

# AU InforMed

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## Key Inforbits

- Healthy behaviors identified
- One book is not necessarily, as good as another
- Heart-healthy foods – stock up!
- 10 ways consumers can save money on drugs
- Auburn HSOP faculty in the literature
- A good drug, according to Galen

## NEW DRUGS, and other related stuff ...

**New Product** ... (4/9/2009) The FDA has approved a new prescription medication for the treatment of head lice (*Pediculosis capitis*) infestation. **Benzyl Alcohol Lotion, 5%** (distributed by Sciele Pharma Inc.), received full market approval as a prescription medication, for use in patients 6 months of age and older. Benzyl Alcohol Lotion, 5%, is the first head lice product approved by the FDA with benzyl alcohol as the active pharmaceutical ingredient. This drug is an effective first line treatment to eliminate lice infestation. Use in premature infants could lead to serious respiratory, heart- or brain-related adverse events such as seizure, coma, or death.  
<http://www.fda.gov/bbs/topics/NEWS/2009/NEW01993.html>

**MedWatch** ... (3/19/2009) The FDA notified healthcare providers and patients that **insulin pens and insulin cartridges are never to be shared among patients**. Sharing of insulin pens may result in transmission of hepatitis viruses, HIV, or other blood-borne pathogens. Even if needles are changed between patients, blood contamination of the pen reservoir could result in transmission of already existing blood-borne pathogens from the previous user. Read the MedWatch 2009 safety summary, including links to the "Information for Healthcare Professionals" page and the FDA News Release, at:  
<http://www.fda.gov/medwatch/safety/2009/safety09.htm#Insulin>

**MedWatch** ... (3/24/2009) The FDA and Novartis notified healthcare professionals of the introduction of a **Myfortic Medication Guide** to provide important safety information in language that patients can easily comprehend. By May 15, 2009, a copy of the Myfortic Medication Guide will be enclosed with every Myfortic bottle. Read the MedWatch safety summary, including links to the Myfortic Dear Healthcare Professional letter, Prescribing Information, and Medication Guide, at:  
<http://www.fda.gov/medwatch/safety/2009/safety09.htm#CellCept>

**MedWatch** ... (3/25/2009) The FDA and Watson Pharmaceuticals notified healthcare professionals and patients of a **recall of Propafenone HCL 225 mg tablets**, used to treat cardiac arrhythmias. The drug is being recalled because some tablets may contain slightly higher levels of the active ingredient than specified. Because it has a narrow therapeutic index, some patients may experience potentially serious side effects, including arrhythmias or low blood pressure. The affected lot [lot number 112680A, expiration date July 31, 2010] of Propafenone HCL tablets

was shipped to customers between October 15, 2008 and November 26, 2008. The Press Release includes instructions for identifying and returning the product.

Read the MedWatch safety summary, including a link to the company Press Release, at:

<http://www.fda.gov/medwatch/safety/2009/safety09.htm#Propafenone>

**MedWatch** ... (3/31/2009) Caraco Pharmaceutical Laboratories and the FDA notified healthcare professionals of a consumer-level **recall of Caraco brand Digoxin**, USP, 0.125 mg, and Digoxin, USP, 0.25 mg, distributed prior to March 31, 2009, and are within the expiration date of September, 2011. The tablets are being recalled because they may differ in size and therefore could have more or less of the active ingredient, digoxin. The drug has a narrow therapeutic index and the existence of higher than labeled dose may pose a risk of digoxin toxicity in patients with renal failure. Digoxin toxicity can cause nausea, vomiting, dizziness, low blood pressure, cardiac instability, and bradycardia. Death can also result. Consumers with the recalled product should return these products to their pharmacy or place of purchase.

Read the MedWatch safety summary, including a link to the company Press Release, at:

<http://www.fda.gov/medwatch/safety/2009/safety09.htm#Digoxin>

**MedWatch** ... (4/8/2009) Genentech and the FDA notified healthcare professionals of the voluntary, phased **withdrawal of Raptiva<sup>®</sup> (efalizumab)**, a medication for treatment of psoriasis, from the U.S. market due to a potential risk to patients of developing progressive multifocal leukoencephalopathy (PML). By June 8, 2009, Raptiva<sup>®</sup> will no longer be available in the United States. Prescribers should immediately begin discussing with patients currently using Raptiva<sup>®</sup> how to transition to alternative therapies. Read the complete MedWatch 2009 Safety Summary, including links to the Dear Healthcare Professional letter, the Dear Patient letter and the FDA statement, at: <http://www.fda.gov/medwatch/safety/2009/safety09.htm#Raptiva>

**MedWatch** ... (4/14/2009) The FDA notified healthcare professionals of an update to a previous alert that addresses the **interaction of ceftriaxone with calcium-containing products**, based on previously reported fatal cases in neonates. Two in vitro studies were conducted in neonatal and adult plasma to assess the potential for precipitation of ceftriaxone-calcium using varying ceftriaxone and calcium concentrations, including concentrations in excess of those achieved in vivo. Based on the results from these studies, the FDA now recommends that ceftriaxone and calcium-containing products may be used concomitantly in patients >28 days of age. This in addition to using noted precautionary recommendations because the risk of precipitation is low in this population. The FDA no longer recommends, that in all age groups ceftriaxone and calcium-containing products should not be administered within 48 hours of one another.

Read the complete MedWatch 2009 Safety Summary, including a link to the updated Healthcare Professional Sheet, at: <http://www.fda.gov/medwatch/safety/2009/safety09.htm#Ceftriaxone>

**MedWatch** ... (4/16/2009) ION Labs and the FDA notified consumers and healthcare professionals of the **recall of all Influenza Cough and Cold products** sold on or after May 30, 2008. This is due to the possibility that the products may be super potent with possible complications ranging from tachycardia, palpitations, arrhythmias, and cardiovascular collapse with hypotension to headaches, dizziness, anxiety, restlessness and nervousness. Customers should stop using it immediately and contact their physician if they have experienced any problems that may be related to taking this product.

Read the complete MedWatch 2009 Safety Summary, including a link to the firm's press release, at: <http://www.fda.gov/medwatch/safety/2009/safety09.htm#Influenza>

## FROM THE MEDICAL LITERATURE ...

**Healthy behaviors ...** In a population-based prospective study in Norfolk, United Kingdom, 20,040 men and women, 40-79 years old were observed for about 11.5 years. They had no previous stroke or myocardial infarction. **Four healthy behaviors were noted:** non-smoker; physically active; moderate alcohol intake (1-14 units/week) and a plasma concentration of vitamin C of  $\geq 50$   $\mu\text{mol/L}$  (indicating adequate fruit/vegetable intake). Based on these four behaviors, the stroke risk after adjustments compared to those having all four desired behaviors for, 3 of them, 2 of them, 1 of them, and none were: 1.15 (95% CI 0.89-1.49), 1.58 (95% CI 1.22-2.05), 2.18 (95% CI 1.63-2.92), and 2.31 (95% CI 1.33-4.02), respectively. Lifestyle does make a difference.

Myint PK, Luben RN, Wareham NJ, Bingham SA, Khaw K-T. Combined effect of health behaviours and risk of first ever stroke in 20,040 men and women over 11 years' follow-up in Norfolk cohort of European prospective investigation of cancer (EPIC Norfolk): prospective population study. *BMJ*. 2009;338:b349 doi: 10.1136/bmj.b349

**Compendia evaluated for off-label uses ...** Six compendia were evaluated based on their coverage of off-label uses for cancer drugs. Compendia are listed in legislation as a means for the Secretary of Health and Human Services to determine (among other things) the value of an off-label use for a drug which ultimately dictates whether the Centers for Medicare & Medicaid Services (CMS), and by default many other insurers, will reimburse the cost of the therapy. The six compendia were: *The American Hospital Formulary Service Drug Information*, *Clinical Pharmacology*, *Drugdex* (by Micromedex), *Drug Facts and Comparisons*, the *National Comprehensive Cancer Network Drugs and Biologics Compendium*, and the *United States Pharmacopeia Drug Information for the Health Professional*. *Drug Facts and Comparisons* is the only compendia in the list that is not part of the legislation dictates. The investigators chose to compare the information on 14 cancer drugs for off-label uses in 2006 (to evaluate coverage) and a follow up on one off-label use in 2008 (to evaluate timeliness of update). The comparison revealed significant deficiencies in all of the compendia relative to the transparency, stated evaluative criteria, methodologies, grading criteria, etc. concerning off-label uses. Individuals will need to determine the "winner" for their purposes.

Abernethy AP, Raman G, Balk E, Hammond JM, Orlando LA, Wheeler JL, Lau J, McCrory DC. Systematic review: Reliability of compendia methods for off-label oncology indications. *Ann Intern Med*. 2009 Mar 3;150(5):336-343. Tillman K, Burton B, Jacques LB, Phurrough SE. Compendia and anticancer therapy under Medicare. *Ann Intern Med*. 2009 Mar 3;150(5):336-343.

## **Reviews of Note ...**

- Krum H, Abraham WT. Heart failure. *Lancet*. 2009 Mar 14;373:941-955.
- Shin J, Kayser SR, Langa TY. Pharmacogenetics: From discovery to patient care. *Am J Health-Syst Pharm*. 2009 Apr 1;66:625-637.
- Romanelli F, Smith KM. Dextromethorphan abuse: Clinical effects and management. *J Am Pharm Assoc*. 2009 Mar/Apr;49(2):e20-e27.
- Koliscak LP, Makela EH. Selective serotonin reuptake inhibitor-induced akathisia. *J Am Pharm Assoc*. 2009 Mar/Apr;49(2):e28-e38.

## FROM THE LAY LITERATURE about medicine ...

**Heart healthy foods – Top 10 ...** According to *Health Magazine*:

Oatmeal	Salmon	Avocado	Olive oil	Nuts
Berries	Legumes	Spinach	Flaxseed	Soy

The hard part will be keeping down your appetite while thinking of all the wonderful combinations that are possible with such an appealing and appetizing group of foods!

Betsch M. 10 best foods for your heart. CNN.com March 23, 2009.

<http://www.cnn.com/2009/HEALTH/03/23/best.foods.for.your.heart/index.html>

**How to save on prescription drugs** ... an article based on a report from Consumer Reports gives 10 tips on how patients can save money on prescription drugs. Some of these are controversial, but it is what is circulating in the lay press. Pharmacists, as sometimes pointed out in the article, can help their patients significantly. Here are these top 10:

- Talk to your physician – tell him the medicines are too expensive!
- Ask specifically – is a generic available.
- Ask your pharmacist about less expensive alternatives.
- Use mail order – for chronic medications.
- Find a prescription assistance program.
- Careful of free samples – they can be more expensive in the long run.
- Be wary of TV (or other) ads – you can ask about them, but don't be easily convinced.
- Split drugs with caution. Definitely ask your pharmacist.
- Shop around pharmacies if you don't have insurance (I'm not wild about this one).
- Ask for a drug review – each of your physicians should know everything you are taking.

Ten ways to save on prescription drugs. CNN.com. March 19, 2009.

<http://www.cnn.com/2009/HEALTH/03/19/ep.prescription.drug.costs/index.html>

### **AUBURN HSOP FACULTY and STUDENTS in the literature ...**

- **Flynn EA, Barker KN, Berger BA, Lloyd KB, Brackett PD.** Dispensing errors and counseling quality in 100 pharmacies. J Am Pharm Assoc. 2009 Mar/Apr;49(2):171-180.
- **Helms KL, Kelley KW.** Insulin glulisine: An evaluation of its pharmacodynamic properties and clinical application. Ann Pharmacother. 2009 Apr;43(4):658-668.
- **Karwa R, Woodis CB.** Midodrine and octreotide in treatment of cirrhosis-related hemodynamic complications. Ann Pharmacother. 2009 Apr;43(4):692-699.
- **Carroll DN, Carroll DG.** Fatal intracranial bleed potentially due to a warfarin and influenza vaccine interaction. Ann Pharmacother. 2009 Apr;43(4):754-760.



#### **The last “dose” ...**

All who drink of this remedy recover in a short time, except those whom it does not help, who all die. Therefore, it is obvious that it fails only in incurable cases.

Galen [131 – 201 C.E.], Greek physician



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