Nationwide Recall of All Lots of Zhen De Shou Fat Loss Capsules

Fashion Sanctuary is recalling all lot codes of Zhen De Shou Fat Loss Capsules sold in 10 count blister cards. The product was primarily distributed in the U.S and sold via the Internet. Samples found the product to contain undeclared sibutramine. Sibutramine is known to substantially increase blood pressure and/or pulse rate in some patients and may present a significant risk for patients with a history of coronary artery disease, congestive heart failure, arrhythmias or stroke.

[Recall Notice](#)

#### Phenytoin and Fosphenytoin Potentially Linked to Serious Skin Reactions

The FDA is investigating new preliminary data that may link phenytoin and fosphenytoin to an increased risk of serious skin reactions, including Stevens Johnson syndrome and toxic epidermal necrolysis, in certain Asian populations. The increased risk has been linked to the human leukocyte antigen allele HLA-B\*1502. This allele occurs almost exclusively in patients with ancestry across broad areas of Asia, including Han Chinese, Filipinos, Malaysians, South Asian Indians, and Thais. Until the FDA's evaluation of this risk is complete, all health-care providers should keep this information in mind when prescribing phenytoin and fosphenytoin to individuals in these Asian populations.

[FDA link](#)

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### News Items:

#### Greater Scrutiny of 'Off-Label' Drug Use Needed

There is often little evidence that "off-label" prescribing (using a drug for an unapproved purpose) is always beneficial or safe, a new study by American researchers found. The study has identified 14 widely prescribed medications that they think need additional study to see how effective and safe they are for off-label use. Many of the drugs are antidepressants and antipsychotics, including: quetiapine, escitalopram, and risperidone. The new report was published in the Nov. 24 issue of the journal *Pharmacotherapy*.

[Link](#)

#### Jet lag pill

A new experimental drug, tasimelteon, promises to reset the body's internal clock and banish jet lag zombies for good. It works by mimicking the effects of the naturally occurring hormone melatonin, which has long been identified as the regulator of the body's sleep and wake patterns.

[Link](#)

#### Use of Epilepsy Drug During Pregnancy May Increase Children's Autism Risk

Pregnant women who take the epilepsy drug valproate may be more likely to have a child with autism than those who don't take the seizure-controlling drug, according to a study published Monday in the journal *Neurology*.

[Link](#)

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### Guidelines Update:

#### ACC/AHA issue guideline for the management of congenital heart disease

The American College of Cardiology (ACC) and the American Heart Association (AHA) have issued guidelines for the management of adults with congenital heart disease. These guidelines are featured in *Circulation* and cover a wide range of congenital heart diseases, including: atrial septal defect, ventricular septal defect, atrioventricular septal defect, and patent ductus arteriosus.

[PubMed Link](#)

#### HIV Screening for everyone over 13

The American College of Physicians recommend in a guidance statement published in the *Annals of Internal Medicine* that physicians should routinely screen all patients older than 13 for HIV. Among the reasons cited for universal testing:

- Early identification and treatment increases survival and probably decreases transmission.
- Basing HIV screening decisions on patients' risk has failed to identify substantial numbers early in their infection.
- Testing all but those who decline has worked well in prenatal HIV screening.
- There's strong evidence that screening is cost-effective even when HIV prevalence is low.

[PubMed Link](#)

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### New and Generic Drug Approvals

#### FDA Approves New Drug to Alleviate Moderate to Severe Pain

The U.S. Food and Drug Administration has approved Tapentadol hydrochloride for the relief of moderate to severe acute pain. Tapentadol works as an opioid analgesic by activating opioid receptors in the brain, spinal cord, and GI tract and as a non-opioid analgesic by inhibiting the reuptake of norepinephrine. The most common adverse effects of Tapentadol are nausea, dizziness, vomiting, and sleepiness. Tapentadol is available as 50 mg, 75 mg, and 100 mg immediate release tablets.

[FDA Link](#)

#### FDA Approves New Drug for Rare Blood Disorder

The U.S. Food and Drug Administration has approved Promacta® (eltomopag) a thrombopoietin receptor agonist for the treatment of thrombocytopenia in patients who have had an insufficient response to corticosteroids, immunoglobulins, or splenectomy. Some of the most common adverse effects of Promacta® are nausea, vomiting, menorrhagia, myalgia and paresthesia. Promacta® carries a Black Box warning for a risk of hepatotoxicity. Promacta® is available as 25 mg and 50 mg oral tablets.

[Link](#)

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### Resource Update

#### FDA Teams With WebMD For New Online Consumer Health Information

The FDA and WebMD have collaborated to provide consumers with expanded access to the timely and reliable important health information. This collaboration will allow the FDA to use innovative, technology based strategies to promote and protect public health.

Benefits of this collaboration include:

**A new online consumer health information resource on WebMD.com ([www.webmd.com/fda](http://www.webmd.com/fda)):** Consumers can access information about the safety of FDA-regulated products, including food, medicine and cosmetics, and learn how to report problems involving the safety of these products directly to the FDA. WebMD will bring the FDA public health alerts to all WebMD registered users and site visitors who request them. The cross-linked joint resource will also feature FDA's Consumer Updates ([www.fda.gov/consumer](http://www.fda.gov/consumer)). FDA Consumer Updates will also be featured at least three times a year in WebMD's bimonthly magazine, which reaches nearly nine million consumers. The magazine is distributed to physician office waiting rooms across the country.

[Press Release](#)

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### **FDA Medwatch Alerts**

#### **FDA Requires Warnings about Risk of Suicidal Thoughts and Behavior**

The FDA has completed its analysis of reports of suicidality (suicidal behavior or ideation) with medications used to treat epilepsy, psychiatric disorders, and other conditions. FDA is now requiring that manufacturers of antiepileptic medications include a warning in their labeling and develop a medication guide to provide the patients with information on the risks of suicidal thoughts or actions.

[FDA Link](#)

#### **Oral Sodium Phosphate (OSP) Products for Bowel Cleansing May be Associated with Kidney Damage**

As a result of reports of acute phosphate nephropathy associated with the use of oral sodium phosphate (OSP) products for bowel cleansing, the FDA is requiring the manufacturer of Visicol and OsmoPrep (the two OSPs available by prescription only), to add a Boxed Warning to the labeling for these products. In some cases when used for bowel cleansing, these serious adverse events have occurred in patients without identifiable factors that would put them at risk for developing acute kidney injury.

[FDA Link](#)

#### **Voluntary Recall of One Lot of 20meq Potassium Chloride in 5% Dextrose and 0.45% Sodium Chloride Injection, USP**

Hospira, Inc. is following up on a nationwide voluntary recall issued Sept. 18 of one lot (lot number 65-620-FW, expiration date May 1, 2010, NDC 0409-7902-09) of 20 mEq Potassium Chloride in 5% Dextrose and 0.45% Sodium Chloride Injection, USP in 1000 mL flexible plastic containers because a small number of the containers may be incorrectly labeled with a bar code for 5% Dextrose Injection, USP (NDC 0409-7922-09). Hospira has not received any reports of adverse health events in connection with the recalled lot. Hospira has identified the root cause of the error and taken action to prevent its recurrence.

[FDA Link](#)

### **FDA Recommends Manufacturers Evaluate Cardiovascular Risks for New Medications Intended to Treat Type 2 Diabetes**

The FDA has recommended that all manufacturers developing new drugs and biologics for Type II Diabetes Mellitus provide evidence that the therapy will not increase the risk of cardiovascular events such as heart attack. This guidance is effective immediately and defines more robust and adequate design and data collection approaches for Phase 2 and Phase 3 clinical trials than were previously required. Patients with diabetes have a 2-4 times greater risk of heart disease than their non-diabetic counterparts, and none of the currently approved antidiabetic therapies has been convincingly proven to reduce that risk.

[FDA Link](#)

### **FDA Study Discovers That Much of Private-Sector Consumer Medication Information Not Consistently Useful**

An *Expert and Consumer Evaluation of Consumer Medication Information* study by the FDA found that the printed consumer medication information (CMI) voluntarily provided with new prescriptions by retail pharmacies does not consistently provide easy-to-read, understandable information about the use and risks of medications. The study showed that while most consumers (94 %) received CMI with new prescriptions, only about 75% of this information met the minimum criteria for usefulness. In early 2009, the FDA Risk Communication Advisory Committee will hold a public meeting to discuss the study's findings.

[FDA Link](#)

### **Opioids Linked to Increase in Overdose Deaths**

According to a report published in the December 10 issue of the *Journal of the American Medical Association* deaths from overdoses of prescription drugs, primarily pain relievers, appear to be on the rise throughout the United States. Methadone was the most common drug linked to fatal overdoses, accounting for 40 percent of the deaths. People who died from a methadone overdose were less likely to have a prescription for the drug than people who overdosed on hydrocodone or oxycodone.

[PubMed Link](#)

### **FDA Panel Votes to Ban Medications Used for Asthma**

A panel of federal drug experts voted that Serevent and Foradil should be banned from use in the treatment of asthma. The experts said that Advair and Symbicort, which together are far more popular, should continue to be used.

Serevent and Foradil widen lung airways but increase the risks of death unless paired with a steroid. The drugs' labels already warn of this risk but many patients taking the medicines do not get a steroid or fail to take it if they are prescribed one. FDA officials caution patients to consult with their doctor before stopping any asthma drug regimen.

[Link](#)

### **FDA panel supports bimatoprost eye drops (Lumigan®) for longer lashes**

Following reports of eyelash growth by users of bimatoprost eye drops (Lumigan®) for glaucoma, Allergan Inc is now seeking FDA approval to market this new use under the brand name Latisse®. At a FDA panel meeting, outside advisers concluded overall that "years of data gathered from the glaucoma use under the name Lumigan® showed the drops helped boost lashes." The Latisse® drops will include a special applicator to apply the drops to the edge of the eyelid rather than into the eye.

[Link](#)

**Updated US consensus algorithm on initiation and adjustment of medical therapy for hyperglycemia in type 2 diabetes**

This American consensus algorithm for the medical management of Type II Diabetes Mellitus was originally published in August 2006 and an update was published in January 2008 to specifically address safety issues surrounding the thiazolidinediones. In this revision, the authors focused on the new classes of medications for which more clinical data and experience are now available.

The updated guidelines and treatment algorithm emphasize the following

- Achievement and maintenance of near normoglycemia (HbA1c < 7.0%).
- Initial therapy with lifestyle intervention and metformin.
- Rapid addition of medications, and transition to new regimens when target glycemic goals are not achieved or sustained.
- Early addition of insulin therapy in patients who do not meet target goals.

[PubMed Link](#)

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**New and Generic Drug Approvals**

**FDA approves plerixafor injection (Mozobil™) for stem cell mobilization**

The U.S. Food and Drug Administration has granted marketing approval for plerixafor injection (Mozobil™) to be used in combination with granulocyte-colony stimulating factor (G-CSF) for stem cell mobilization in non-Hodgkin's lymphoma and multiple myeloma. Early preclinical and clinical investigations are already underway to explore additional therapeutic indications for plerixafor, including stem cell mobilization in allogeneic stem cell transplants and tumor sensitization in oncology/hematology treatments such as adult myeloid leukemia.

[Link](#)

**New FDA Approval for Tdap**

GlaxoSmithKline has announced that the FDA has approved its vaccine Boostrix for tetanus, diphtheria and whooping cough for adults. The Tdap (tetanus, diphtheria and pertussis) vaccine is approved for those age 10 to 64, which Glaxo said was the broadest age range for any Tdap vaccine. Boostrix already had been approved as a booster for preteens and teens. Since 2005, more than 7.5 million doses of it have been distributed in the United States to protect adolescents from whooping cough.

[Link](#)

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