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Key Inforbits

- Reality check on chocolate
- Medical myths revealed
- Another myth research exceeds ad budget
- Neti pot rediscovered
- Sometimes, it's the simple things
- Infectious diseases residency spotlight

NEW DRUGS, and other related stuff ...

Adverse effects confirmed ... (1/3/2008) The FDA is reviewing new data from two studies that provide further evidence of the risks of erythropoiesis-stimulating agents, or ESAs (eg, epoetin alfa, darbepoetin alfa). The studies show that patients with breast or advanced cervical cancers who received ESAs to treat anemia caused by chemotherapy died sooner or had more rapid tumor growth than similar patients who did not receive the anemia drug. These two studies were not among the six studies that were described in revised labeling approved by FDA Nov. 8, 2007, which strengthened warnings about ESAs in cancer patients. Taken together, all eight studies show more rapid tumor growth or shortened survival when patients with breast, non-small cell lung, head and neck, lymphoid or cervical cancers received ESAs compared to patients who did not receive this treatment.

http://www.fda.gov/bbs/topics/NEWS/2008/NEW01769.html

MedWatch ... (12/31/2007) FDA notified consumers and healthcare professionals **not to buy or use Super Shangai, Strong Testis, Shangai Ultra, Shangai Ultra X, Lady Shangai, and Shangai Regular (also known as Shangai Chaojimengnan) products**. The products are marketed as dietary supplements and used for the treatment of erectile dysfunction (ED) and for sexual enhancement. The products contain undeclared active ingredients (sildenafil or an analog). The products are thus drugs that are illegal because they lack FDA approval. Additionally, the safety, efficacy, and purity of the ingredients can not be validated. The undeclared ingredients in the referenced products may interact with nitrates found in some prescription drugs (such as nitroglycerin) and can lower blood pressure to dangerous levels. Discontinue use and consult a healthcare professional.

Read the complete 2007 MedWatch Safety Summary including a link to the FDA News Release regarding this issue at:

http://www.fda.gov/medwatch/safety/2007/safety07.htm#Shangai

MedWatch ... (1/7/2008) The FDA announced the possibility of severe and sometimes **incapacitating bone, joint, and/or muscle (musculoskeletal) pain in patients taking bisphosphonates**. Although severe musculoskeletal pain is included in the prescribing information for all bisphosphonates, the association may be overlooked by healthcare professionals, delaying diagnosis, prolonging pain and/or impairment, and necessitating the use of analgesics. The severe musculoskeletal pain may occur within days, months, or years after starting a bisphosphonates. Some patients have reported complete relief of symptoms after

discontinuing the bisphosphonate, whereas others have reported slow or incomplete resolution. The risk factors for and incidence of severe musculoskeletal pain associated with bisphosphonates are unknown. Consider whether bisphosphonate use might be responsible for severe musculoskeletal pain in patients who present with these symptoms and consider temporary or permanent discontinuation of the drug.

Read the complete 2007 and 2008 MedWatch Safety Summary including a link to the FDA Drug Information Page regarding this issue at:

http://www.fda.gov/medwatch/safety/2008/safety08.htm#Bisphosphonates

FROM THE MEDICAL LITERATURE ...

Dark chocolate health benefit – reality check ... A short editorial brings a little reality to the - "chocolate is good for you" craze. Two main points: 1) the health benefit is derived from the flavonols in the dark chocolate. There is no labeling requirement for flavonol content so even if it is dark chocolate, flavonols may be absent. 2) With or without flavonols, chocolate products still have fat, sugar and calories. Sorry guys ...

The devil in the dark chocolate. Lancet. 2007 Dec 22/29;370:2070.

Vaccine Management ... The Centers for Disease Control and Prevention (CDC) has made

available an online publication describing the physical management for currently recommended vaccines. Included are shipping and storage recommendations for specific vaccines, how to reconstitute them, information about vaccine shelf life

before and after reconstitution, and other special handling instructions. Over 25 vaccine products are included.

Vaccine Management. Atlanta: Centers for Disease Control and Prevention, 2007 November. <u>http://www.cdc.gov/vaccines/pubs/downloads/bk-vac-mgt.pdf</u>

Medical Myths ... Two physicians decided to research seven "common medical or medicinerelated beliefs" held by physicians and the lay public, and make a ruling on their validity. These seven common beliefs were judged to be not true; however, some of the documentation and context are interesting reading – don't worry, it's a short article. Myths were:

- Drink at least 8 glasses of water daily.
- We use only 10% of our brains.
- Hair and fingernails continue to grow after death.
- Reading in dim light ruins your eyesight.
- Shaving causes hair to grow back faster or coarser.
- Mobile phones are dangerous in hospitals.
- Eating turkey makes people especially drowsy.

Vreeman RC, Carroll AE. Medical myths: Sometimes even doctors are duped. *Br Med J*. 2007 Dec 22/29;335:1288-1289.

Research vs. Advertising budget ... Charges of patents sustaining predatory prices and excessive margins; costs and prices extravagantly increased by large expenditures in marketing and; most new drugs are no more effective than currently marketed drugs, have been debated for at least 50 years. The industry generally touts that its research budget exceeds its advertising budget, based generally on one database (IMS). Authors of this paper compared that database with a newer one with different data sources (CAM) and their analysis revealed that the





pharmaceutical industry spends nearly twice as much on advertising/promotion than on research/development. Nearly all dollar amounts are in BILLIONs of dollars, so were are talking serious money. Various categories in each are discussed and are very illuminating. Gagnon MA, Lexchin J. The cost of pushing pills: A new estimate of pharmaceutical promotion expenditures in the United States. PLoS Med 2008;5(1): e1.doi:10.1371/journal.pmed.0050001.

http://medicine.plosjournals.org/archive/1549-1676/5/1/pdf/10.1371 journal.pmed.0050001-L.pdf

Reviews of Note ...

- Dobesh PP, Trujillo TC. Ranolazine: A new option in the management of chronic stable angina. Pharmacotherapy. 2007 Dec;27(12):1659.
- Trujillo TC, Dobesh PP. Traditional management of chronic stable angina. Pharmacotherapy. 2007 Dec;27(12):1677.
- Reynolds J, Shojania K, Marra CA. Abatacept: A novel treatment for moderate-to-severe rheumatoid arthritis. Pharmacotherapy. 2007 Dec;27(12):1693.
- Schuna AA. Rituximab for the treatment of rheumatoid arthritis. *Pharmacotherapy*. 2007 Dec;27(12):1702.
- Goldsmith DR, Scott LJ, Cvetković RS, Plosker GL. Sevelamer hydrochloride: A review of its use for hyperphosphataemia in patients with end-stage renal disease on haemodialysis. Drugs. 2008;68(1):85-104.
- Agbabiaka TB, Savovi J, Ernst E. Methods for causality assessment of adverse drug reactions. Drug Safety. 2008;31(1):21-37.
- Charlton RA, Cunnington MC, de Vries CS, Weil JG. Data resources for investigating drug exposure during pregnancy and associated outcomes: The General Practice Research Database (GPRD) as an alternative to pregnancy registries. Drug Safety. 2008;31(1):39.

FROM THE LAY LITERATURE about medicine ...

Vocabulary ... Neti pot makes a comeback ... The neti pot is a small, oblong ceramic pot with a handle on one end and a short spout on the other, holding 6 to 8 oz of fluid. Its purpose is nasal irrigation (aka, "nose bidet" or jala neti [from voga]). The practice is centuries old from Indian yogic tradition, but came to the U.S. in the early 1970's. It went mainstream when introduced by Oprah Winfrey and now is commonly used for "nasal issues" such as congestion and sinus infection. The process consists of pouring a non-iodized saline solution in one nostril and letting it flow out of the other. There are many believers.

Sweenv C. Short, stout, has a handle on colds. New York Times. 2008 Jan 3. http://www.nytimes.com/2008/01/03/fashion/03skin.html? r=1&ref=health&oref=slogin

Simple, but life-saving ... We are reminded how preparation can not only be easy and convenient, but can be life-saving. Everyone should keep a record of their health issues, especially current medical problems and medications, on their person. This is especially important if you make an unexpected (what else is there?) visit to the



emergency room, conscious or unconscious, and the treating staff have no clue as to your medical history. Keeping a business card size record behind your driver's license could make a big difference. It is also of value when making health-provider visits when you may not be able to immediately shake the important details from your memory. Remind your patients. Cohen E. 2008 resolution: Keep track of your health. CNN.com 2008 Jan 2.

http://www.cnn.com/2008/HEALTH/01/02/ep.health.records/index.html

Elder backlash ... Another very influential group is going after the pharmaceutical industry's cozy relationship with physicians. The AARP has revisited some of the issues such as the



amount of money spent on promotion, the effects of promotion (particularly gifts, meals, etc) on prescribing patterns, the attempts to unbind the industry from prescribing decisions and attempts of legislatures to try to curb the practices that exert undue influence. Several instances are cited where some state legislatures have

attempted to pass laws restricting these activities and often "an army of lobbyists" descend on the scene and scuttle the effort. *Submitted by Dr. Robert Smith*

Basler B. Ties that bind. AARP Bull. 2008 Jan/Feb;49(1):20, 24,26.

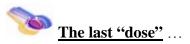
<u>Update</u> ...

Infectious diseases pharmacy residency programs ... are discussed in a recent article. These programs are classified as PGY2 and require a prerequisite of a PGY1 General Practice residency. There are currently 22 ASHP-accredited infectious disease pharmacy residency programs. The career outlook is more diverse than you may think, ranging from academia, clinical pharmacy staff, pharmaceutical industry or further fellowship training for research.

Jodlowski TZ. Infectious diseases pharmacy residency programs. *Am J Health-Syst Pharm*. 2007 Nov 15;64:2330-2333.

<u>NEW RESOURCES in the DILRC</u> ...

- *Physicians' Desk Reference* (PDR). 62nd ed. Montvale, NJ: Thomson Healthcare Inc, 2008.
- Tierney LM Jr, McPhee SJ, Papadakis MA. *Current Medical Diagnosis and Treatment* 2008. 47th ed. NY: McGraw-Hill Lange, 2008.
- Murphy JE. *Clinical Pharmacokinetics*. 4th ed. Bethesda, MD: American Society of Health-System Pharmacists, 2008.
- Grabenstein JD. *ImmunoFacts: Vaccines and Immunologic Drugs 2008*. St. Louis: Wolters Kluwer Health, 2007.



"Fírst say to yourself what you would be; and then do what you have to do." --Epíctetus, Greek phílosopher (55-135)

> An electronic bulletin of drug and health-related news highlights, a service of ... Auburn University, Harrison School of Pharmacy, Drug Information Center
> Phone 334-844-4400 • Fax 334-844-8366 • <u>http://www.pharmacy.auburn.edu/dilrc/dilrc.htm</u> Bernie R. Olin, Pharm.D., Director